

**Header Text:** c4591001

**Visit:** COHORT\_SELECTION

**Form:** COHORT\_SELECTION

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

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

**Site No:** 1044

**Site Name:** (1044) Virginia Research Center

**Subject No:** 10441139

**Subject Initials:** ---

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

**Generated Time (GMT):** 21-Apr-2021 18:02

[eCRF Audit Trail History](#)

**Cohort Selection**

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

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

090177e196d89032\Final\Final On: 22-Apr-2021 02:14 (GMT)

**Header Text:** c4591001

**Visit:** COHORT\_SELECTION

**Form:** MAIN INFORMED CONSENT

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

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

**Site No:** 1044

**Site Name:** (1044) Virginia Research Center

**Subject No:** 10441139

**Subject Initials:** ---

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

**Generated Time (GMT):** 21-Apr-2021 18:02

[eCRF Audit Trail History](#)

**Informed Consent**

1.	Consent Was:	OBTAINED Date Written Consent Obtained Sep/23/2020
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**Header Text:** c4591001

**Visit:** COHORT\_SELECTION

**Form:** DEMOGRAPHY

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

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

**Site No:** 1044

**Site Name:** (1044) Virginia Research Center

**Subject No:** 10441139

**Subject Initials:** ---

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

**Generated Time (GMT):** 21-Apr-2021 18:02

[eCRF Audit Trail History](#)

**Demography**

1.	Subject ID	[10441139]
2.	Birth Date:	(b) (6)/1985
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:	

090177e196d89032\Final\Final On: 22-Apr-2021 02:14 (GMT)

**Header Text:** c4591001

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

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

**Site No:** 1044

**Subject No:** 10441139

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

**Form:** DATE OF VISIT

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

**Site Name:** (1044) Virginia Research Center

**Subject Initials:** ---

**Generated Time (GMT):** 21-Apr-2021 18:02

[eCRF Audit Trail History](#)

**Date of Visit**

1.	Date of Visit	Sep/23/2020
2.	Erroneous Visit	

**Header Text:** c4591001

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

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

**Site No:** 1044

**Subject No:** 10441139

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

**Form:** INCLUSION/EXCLUSION CRITERIA

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

**Site Name:** (1044) Virginia Research Center

**Subject Initials:** ---

**Generated Time (GMT):** 21-Apr-2021 18:02

**Form Comments**

**Inclusion Criteria Not Met**

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

2.	Description of Exclusion Criterion Met	Not Applicable _____
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090177e196d89032\Final\Final On: 22-Apr-2021 02:14 (GMT)

**Header Text:** c4591001

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

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

**Site No:** 1044

**Subject No:** 10441139

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

**Form:** DISPOSITION - SCREENING

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

**Site Name:** (1044) Virginia Research Center

**Subject Initials:** ---

**Generated Time (GMT):** 21-Apr-2021 18:02

[eCRF Audit Trail History](#)

**Disposition - Screening**

1.	Date of Completion/Discontinuation/Death	Sep/23/2020
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:** 1044

**Subject No:** 10441139

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

**Form:** GENERAL MEDICAL HISTORY

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

**Site Name:** (1044) Virginia Research Center

**Subject Initials:** ---

**Generated Time (GMT):** 21-Apr-2021 18:02

**Form Comments**

**Medical History Details**

1.	Line/MH Number:	Not Applicable _____ [ ]
	Disease/Syndrome /Surgery/Non-Drug Allergies/Drug Allergies:	Not Applicable _____ [ ]
	Start Date:	Not Applicable _____ //
	Ongoing:	Not Applicable _____

090177e196d89032\Final\Final On: 22-Apr-2021 02:14 (GMT)

**Header Text:** c4591001

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

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

**Site No:** 1044

**Subject No:** 10441139

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

**Form:** HIV STATUS

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

**Site Name:** (1044) Virginia Research Center

**Subject Initials:** ---

**Generated Time (GMT):** 21-Apr-2021 18:02

[eCRF Audit Trail History](#)

**HIV Status**

1.	Select appropriate response - What is the subject HIV status?	The subject is NOT known to be HIV POSITIVE
----	--	---



**Header Text:** c4591001

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

**Form Version:** 15-Sep-2020 21:56

**Site No:** 1044

**Subject No:** 10441139

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

**Form:** VITAL SIGNS - BASELINE

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

**Site Name:** (1044) Virginia Research Center

**Subject Initials:** ---

**Generated Time (GMT):** 21-Apr-2021 18:02

[eCRF Audit Trail History](#)

**Vital Signs**

1.	Date:	Sep/23/2020
2.	Weight:	[147.1]
3.	Unit:	kg
4.	Height:	[175.3]
5.	Unit:	cm
6.	Body Mass Index:	[47.9]

**Vital Signs Details**

7.a	Record Identifier:	1
	Temperature:	[98.5]
	Unit:	F
	Temperature Location:	ORAL CAVITY

090177e196d89032\Final\Final On: 22-Apr-2021 02:14 (GMT)

**Header Text:** c4591001

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

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

**Site No:** 1044

**Subject No:** 10441139

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

**Form:** RANDOMIZATION

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

**Site Name:** (1044) Virginia Research Center

**Subject Initials:** ---

**Generated Time (GMT):** 21-Apr-2021 18:02

[eCRF Audit Trail History](#)

**Disposition**

1.	Randomization Date :	Sep/23/2020
2.	Randomization Number:	[98399]
3.	Randomization Group:	[ ]

**Header Text:** c4591001

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

**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

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

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

**Site No:** 1044

**Site Name:** (1044) Virginia Research Center

**Subject No:** 10441139

**Subject Initials:** ---

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

**Generated Time (GMT):** 21-Apr-2021 18:02

[eCRF Audit Trail History](#)

**Electronic Sample Tracking**

1.	Data Origin	SITE
2.	Sample Type	SERUM
3.	Sample Collected?	YES Date of Collection: Sep/23/2020
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	[BLB644]
5.b	Sample ID	[BLB637]
5.c	Sample ID	[BN66TG]

090177e196d89032\Final\Final On: 22-Apr-2021 02:14 (GMT)

**Header Text:** c4591001

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

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

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

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

**Site No:** 1044

**Site Name:** (1044) Virginia Research Center

**Subject No:** 10441139

**Subject Initials:** ---

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

**Generated Time (GMT):** 21-Apr-2021 18:02

[eCRF Audit Trail History](#)

**Electronic Sample Tracking**

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Sep/23/2020
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	[BN66TY]
-----	-----------	----------

**Header Text:** c4591001

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

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

**Site No:** 1044

**Subject No:** 10441139

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

**Form:** VACCINATION

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

**Site Name:** (1044) Virginia Research Center

**Subject Initials:** ---

**Generated Time (GMT):** 21-Apr-2021 18:02

**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/23/2020 18:31
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

090177e196d89032\Final\Final On: 22-Apr-2021 02:14 (GMT)

**Header Text:** c4591001

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

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

**Site No:** 1044

**Subject No:** 10441139

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

**Form:** REACTOGENICITY DIARY

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

**Site Name:** (1044) Virginia Research Center

**Subject Initials:** ---

**Generated Time (GMT):** 21-Apr-2021 18:02

[eCRF Audit Trail History](#)

**Reactogenicity Diary**

1.	Select appropriate response - Reactogenicity diary collection	NO - REACTOGENICITY E-DIARY NOT COLLECTED FOR THIS SUBJECT
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**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

**Form:** DATE OF VISIT

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

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

**Site No:** 1044

**Site Name:** (1044) Virginia Research Center

**Subject No:** 10441139

**Subject Initials:** ---

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

**Generated Time (GMT):** 21-Apr-2021 18:02

[eCRF Audit Trail History](#)

**Date of Visit**

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

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

**Form:** VITAL SIGNS - TEMP

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

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

**Site No:** 1044

**Site Name:** (1044) Virginia Research Center

**Subject No:** 10441139

**Subject Initials:** ---

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

**Generated Time (GMT):** 21-Apr-2021 18:02

[eCRF Audit Trail History](#)

**Vital Signs**

1.	Date:	Oct/14/2020
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**Vital Signs Details**

2.a	Record Identifier:	1
	Temperature:	[98.9]
	Unit:	F
	Temperature Location:	ORAL CAVITY

090177e196d89032\Final\Final On: 22-Apr-2021 02:14 (GMT)



**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

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

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

**Site No:** 1044

**Site Name:** (1044) Virginia Research Center

**Subject No:** 10441139

**Subject Initials:** ---

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

**Generated Time (GMT):** 21-Apr-2021 18:02

[eCRF Audit Trail History](#)

**Electronic Sample Tracking**

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

**Aliquot**

Please enter barcode for each aliquot.

5.a	Sample ID	[BN66XD]
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090177e196d89032\Final\Final On: 22-Apr-2021 02:14 (GMT)

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1044

**Subject No:** 10441139

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

**Form:** VACCINATION

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

**Site Name:** (1044) Virginia Research Center

**Subject Initials:** ---

**Generated Time (GMT):** 21-Apr-2021 18:02

[eCRF Audit Trail History](#)

**Vaccination**

1.	Was there a temporary delay of vaccination?	NO
2.	Treatment Name	[BLINDED THERAPY]
3.	Formulation:	INJECTION
4.	Dose Date Time:	Oct/14/2020 10:23
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

090177e196d89032\Final\Final On: 22-Apr-2021 02:14 (GMT)

**Header Text:** c4591001

**Visit:** V3\_MONTH1\_POSTVAX2\_L **Form:** DATE OF VISIT

**Form Version:** 22-Apr-2020 21:02 **Form Status:** Data Complete, Locked, Frozen, Verified

**Site No:** 1044 **Site Name:** (1044) Virginia Research Center

**Subject No:** 10441139 **Subject Initials:** ---

**Generated By:** (b) (4) **Generated Time (GMT):** 21-Apr-2021 18:02

[eCRF Audit Trail History](#)

**Date of Visit**

1.	Date of Visit	Nov/11/2020
2.	Erroneous Visit	

**Header Text:** c4591001

**Visit:** V3\_MONTH1\_POSTVAX2\_L **Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

**Form Version:** 22-Apr-2020 21:03 **Form Status:** Data Complete, Locked, Frozen, Verified

**Site No:** 1044 **Site Name:** (1044) Virginia Research Center

**Subject No:** 10441139 **Subject Initials:** ---

**Generated By:** (b) (4) **Generated Time (GMT):** 21-Apr-2021 18:02

[eCRF Audit Trail History](#)

**Electronic Sample Tracking**

1.	Data Origin	SITE
2.	Sample Type	SERUM
3.	Sample Collected?	YES Date of Collection: Nov/11/2020
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	[BPW0HK]
5.b	Sample ID	[BRVKRJ]
5.c	Sample ID	[BRVKSD]

090177e196d89032\Final\Final On: 22-Apr-2021 02:14 (GMT)

**Header Text:** c4591001

**Visit:** V4\_MONTH6\_L

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

**Site No:** 1044

**Subject No:** 10441139

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

**Form:** DATE OF VISIT

**Form Status:** Not Started

**Site Name:** (1044) Virginia Research Center

**Subject Initials:** ---

**Generated Time (GMT):** 21-Apr-2021 18:02

**Date of Visit**

1.	Date of Visit	//
2.	Erroneous Visit	

**Header Text:** c4591001

**Visit:** V4\_MONTH6\_L

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

**Site No:** 1044

**Subject No:** 10441139

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

**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

**Form Status:** Not Started

**Site Name:** (1044) Virginia Research Center

**Subject Initials:** ---

**Generated Time (GMT):** 21-Apr-2021 18:02

**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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090177e196d89032\Final\Final On: 22-Apr-2021 02:14 (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:** 1044

**Site Name:** (1044) Virginia Research Center

**Subject No:** 10441139

**Subject Initials:** ---

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

**Generated Time (GMT):** 21-Apr-2021 18:02

**Date of Visit**

1.	Date of Visit	//
2.	Erroneous Visit	

**COVID-19 Illness Visit**

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

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

**Form Version:** 20-Feb-2021 02:17

**Site No:** 1044

**Subject No:** 10441139

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

**Form:** SIGNS AND SYMPTOMS OF POTENTIAL  
COVID-19

**Form Status:** Not Started

**Site Name:** (1044) Virginia Research Center

**Subject Initials:** ---

**Generated Time (GMT):** 21-Apr-2021 18:02

**Signs and Symptoms**

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

**Symptoms**

4.	Symptoms:	
	Was symptom present?	

**Symptoms - Other**

5.	Symptoms - Other Text:	[ ]
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090177e196d89032\Final\Final On: 22-Apr-2021 02:14 (GMT)



**Header Text:** c4591001

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

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

**Site No:** 1044

**Subject No:** 10441139

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

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

**Form Status:** Not Started

**Site Name:** (1044) Virginia Research Center

**Subject Initials:** ---

**Generated Time (GMT):** 21-Apr-2021 18:02

**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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090177e196d89032\Final\Final On: 22-Apr-2021 02:14 (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:** 1044

**Site Name:** (1044) Virginia Research Center

**Subject No:** 10441139

**Subject Initials:** ---

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

**Generated Time (GMT):** 21-Apr-2021 18:02

**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:** 1044

**Site Name:** (1044) Virginia Research Center

**Subject No:** 10441139

**Subject Initials:** ---

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

**Generated Time (GMT):** 21-Apr-2021 18:02

**Health Care Utilization**

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

**Health Care Utilization Other**

2.	Other Type of Practitioner Specify:	[ ]
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**Health Care Utilization**

3.	Has the subject been hospitalized due to potential COVID-19 illness?	
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090177e196d89032\Final\Final On: 22-Apr-2021 02:14 (GMT)

**Header Text:** c4591001

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

**Form:** ILLNESS DETAILS

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

**Form Status:** Not Started

**Site No:** 1044

**Site Name:** (1044) Virginia Research Center

**Subject No:** 10441139

**Subject Initials:** ---

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

**Generated Time (GMT):** 21-Apr-2021 18:02

**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:** 1044

**Site Name:** (1044) Virginia Research Center

**Subject No:** 10441139

**Subject Initials:** ---

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

**Generated Time (GMT):** 21-Apr-2021 18:02

**Date of Visit**

1.	Date of Visit	//
2.	Erroneous Visit	

**COVID-19 Illness Visit**

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

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

**Form:** ELECTRONIC SAMPLE TRACKING -  
IMMUNOGENICITY

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

**Form Status:** Not Started

**Site No:** 1044

**Site Name:** (1044) Virginia Research Center

**Subject No:** 10441139

**Subject Initials:** ---

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

**Generated Time (GMT):** 21-Apr-2021 18:02

**Electronic Sample Tracking**

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

**Aliquot**

Please enter barcode for each aliquot.

5.	Sample ID	[ ]
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**Header Text:** c4591001

**Visit:** POT\_COVID\_REPEAT\_SWAB **Form:** DATE OF VISIT - REPEAT SWAB  
- New Unscheduled Visit

**Form Version:** 10-Oct-2020 15:57 **Form Status:** Not Started

**Site No:** 1044

**Site Name:** (1044) Virginia Research Center

**Subject No:** 10441139

**Subject Initials:** ---

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

**Generated Time (GMT):** 21-Apr-2021 18:02

**Date of Visit**

1.	Date of Visit	//
2.	Erroneous Visit	

**COVID-19 Repeat Swab**

3.	COVID-19 Repeat Swab:	
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**Header Text:** c4591001

**Visit:** POT\_COVID\_REPEAT\_SWAB - New Unscheduled Visit **Form:** ELECTRONIC SAMPLE TRACKING - REPEAT SWAB

**Form Version:** 10-Oct-2020 15:57 **Form Status:** Not Started

**Site No:** 1044 **Site Name:** (1044) Virginia Research Center

**Subject No:** 10441139 **Subject Initials:** ---

**Generated By:** (b) (4) **Generated Time (GMT):** 21-Apr-2021 18:02

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

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

**Site No:** 1044 **Site Name:** (1044) Virginia Research Center

**Subject No:** 10441139 **Subject Initials:** ---

**Generated By:** (b) (4) **Generated Time (GMT):** 21-Apr-2021 18:02

**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:** 1044    **Site Name:** (1044) Virginia Research Center

**Subject No:** 10441139    **Subject Initials:** ---

**Generated By:** (b) (4)    **Generated Time (GMT):** 21-Apr-2021 18:02

**Unplanned Assessments**

1.	Assessments	
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**Header Text:** c4591001

**Visit:** Logs

**Form:** ADVERSE EVENT REPORT

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

**Site No:** 1044

**Site Name:** (1044) Virginia Research Center

**Subject No:** 10441139

**Subject Initials:** ---

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

**Generated Time (GMT):** 21-Apr-2021 18:02

#	Category	AE Identifier	Adverse Event	Start Date	Is the Adverse Event Still Ongoing	Form Instance
1.	ADVERSE EVENT	1	chills	Oct/15/2020 UNK:UNK	NO End Date Time:  Oct/15/2020 UNK: UNK	<a href="#">Repeating Pages</a>
2.	ADVERSE EVENT	2	fever	Oct/15/2020 UNK:UNK	NO End Date Time:  Oct/16/2020 UNK: UNK	<a href="#">Repeating Pages</a>
3.	ADVERSE EVENT	3	injection site pain	Oct/14/2020 UNK:UNK	NO End Date Time:  Oct/15/2020 UNK: UNK	<a href="#">Repeating Pages</a>
4.	ADVERSE EVENT	4	fatigue	Oct/14/2020 18:00	NO End Date Time:  Oct/16/2020 UNK: UNK	<a href="#">Repeating Pages</a>
5.	ADVERSE EVENT	5	headache	Oct/14/2020 18:00	NO End Date Time:  Oct/16/2020 UNK: UNK	<a href="#">Repeating Pages</a>

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**Header Text:** c4591001

**Visit:** Logs

**Form:** ADVERSE EVENT REPORT

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

**Site No:** 1044

**Site Name:** (1044) Virginia Research Center

**Subject No:** 10441139

**Subject Initials:** ---

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

**Generated Time (GMT):** 21-Apr-2021 18:02

#	Category	AE Identifier	Adverse Event	Start Date	Is the Adverse Event Still Ongoing	Form Instance
6.	ADVERSE EVENT	6	Angioede ma face	Oct/16/2020 U NK:UNK	NO End Date Time:  Oct/17/2020 UNK: UNK	<a href="#">Repeating Pages</a>

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**Header Text:** c4591001

**Visit:** Logs - Unscheduled

**Form:** ADVERSE EVENT REPORT

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

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

**Site No:** 1044

**Site Name:** (1044) Virginia Research Center

**Subject No:** 10441139

**Subject Initials:** ---

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

**Generated Time (GMT):** 21-Apr-2021 18:02

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**Adverse Event Report**

1.	Category:	ADVERSE EVENT
2.	AE ID:	[1]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[chills]
4.	Start Date Time:	Oct/15/2020 UNK:UNK
5.	Is the adverse event still ongoing?	NO End Date Time: Oct/15/2020 UNK:UNK
6.	Toxicity Grade:	1

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

**Site No:** 1044

**Site Name:** (1044) Virginia Research Center

**Subject No:** 10441139

**Subject Initials:** ---

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

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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).	NO
8.	Is this adverse event the result of a study Medication Error? If Yes, record the type of medication error on the Medication Error Log.	NO
9.	Is this event related to study treatment:	RELATED
10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE
11.	Was a Concomitant Medication given?	NO
12.	Was a Non-Drug Treatment given?	NO

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**Header Text:** c4591001

**Visit:** Logs - Unscheduled

**Form:** ADVERSE EVENT REPORT

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

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

**Site No:** 1044

**Site Name:** (1044) Virginia Research Center

**Subject No:** 10441139

**Subject Initials:** ---

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

**Generated Time (GMT):** 21-Apr-2021 18:02

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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**Subject No:** 10441139

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

**Form:** ADVERSE EVENT REPORT

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

**Site Name:** (1044) Virginia Research Center

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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)	[fever]
4.	Start Date Time:	Oct/15/2020 UNK:UNK
5.	Is the adverse event still ongoing?	NO End Date Time: Oct/16/2020 UNK:UNK
6.	Toxicity Grade:	1

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

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

**Site No:** 1044

**Site Name:** (1044) Virginia Research Center

**Subject No:** 10441139

**Subject Initials:** ---

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

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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).	NO
8.	Is this adverse event the result of a study Medication Error? If Yes, record the type of medication error on the Medication Error Log.	NO
9.	Is this event related to study treatment:	RELATED
10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE
11.	Was a Concomitant Medication given?	NO
12.	Was a Non-Drug Treatment given?	NO

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

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

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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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### Adverse Event Report

1.	Category:	ADVERSE EVENT
2.	AE ID:	[3]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[injection site pain]
4.	Start Date Time:	Oct/14/2020 UNK:UNK
5.	Is the adverse event still ongoing?	NO End Date Time: Oct/15/2020 UNK:UNK
6.	Toxicity Grade:	1

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

**Site No:** 1044

**Site Name:** (1044) Virginia Research Center

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**Subject Initials:** ---

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

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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).	NO
8.	Is this adverse event the result of a study Medication Error? If Yes, record the type of medication error on the Medication Error Log.	NO
9.	Is this event related to study treatment:	RELATED
10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE
11.	Was a Concomitant Medication given?	NO
12.	Was a Non-Drug Treatment given?	NO

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**Site No:** 1044

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

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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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### Adverse Event Report

1.	Category:	ADVERSE EVENT
2.	AE ID:	[4]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[fatigue]
4.	Start Date Time:	Oct/14/2020 18:00
5.	Is the adverse event still ongoing?	NO End Date Time: Oct/16/2020 UNK:UNK
6.	Toxicity Grade:	1

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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).	NO
8.	Is this adverse event the result of a study Medication Error? If Yes, record the type of medication error on the Medication Error Log.	NO
9.	Is this event related to study treatment:	RELATED
10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE
11.	Was a Concomitant Medication given?	NO
12.	Was a Non-Drug Treatment given?	NO

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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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**Site Name:** (1044) Virginia Research Center

**Subject Initials:** ---

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### Adverse Event Report

1.	Category:	ADVERSE EVENT
2.	AE ID:	[5]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[headache]
4.	Start Date Time:	Oct/14/2020 18:00
5.	Is the adverse event still ongoing?	NO End Date Time: Oct/16/2020 UNK:UNK
6.	Toxicity Grade:	1

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**Form:** ADVERSE EVENT REPORT

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

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

**Site No:** 1044

**Site Name:** (1044) Virginia Research Center

**Subject No:** 10441139

**Subject Initials:** ---

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

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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).	NO
8.	Is this adverse event the result of a study Medication Error? If Yes, record the type of medication error on the Medication Error Log.	NO
9.	Is this event related to study treatment:	RELATED
10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE
11.	Was a Concomitant Medication given?	NO
12.	Was a Non-Drug Treatment given?	NO

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

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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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**Form:** ADVERSE EVENT REPORT

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### Adverse Event Report

1.	Category:	ADVERSE EVENT
2.	AE ID:	[6]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[Angioedema face]
4.	Start Date Time:	Oct/16/2020 UNK:UNK
5.	Is the adverse event still ongoing?	NO End Date Time: Oct/17/2020 UNK:UNK
6.	Toxicity Grade:	1

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**Site No:** 1044

**Subject No:** 10441139

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

**Form:** ADVERSE EVENT REPORT

**Form Status:** Data Complete, Locked, Frozen, Not Complete

**Site Name:** (1044) Virginia Research Center

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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).	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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**Form Status:** Data Complete, Locked, Frozen, Not Complete

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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:** 1044

**Site Name:** (1044) Virginia Research Center

**Subject No:** 10441139

**Subject Initials:** ---

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

**Generated Time (GMT):** 21-Apr-2021 18:02

#	Category	Medication Error	Start Date	Is the medication error Still Ongoing	Study Medication Errors Action	Form Instance
1.						<a href="#">Repeating Pages</a>

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

**Form:** MEDICATION ERROR

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

**Form Status:** Not Started

**Site No:** 1044

**Site Name:** (1044) Virginia Research Center

**Subject No:** 10441139

**Subject Initials:** ---

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

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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	[ ]

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**Header Text:** c4591001

**Visit:** Logs

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

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

**Site No:** 1044

**Site Name:** (1044) Virginia Research Center

**Subject No:** 10441139

**Subject Initials:** ---

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

**Generated Time (GMT):** 21-Apr-2021 18:02

#	Sponsor-Defined Identifier	Category for Medication	Concomitant Medications Pre-specified	Name of Medication	Start Date	Form Instance
1.	1	VACCINATIONS	NO	Influenza Vaccines	Nov/9/2020	<a href="#">Repeating Pages</a>

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**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

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

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

**Site No:** 1044

**Site Name:** (1044) Virginia Research Center

**Subject No:** 10441139

**Subject Initials:** ---

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

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**Concomitant Medications**

1.	What is the medication identifier?	[1]
2.	Category:	VACCINATIONS
3.	Concomitant Medications Pre-specified:	NO
4.	Medication:  Provide the complete generic drug name (including salt form, where applicable). Where generic name is unknown, enter the full trade or proprietary name. Include clarifying information in the Medication text (e.g., Ingredient(s), route, use, formulation).	[Influenza Vaccine]
5.	Date:	Nov/9/2020

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**Header Text:** c4591001

**Visit:** Logs

**Form:** CONCOMITANT MEDICATIONS - PROHIBITED

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

**Site No:** 1044

**Site Name:** (1044) Virginia Research Center

**Subject No:** 10441139

**Subject Initials:** ---

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

**Generated Time (GMT):** 21-Apr-2021 18:02

#	Sponsor-Defined Identifier	Category for Medication	Concomitant Medications Pre-specified	Name of Medication	Dose Description	Form Instance
1.						<a href="#">Repeating Pages</a>

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

**Form:** CONCOMITANT MEDICATIONS - PROHIBITED

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

**Form Status:** Not Started

**Site No:** 1044

**Site Name:** (1044) Virginia Research Center

**Subject No:** 10441139

**Subject Initials:** ---

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

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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?	

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**Header Text:** c4591001

**Visit:** Logs

**Form:** RADIATION TREATMENT

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**Site Name:** (1044) Virginia Research Center

**Subject No:** 10441139

**Subject Initials:** ---

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

**Generated Time (GMT):** 21-Apr-2021 18:02

#	Category	Treatment Identifier	Con Non-Drug Treatments Pre-specified	Treatment	Start Date	Form Instance
1.						<a href="#">Repeating Pages</a>

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**Header Text:** c4591001

**Visit:** Logs - Unscheduled

**Form:** RADIATION TREATMENT

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

**Form Status:** Not Started

**Site No:** 1044

**Site Name:** (1044) Virginia Research Center

**Subject No:** 10441139

**Subject Initials:** ---

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

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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

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

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

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

**Form:** TRANSFUSIONS

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**Form Status:** Not Started

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



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**Visit:** End of Treatment - Unscheduled **Form:** DISPOSITION - TREATMENT

**Form Version:** 15-Sep-2020 21:55 **Form Status:** Data Complete, Locked, Frozen, Verified

**Site No:** 1044

**Site Name:** (1044) Virginia Research Center

**Subject No:** 10441139

**Subject Initials:** ---

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

**Generated Time (GMT):** 21-Apr-2021 18:02

[eCRF Audit Trail History](#)

**Disposition - Treatment**

1.	Date of Completion/Discontinuation/Death :	Nov/11/2020
2.	Phase of Disposition:	VACCINATION
3.	Status:	COMPLETED
4.	Specify Status:	[ ]

090177e196d89032\Final\Final On: 22-Apr-2021 02:14 (GMT)

**Header Text:** c4591001

**Visit:** Unplanned Vaccination -  
Unscheduled

**Form:** DATE OF VISIT

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

**Form Status:** Not Started

**Site No:** 1044

**Site Name:** (1044) Virginia Research Center

**Subject No:** 10441139

**Subject Initials:** ---

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

**Generated Time (GMT):** 21-Apr-2021 18:02

**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:** 1044

**Site Name:** (1044) Virginia Research Center

**Subject No:** 10441139

**Subject Initials:** ---

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

**Generated Time (GMT):** 21-Apr-2021 18:02

**Vital Signs**

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

**Vital Signs Details**

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

090177e196d89032\Final\Final On: 22-Apr-2021 02:14 (GMT)

**Header Text:** c4591001

**Visit:** Unplanned Vaccination -  
Unscheduled

**Form:** VACCINATION

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

**Form Status:** Not Started

**Site No:** 1044

**Site Name:** (1044) Virginia Research Center

**Subject No:** 10441139

**Subject Initials:** ---

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

**Generated Time (GMT):** 21-Apr-2021 18:02

**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?	

090177e196d89032\Final\Final On: 22-Apr-2021 02:14 (GMT)

**Header Text:** c4591001

**Visit:** Unplanned Vaccination -  
Unscheduled

**Form:** CONTACT OUTCOME - MONTH 1

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

**Form Status:** Not Started

**Site No:** 1044

**Site Name:** (1044) Virginia Research Center

**Subject No:** 10441139

**Subject Initials:** ---

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

**Generated Time (GMT):** 21-Apr-2021 18:02

**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:** 1044

**Site Name:** (1044) Virginia Research Center

**Subject No:** 10441139

**Subject Initials:** ---

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

**Generated Time (GMT):** 21-Apr-2021 18:02

**Contact Outcome**

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

**Header Text:** c4591001

**Visit:** V201\_SURVEIL\_CONSENT - **Form:** DATE OF VISIT  
Unscheduled

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

**Site No:** 1044 **Site Name:** (1044) Virginia Research Center

**Subject No:** 10441139 **Subject Initials:** ---

**Generated By:** (b) (4) **Generated Time (GMT):** 21-Apr-2021 18:02

**Date of Visit**

1.	Date of Visit	//
2.	Erroneous Visit	

**Header Text:** c4591001

**Visit:** V201\_SURVEIL\_CONSENT -  
Unscheduled

**Form:** INFORMED CONSENT - ASYMPTOMATIC  
SURVEILLANCE

**Form Version:** 14-Jan-2021 02:29

**Form Status:** Not Started

**Site No:** 1044

**Site Name:** (1044) Virginia Research Center

**Subject No:** 10441139

**Subject Initials:** ---

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

**Generated Time (GMT):** 21-Apr-2021 18:02

**Informed Consent - Asymptomatic Surveillance**

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



**Header Text:** c4591001

**Visit:** V201\_SURVEIL\_CONSENT -  
Unscheduled

**Form:** ELECTRONIC SAMPLE TRACKING -  
IMMUNOGENICITY

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

**Form Status:** Not Started

**Site No:** 1044

**Site Name:** (1044) Virginia Research Center

**Subject No:** 10441139

**Subject Initials:** ---

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

**Generated Time (GMT):** 21-Apr-2021 18:02

**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	[ ]
----	-----------	-----

090177e196d89032\Final\Final On: 22-Apr-2021 02:14 (GMT)

**Header Text:** c4591001

**Visit:** V201\_SURVEIL\_CONSENT -  
Unscheduled

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

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

**Form Status:** Not Started

**Site No:** 1044

**Site Name:** (1044) Virginia Research Center

**Subject No:** 10441139

**Subject Initials:** ---

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

**Generated Time (GMT):** 21-Apr-2021 18:02

**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:** Follow-Up - Unscheduled

**Form:** DISPOSITION - FOLLOW-UP

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

**Form Status:** Not Started

**Site No:** 1044

**Site Name:** (1044) Virginia Research Center

**Subject No:** 10441139

**Subject Initials:** ---

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

**Generated Time (GMT):** 21-Apr-2021 18:02

**Disposition - Follow-Up**

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

**Header Text:** c4591001

**Visit:** Potential ReVax Initial Contact - **Form:** DATE OF VISIT  
Unscheduled

**Form Version:** 22-Apr-2020 21:02      **Form Status:** Data Complete, Frozen, Verified

**Site No:** 1044      **Site Name:** (1044) Virginia Research Center

**Subject No:** 10441139      **Subject Initials:** ---

**Generated By:** (b) (4)      **Generated Time (GMT):** 21-Apr-2021 18:02

[eCRF Audit Trail History](#)

Date of Visit		
1.	Date of Visit	Jan/8/2021
2.	Erroneous Visit	

**Header Text:** c4591001

**Visit:** Potential ReVax Initial Contact - **Form:** FURTHER VACCINATION CONFIRMATION  
Unscheduled

**Form Version:** 10-Dec-2020 02:25      **Form Status:** Data Complete, Frozen

**Site No:** 1044      **Site Name:** (1044) Virginia Research Center

**Subject No:** 10441139      **Subject Initials:** ---

**Generated By:** (b) (4)      **Generated Time (GMT):** 21-Apr-2021 18:02

[eCRF Audit Trail History](#)

**Further Vaccination Confirmation**

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

**Header Text:** c4591001

**Visit:** Disposition - Unscheduled

**Form:** TREATMENT UNBLINDED

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

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

**Site No:** 1044

**Site Name:** (1044) Virginia Research Center

**Subject No:** 10441139

**Subject Initials:** ---

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

**Generated Time (GMT):** 21-Apr-2021 18:02

[eCRF Audit Trail History](#)

**Treatment Unblinded**

1.	Date Treatment Unblinded :	Jan/8/2021
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:** 1044

**Subject No:** 10441139

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

**Form:** WITHDRAWAL OF CONSENT

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

**Site Name:** (1044) Virginia Research Center

**Subject Initials:** ---

**Generated Time (GMT):** 21-Apr-2021 18:02

[Form Comments](#)

[eCRF Audit Trail History](#)

**Withdrawal Of Consent**

1.	Withdrawal of Consent Date :	Not Applicable _____ //	<a href="#">Comments</a>

**Header Text:** c4591001

**Visit:** Disposition - Unscheduled

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

**Site No:** 1044

**Subject No:** 10441139

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

**Form:** DEATH DETAILS CODED

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

**Site Name:** (1044) Virginia Research Center

**Subject Initials:** ---

**Generated Time (GMT):** 21-Apr-2021 18:02

[Form Comments](#)

[eCRF Audit Trail History](#)

**Death Details**

1.	Date of Collection / Notification of Death:	Not Applicable _____ //	<a href="#">Comments</a>
----	---	-------------------------------	--------------------------

**Cause of Death**

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

090177e196d89032\Final\Final On: 22-Apr-2021 02:14 (GMT)



**Header Text:** c4591001

**Visit:** Subject Status - Unscheduled

**Form:** SUBJECT STATUS

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

**Form Status:** Data Complete, Verified

**Site No:** 1044

**Site Name:** (1044) Virginia Research Center

**Subject No:** 10441139

**Subject Initials:** ---

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

**Generated Time (GMT):** 21-Apr-2021 18:02

[eCRF Audit Trail History](#)

**Subject Status**

1.	Subject Status	FOLLOW-UP
2.	Subject Status Date	Nov/11/2020

**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:** 1044

**Site Name:** (1044) Virginia Research Center

**Subject No:** 10441139

**Subject Initials:** ---

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

**Generated Time (GMT):** 21-Apr-2021 18:02

[eCRF Audit Trail History](#)

**Casebook Signature Form**

1.	Casebook Signature	Click Here to Enable
----	--------------------	----------------------

**Header Text:** c4591001

**Visit:** Investigator Signature -  
Unscheduled

**Form:** CASEBOOK SIGNATURE FORM

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

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

**Site No:** 1044

**Site Name:** (1044) Virginia Research Center

**Subject No:** 10441139

**Subject Initials:** ---

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

**Generated Time (GMT):** 21-Apr-2021 18:02

[Audit Trail](#)

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

- CRF\_Sign

Name	Signature Meaning	Date	Type	Action
Aaron Hartman	Approved	Mar-03-2021 13:54:16 (UTC-05:00) Eastern Time (US & Canada)	BOOK	Signed

**Affidavit:**

By my dated signature below, I, AaronHartman, 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.

090177e196d89032\Final\Final On: 22-Apr-2021 02:14 (GMT)

**Header Text:** c4591001

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

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

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

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

**Site No:** 1044

**Site Name:** (1044) Virginia Research Center

**Subject No:** 10441139

**Subject Initials:** ---

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

**Generated Time (GMT):** 21-Apr-2021 18:02

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Item	Date	User	Comment
Form	Sep-24-2020 07:55:19 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6) [Redacted]	Not Applicable

**Header Text:** c4591001

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

**Form:** GENERAL MEDICAL HISTORY - Comments

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

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

**Site No:** 1044

**Site Name:** (1044) Virginia Research Center

**Subject No:** 10441139

**Subject Initials:** ---

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

**Generated Time (GMT):** 21-Apr-2021 18:02

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Item	Date	User	Comment
Form	Sep-24-2020 07:56:33 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

**Header Text:** c4591001

**Visit:** Disposition - Unscheduled

**Form:** WITHDRAWAL OF CONSENT - Comments

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

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

**Site No:** 1044

**Site Name:** (1044) Virginia Research Center

**Subject No:** 10441139

**Subject Initials:** ---

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

**Generated Time (GMT):** 21-Apr-2021 18:02

[Back to Form](#)

Item	Date	User	Comment
Form	Jan-20-2021 08:02:32 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

**Header Text:** c4591001

**Visit:** Disposition

**Form:** WITHDRAWAL OF CONSENT - Comments

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

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

**Site No:** 1044

**Site Name:** (1044) Virginia Research Center

**Subject No:** 10441139

**Subject Initials:** ---

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

**Generated Time (GMT):** 21-Apr-2021 18:02

[Back to Form](#)

Item	Date	User	Comment
1	Jan-20-2021 08:02:32 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

**Header Text:** c4591001

**Visit:** Disposition - Unscheduled

**Form:** DEATH DETAILS CODED - Comments

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

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

**Site No:** 1044

**Site Name:** (1044) Virginia Research Center

**Subject No:** 10441139

**Subject Initials:** ---

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

**Generated Time (GMT):** 21-Apr-2021 18:02

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Item	Date	User	Comment
Form	Jan-20-2021 08:02:49 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable



**Header Text:** c4591001

**Visit:** Disposition

**Form:** DEATH DETAILS CODED - Comments

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

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

**Site No:** 1044

**Site Name:** (1044) Virginia Research Center

**Subject No:** 10441139

**Subject Initials:** ---

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

**Generated Time (GMT):** 21-Apr-2021 18:02

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Item	Date	User	Comment
1	Jan-20-2021 08:02:49 (UTC-05:00) Eastern Time (US & Canada)	(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:** 1044

**Site Name:** (1044) Virginia Research Center

**Subject No:** 10441139

**Subject Initials:** ---

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

**Generated Time (GMT):** 21-Apr-2021 18:02

[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
Aaron Hartman	Approved	Mar-03-2021 13:54:16 (UTC-05:00) Eastern Time (US & Canada)	BOOK	Signed

**Affidavit:**

By my dated signature below, I, AaronHartman, 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-16-2021 11:18:38 (UTC-05:00) Eastern Time (US & Canada)		Edit - All signatures invalidated
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**Affidavit:**

N/A

Aaron Hartman	Approved	Jan-21-2021 16:35:53 (UTC-05:00) Eastern Time (US & Canada)	BOOK	Signed
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090177e196d89032\Final\Final On: 22-Apr-2021 02:14 (GMT)

**Header Text:** c4591001

**Visit:** Investigator Signature -  
Unscheduled

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

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

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

**Site No:** 1044

**Site Name:** (1044) Virginia Research Center

**Subject No:** 10441139

**Subject Initials:** ---

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

**Generated Time (GMT):** 21-Apr-2021 18:02

**Affidavit:**

By my dated signature below, I, AaronHartman, 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	Jan-20-2021 08:02:00 (UTC-05:00) Eastern Time (US & Canada)		Edit - All signatures invalidated
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**Affidavit:**

N/A

Aaron Hartman	Approved	Nov-12-2020 17:01:00 (UTC-05:00) Eastern Time (US & Canada)	BOOK	Signed
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**Affidavit:**

By my dated signature below, I, AaronHartman, 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.

090177e196d89032\Final\Final On: 22-Apr-2021 02:14 (GMT)

**Header Text:** c4591001

**Visit:** Investigator Signature -  
Unscheduled

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

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

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

**Site No:** 1044

**Site Name:** (1044) Virginia Research Center

**Subject No:** 10441139

**Subject Initials:** ---

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

**Generated Time (GMT):** 21-Apr-2021 18:02

(b) (6)	N/A	Nov-11-2020 09:49:15 (UTC-05:00) Eastern Time (US & Canada)		Edit - All signatures invalidated
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**Affidavit:**

N/A

Aaron Hartman	Approved	Nov-10-2020 17:21:06 (UTC-05:00) Eastern Time (US & Canada)	BOOK	Signed
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**Affidavit:**

By my dated signature below, I, AaronHartman, 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.

090177e196d89032\Final\Final On: 22-Apr-2021 02:14 (GMT)

**Header Text:** c4591001

**Visit:** COHORT\_SELECTION

**Form:** COHORT SELECTION - eCRF Audit Trail History

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

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

**Site No:** 1044

**Site Name:** (1044) Virginia Research Center

**Subject No:** 10441139

**Subject Initials:** ---

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

**Generated Time (GMT):** 21-Apr-2021 18:02

[Back to Form](#)

*1. Select appropriate response - Protocol version*

Date	Location	User	Value	Reason
Sep-24-2020 07:54:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 08 SEP 2020	Initial Entry

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

Date	Location	User	Value	Reason
Sep-24-2020 07:54:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> STAGE 3 COHORT S	Initial Entry

090177e196d89032\Final\Final On: 22-Apr-2021 02:14 (GMT)

**Header Text:** c4591001

**Visit:** COHORT\_SELECTION

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

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

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

**Site No:** 1044

**Site Name:** (1044) Virginia Research Center

**Subject No:** 10441139

**Subject Initials:** ---

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

**Generated Time (GMT):** 21-Apr-2021 18:02

[Back to Form](#)

**1. Consent Was:**

Date	Location	User	Value	Reason
Sep-24-2020 07:54:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> OBTAINED Date Written Consent Obtained  Sep/23/2020	Initial Entry

**Header Text:** c4591001

**Visit:** COHORT\_SELECTION

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

**Site No:** 1044

**Subject No:** 10441139

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

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

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

**Site Name:** (1044) Virginia Research Center

**Subject Initials:** ---

**Generated Time (GMT):** 21-Apr-2021 18:02

[Back to Form](#)

**1. Subject ID**

Date	Location	User	Value	Reason
Sep-24-2020 07:54:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 10441139	Item copied from previous form

**2. Birth Date:**

Date	Location	User	Value	Reason
Sep-24-2020 07:54:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> (b) (6)/1985	Enrollment Entry

**3. Sex:**

Date	Location	User	Value	Reason
Sep-24-2020 07:55:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> MALE	Initial Entry

**4. Ethnicity:**

Date	Location	User	Value	Reason
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090177e196d89032\Final\Final On: 22-Apr-2021 02:14 (GMT)

**Header Text:** c4591001

**Visit:** COHORT\_SELECTION

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

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

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

**Site No:** 1044

**Site Name:** (1044) Virginia Research Center

**Subject No:** 10441139

**Subject Initials:** ---

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

**Generated Time (GMT):** 21-Apr-2021 18:02

Sep-24-2020 07:55:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NOT HISPANIC O R LATINO(A) OR OF SPANISH ORI GIN	Initial Entry
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**5. Race: (Check X all that apply):**

Date	Location	User	Value	Reason
Sep-24-2020 07:55:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> WHITE	Initial Entry



**Header Text:** c4591001

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

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

**Site No:** 1044

**Subject No:** 10441139

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

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

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

**Site Name:** (1044) Virginia Research Center

**Subject Initials:** ---

**Generated Time (GMT):** 21-Apr-2021 18:02

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*1. Date of Visit*

Date	Location	User	Value	Reason
Sep-24-2020 07:55:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sep/23/2020	Initial Entry

090177e196d89032\Final\Final On: 22-Apr-2021 02:14 (GMT)

**Header Text:** c4591001

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

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

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

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

**Site No:** 1044

**Site Name:** (1044) Virginia Research Center

**Subject No:** 10441139

**Subject Initials:** ---

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

**Generated Time (GMT):** 21-Apr-2021 18:02

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

Date	Location	User	Value	Reason
Sep-24-2020 07:55:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sep/23/2020	Initial Entry

**2. Phase of Disposition:**

Date	Location	User	Value	Reason
Sep-24-2020 07:55:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SCREENING	Initial Entry

**3. Status:**

Date	Location	User	Value	Reason
Sep-24-2020 07:55:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> COMPLETED	Initial Entry

090177e196d89032\Final\Final On: 22-Apr-2021 02:14 (GMT)

**Header Text:** c4591001

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

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

**Site No:** 1044

**Subject No:** 10441139

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

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

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

**Site Name:** (1044) Virginia Research Center

**Subject Initials:** ---

**Generated Time (GMT):** 21-Apr-2021 18:02

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

Date	Location	User	Value	Reason
Sep-24-2020 07:56:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> The subject is NOT known to be HIV P OSITIVE	Initial Entry

**Header Text:** c4591001

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

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

**Form Version:** 15-Sep-2020 21:56

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

**Site No:** 1044

**Site Name:** (1044) Virginia Research Center

**Subject No:** 10441139

**Subject Initials:** ---

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

**Generated Time (GMT):** 21-Apr-2021 18:02

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**1. Date:**

Date	Location	User	Value	Reason
Sep-24-2020 08:00:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sep/23/2020	Initial Entry

**2. Weight:**

Date	Location	User	Value	Reason
Sep-25-2020 03:46:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Sep-24-2020 17:03:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	not clinically significant
Sep-24-2020 13:33:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued: Opened	Please confirm if this is clinically significant or not.
Sep-24-2020	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Original

090177e196d89032\Final\Final On: 22-Apr-2021 02:14 (GMT)

**Header Text:** c4591001

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

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

**Form Version:** 15-Sep-2020 21:56

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

**Site No:** 1044

**Site Name:** (1044) Virginia Research Center

**Subject No:** 10441139

**Subject Initials:** ---

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

**Generated Time (GMT):** 21-Apr-2021 18:02

08:00:39 (UTC-05:00) Eastern Time (US & Canada)		(b) (4), (b) (6)		value is correct
Sep-24-2020 08:00:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	Weight 147.1 is outside of Normal Range 25 - 136 for kg or 50 - 300 for lb.
Sep-24-2020 08:00:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 147.1	Initial Entry

**3. Unit:**

Date	Location	User	Value	Reason
Sep-24-2020 08:00:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> kg	Initial Entry

**4. Height:**

Date	Location	User	Value	Reason
Sep-24-2020 08:00:09 (UTC-05:00)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 175.3	Initial Entry

090177e196d89032\Final\Final On: 22-Apr-2021 02:14 (GMT)

**Header Text:** c4591001

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

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

**Form Version:** 15-Sep-2020 21:56

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

**Site No:** 1044

**Site Name:** (1044) Virginia Research Center

**Subject No:** 10441139

**Subject Initials:** ---

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

**Generated Time (GMT):** 21-Apr-2021 18:02

Eastern Time (US & Canada)				
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**5. Unit:**

Date	Location	User	Value	Reason
Sep-24-2020 08:00:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> cm	Initial Entry

**6. Body Mass Index:**

Date	Location	User	Value	Reason
Sep-24-2020 08:00:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 47.9	Initial Entry

**7.a**

Date	Location	User	Value	Reason
Sep-24-2020 08:00:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Record Id 1</b> <b>entifier::</b> <b>Temperat 98.5</b> <b>ure:</b> <b>Temperat F</b> <b>ure Unit:</b>	Initial Entry

090177e196d89032\Final\Final On: 22-Apr-2021 02:14 (GMT)

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form: VITAL SIGNS - BASELINE - eCRF Audit Trail History

Form Version: 15-Sep-2020 21:56

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1044

Site Name: (1044) Virginia Research Center

Subject No: 10441139

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 21-Apr-2021 18:02

			Temperat ure Locati on::	ORAL CAVIT Y
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**7.a Record Identifier:**

Date	Location	User	Value	Reason
Sep-24-2020 08:00:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 1	Initial Entry

**7.a Temperature:**

Date	Location	User	Value	Reason
Sep-24-2020 08:00:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 98.5	Initial Entry

**7.a Unit:**

Date	Location	User	Value	Reason
Sep-24-2020 08:00:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> F	Initial Entry

**7.a Temperature Location:**

090177e196d89032\Final\Final On: 22-Apr-2021 02:14 (GMT)

**Header Text:** c4591001

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

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

**Form Version:** 15-Sep-2020 21:56

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

**Site No:** 1044

**Site Name:** (1044) Virginia Research Center

**Subject No:** 10441139

**Subject Initials:** ---

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

**Generated Time (GMT):** 21-Apr-2021 18:02

Date	Location	User	Value	Reason
Sep-24-2020 08:00:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> ORAL CAVITY	Initial Entry



**Header Text:** c4591001

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

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

**Site No:** 1044

**Subject No:** 10441139

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

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

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

**Site Name:** (1044) Virginia Research Center

**Subject Initials:** ---

**Generated Time (GMT):** 21-Apr-2021 18:02

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**1. Randomization Date :**

Date	Location	User	Value	Reason
Sep-24-2020 07:57:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sep/23/2020	Initial Entry

**2. Randomization Number:**

Date	Location	User	Value	Reason
Sep-24-2020 07:57:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 98399	Initial Entry

090177e196d89032\Final\Final On: 22-Apr-2021 02:14 (GMT)

**Header Text:** c4591001

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

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

**Site No:** 1044

**Subject No:** 10441139

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

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

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

**Site Name:** (1044) Virginia Research Center

**Subject Initials:** ---

**Generated Time (GMT):** 21-Apr-2021 18:02

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**1. Data Origin**

Date	Location	User	Value	Reason
Sep-24-2020 07:57:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SITE	Initial Entry

**2. Sample Type**

Date	Location	User	Value	Reason
Sep-24-2020 07:57:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SERUM	Initial Entry

**3. Sample Collected?**

Date	Location	User	Value	Reason
Sep-24-2020 07:57:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Sep-24-2020 07:57:29 (UTC-05:00)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidat e	'Sample Collected?' is Yes, however

090177e196d89032\Final\Final On: 22-Apr-2021 02:14 (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:** 1044

**Site Name:** (1044) Virginia Research Center

**Subject No:** 10441139

**Subject Initials:** ---

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

**Generated Time (GMT):** 21-Apr-2021 18:02

Eastern Time (US & Canada)				no barcodes are entered. Please review and correct as appropriate.
Sep-24-2020 07:57:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES Date of Collection:  Sep/23/2020	Initial Entry

**5.a**

Date	Location	User	Value	Reason
Sep-24-2020 07:58:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample I</b> BLB6 <b>D:</b> 44	Transcription Error
Sep-24-2020 07:57:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample I</b> BN66 <b>D:</b> TZ	Initial Entry

**5.a Sample ID**

Date	Location	User	Value	Reason
Sep-24-2020 07:58:44 (UTC-05:00)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BLB644	Transcription Error

090177e196d89032\Final\Final On: 22-Apr-2021 02:14 (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: 1044

Site Name: (1044) Virginia Research Center

Subject No: 10441139

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 21-Apr-2021 18:02

Eastern Time (US & Canada)				
Sep-24-2020 07:57:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BN66TZ	Initial Entry

5.b

Date	Location	User	Value	Reason
Sep-24-2020 07:58:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample I</b> BLB63 <b>D:</b> 7	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Sep-24-2020 07:58:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BLB637	Initial Entry

5.c

Date	Location	User	Value	Reason
Sep-24-2020 07:59:10 (UTC-05:00)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample I</b> BN66T	Initial Entry

090177e196d89032\Final\Final On: 22-Apr-2021 02:14 (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:** 1044

**Site Name:** (1044) Virginia Research Center

**Subject No:** 10441139

**Subject Initials:** ---

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

**Generated Time (GMT):** 21-Apr-2021 18:02

Eastern Time (US & Canada)			<b>D:</b>	<b>G</b>	
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**5.c Sample ID**

<b>Date</b>	<b>Location</b>	<b>User</b>	<b>Value</b>	<b>Reason</b>
Sep-24-2020 07:59:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BN66TG	Initial Entry

090177e196d89032\Final\Final On: 22-Apr-2021 02:14 (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:** 1044

**Site Name:** (1044) Virginia Research Center

**Subject No:** 10441139

**Subject Initials:** ---

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

**Generated Time (GMT):** 21-Apr-2021 18:02

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**1. Data Origin**

Date	Location	User	Value	Reason
Sep-24-2020 07:56:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SITE	Initial Entry

**2. Sample Type**

Date	Location	User	Value	Reason
Sep-24-2020 07:56:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> NASAL_SWAB	Initial Entry

**3. Sample Collected?**

Date	Location	User	Value	Reason
Sep-24-2020 07:58:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Sep-24-2020 07:56:57 (UTC-05:00)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidat e	'Sample Collected?' is Yes, however

090177e196d89032\Final\Final On: 22-Apr-2021 02:14 (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:** 1044

**Site Name:** (1044) Virginia Research Center

**Subject No:** 10441139

**Subject Initials:** ---

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

**Generated Time (GMT):** 21-Apr-2021 18:02

Eastern Time (US & Canada)				no barcodes are entered. Please review and correct as appropriate.
Sep-24-2020 07:56:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES Date of Collection:  Sep/23/2020	Initial Entry

**5.a**

Date	Location	User	Value	Reason
Sep-25-2020 10:30:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample I</b> BN66T <b>D:</b> Y	Transcription Error
Sep-24-2020 07:58:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample I</b> BN66 <b>D:</b> TZ	Initial Entry

**5.a Sample ID**

Date	Location	User	Value	Reason
Sep-25-2020 10:30:30 (UTC-05:00)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BN66TY	Transcription Error

090177e196d89032\Final\Final On: 22-Apr-2021 02:14 (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:** 1044

**Site Name:** (1044) Virginia Research Center

**Subject No:** 10441139

**Subject Initials:** ---

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

**Generated Time (GMT):** 21-Apr-2021 18:02

Eastern Time (US & Canada)				
Sep-24-2020 07:58:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BN66TZ	Initial Entry



**Header Text:** c4591001

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

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

**Site No:** 1044

**Subject No:** 10441139

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

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

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

**Site Name:** (1044) Virginia Research Center

**Subject Initials:** ---

**Generated Time (GMT):** 21-Apr-2021 18:02

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

Date	Location	User	Value	Reason
Sep-24-2020 07:56:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**2. Treatment Name**

Date	Location	User	Value	Reason
Sep-24-2020 07:56:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> BLINDED THERAPY	Initial Entry

**3. Formulation:**

Date	Location	User	Value	Reason
Sep-24-2020 07:56:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> INJECTION	Initial Entry

**4. Dose Date Time:**

Date	Location	User	Value	Reason
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090177e196d89032\Final\Final On: 22-Apr-2021 02:14 (GMT)

**Header Text:** c4591001

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

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

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

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

**Site No:** 1044

**Site Name:** (1044) Virginia Research Center

**Subject No:** 10441139

**Subject Initials:** ---

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

**Generated Time (GMT):** 21-Apr-2021 18:02

Sep-24-2020 07:56:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sep/23/2020 18:31	Initial Entry
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**5. Anatomical Location:**

Date	Location	User	Value	Reason
Sep-24-2020 07:56:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> DELTOID MUSCLE	Initial Entry

**6. Body Side:**

Date	Location	User	Value	Reason
Sep-24-2020 07:56:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> LEFT	Initial Entry

**7. Route:**

Date	Location	User	Value	Reason
Sep-24-2020 07:56:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> INTRAMUSCULAR	Initial Entry

090177e196d89032\Final\Final On: 22-Apr-2021 02:14 (GMT)

**Header Text:** c4591001

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

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

**Site No:** 1044

**Subject No:** 10441139

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

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

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

**Site Name:** (1044) Virginia Research Center

**Subject Initials:** ---

**Generated Time (GMT):** 21-Apr-2021 18:02

**10. Timeframe Subject Was Observed**

Date	Location	User	Value	Reason
Sep-24-2020 07:56:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> THE PROTOCOL SPE CIFIED OBSERVATIO N 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-24-2020 07:56:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

090177e196d89032\Final\Final On: 22-Apr-2021 02:14 (GMT)

**Header Text:** c4591001

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

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

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

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

**Site No:** 1044

**Site Name:** (1044) Virginia Research Center

**Subject No:** 10441139

**Subject Initials:** ---

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

**Generated Time (GMT):** 21-Apr-2021 18:02

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*1. Select appropriate response - Reactogenicity diary collection*

Date	Location	User	Value	Reason
Sep-24-2020 07:55:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO - REACTOGE NICITY E-DIARY NOT COLLECTED FOR THIS SUBJE CT	Initial Entry

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1044

**Subject No:** 10441139

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

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

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

**Site Name:** (1044) Virginia Research Center

**Subject Initials:** ---

**Generated Time (GMT):** 21-Apr-2021 18:02

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*1. Date of Visit*

Date	Location	User	Value	Reason
Oct-14-2020 11:44:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Oct/14/2020	Initial Entry

090177e196d89032\Final\Final On: 22-Apr-2021 02:14 (GMT)

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1044

**Subject No:** 10441139

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

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

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

**Site Name:** (1044) Virginia Research Center

**Subject Initials:** ---

**Generated Time (GMT):** 21-Apr-2021 18:02

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**1. Date:**

Date	Location	User	Value	Reason
Oct-14-2020 11:44:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Oct/14/2020	Initial Entry

**2.a**

Date	Location	User	Value	Reason
Oct-14-2020 11:44:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Record Id 1</b> <b>entifier::</b> <b>Temperat 98.9</b> <b>ure:</b> <b>Temperat F</b> <b>ure Unit:</b> <b>Temperat ORAL</b> <b>ure Locati CAVIT</b> <b>on:: Y</b>	Initial Entry

**2.a Record Identifier:**

Date	Location	User	Value	Reason
Oct-14-2020 11:44:33 (UTC-05:00) Eastern Time (US	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 1	Initial Entry

090177e196d89032\Final\Final On: 22-Apr-2021 02:14 (GMT)

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

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

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

**Site No:** 1044

**Site Name:** (1044) Virginia Research Center

**Subject No:** 10441139

**Subject Initials:** ---

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

**Generated Time (GMT):** 21-Apr-2021 18:02

& Canada)

**2.a Temperature:**

Date	Location	User	Value	Reason
Oct-14-2020 11:44:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 98.9	Initial Entry

**2.a Unit:**

Date	Location	User	Value	Reason
Oct-14-2020 11:44:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> F	Initial Entry

**2.a Temperature Location:**

Date	Location	User	Value	Reason
Oct-14-2020 11:44:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> ORAL CAVITY	Initial Entry

090177e196d89032\Final\Final On: 22-Apr-2021 02:14 (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:** 1044

**Site Name:** (1044) Virginia Research Center

**Subject No:** 10441139

**Subject Initials:** ---

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

**Generated Time (GMT):** 21-Apr-2021 18:02

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**1. Data Origin**

Date	Location	User	Value	Reason
Oct-14-2020 11:44:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SITE	Initial Entry

**2. Sample Type**

Date	Location	User	Value	Reason
Oct-14-2020 11:44:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> NASAL_SWAB	Initial Entry

**3. Sample Collected?**

Date	Location	User	Value	Reason
Oct-14-2020 11:45:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Oct-14-2020 11:44:45 (UTC-05:00)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however

090177e196d89032\Final\Final On: 22-Apr-2021 02:14 (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:** 1044

**Site Name:** (1044) Virginia Research Center

**Subject No:** 10441139

**Subject Initials:** ---

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

**Generated Time (GMT):** 21-Apr-2021 18:02

Eastern Time (US & Canada)				no barcodes are entered. Please review and correct as appropriate.
Oct-14-2020 11:44:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES Date of Collection:  Oct/14/2020	Initial Entry

**5.a**

Date	Location	User	Value	Reason
Oct-14-2020 11:45:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample I</b> BN66X <b>D:</b> D	Initial Entry

**5.a Sample ID**

Date	Location	User	Value	Reason
Oct-14-2020 11:45:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BN66XD	Initial Entry

090177e196d89032\Final\Final On: 22-Apr-2021 02:14 (GMT)

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1044

**Subject No:** 10441139

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

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

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

**Site Name:** (1044) Virginia Research Center

**Subject Initials:** ---

**Generated Time (GMT):** 21-Apr-2021 18:02

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

Date	Location	User	Value	Reason
Oct-14-2020 11:45:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**2. Treatment Name**

Date	Location	User	Value	Reason
Oct-14-2020 11:45:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> BLINDED THERAPY	Initial Entry

**3. Formulation:**

Date	Location	User	Value	Reason
Oct-14-2020 11:45:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> INJECTION	Initial Entry

**4. Dose Date Time:**

Date	Location	User	Value	Reason
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090177e196d89032\Final\Final On: 22-Apr-2021 02:14 (GMT)

Header Text: c4591001

Visit: V2\_VAX2\_L

Form: VACCINATION - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1044

Site Name: (1044) Virginia Research Center

Subject No: 10441139

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 21-Apr-2021 18:02

Oct-14-2020 11:45:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Oct/14/2020 10:23	Initial Entry
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**5. Anatomical Location:**

Date	Location	User	Value	Reason
Oct-14-2020 11:45:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> DELTOID MUSCLE	Initial Entry

**6. Body Side:**

Date	Location	User	Value	Reason
Oct-14-2020 11:45:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> LEFT	Initial Entry

**7. Route:**

Date	Location	User	Value	Reason
Oct-14-2020 11:45:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> INTRAMUSCULAR	Initial Entry

090177e196d89032\Final\Final On: 22-Apr-2021 02:14 (GMT)

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

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

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

**Site No:** 1044

**Site Name:** (1044) Virginia Research Center

**Subject No:** 10441139

**Subject Initials:** ---

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

**Generated Time (GMT):** 21-Apr-2021 18:02

**10. Timeframe Subject Was Observed**

Date	Location	User	Value	Reason
Oct-14-2020 11:45:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> THE PROTOCOL SPE CIFIED OBSERVATIO N PERIOD	Initial Entry

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

Date	Location	User	Value	Reason
Oct-14-2020 11:45:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

090177e196d89032\Final\Final On: 22-Apr-2021 02:14 (GMT)

**Header Text:** c4591001

**Visit:** V3\_MONTH1\_POSTVAX2\_L **Form:** DATE OF VISIT - eCRF Audit Trail History

**Form Version:** 22-Apr-2020 21:02 **Form Status:** Data Complete, Locked, Frozen, Verified

**Site No:** 1044 **Site Name:** (1044) Virginia Research Center

**Subject No:** 10441139 **Subject Initials:** ---

**Generated By:** (b) (4) **Generated Time (GMT):** 21-Apr-2021 18:02

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*1. Date of Visit*

Date	Location	User	Value	Reason
Nov-11-2020 09:49:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Nov/11/2020	Initial Entry

090177e196d89032\Final\Final On: 22-Apr-2021 02:14 (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:** 1044 **Site Name:** (1044) Virginia Research Center

**Subject No:** 10441139 **Subject Initials:** ---

**Generated By:** (b) (4) **Generated Time (GMT):** 21-Apr-2021 18:02

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**1. Data Origin**

Date	Location	User	Value	Reason
Nov-11-2020 09:49:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SITE	Initial Entry

**2. Sample Type**

Date	Location	User	Value	Reason
Nov-11-2020 09:49:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SERUM	Initial Entry

**3. Sample Collected?**

Date	Location	User	Value	Reason
Nov-11-2020 09:49:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Nov-11-2020 09:49:38 (UTC-05:00)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidat e	'Sample Collected?' is Yes, however

090177e196d89032\Final\Final On: 22-Apr-2021 02:14 (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:** 1044 **Site Name:** (1044) Virginia Research Center

**Subject No:** 10441139 **Subject Initials:** ---

**Generated By:** (b) (4) **Generated Time (GMT):** 21-Apr-2021 18:02

Eastern Time (US & Canada)				no barcodes are entered. Please review and correct as appropriate.
Nov-11-2020 09:49:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES Date of Collection:  Nov/11/2020	Initial Entry

**5.a**

Date	Location	User	Value	Reason
Nov-11-2020 09:49:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample I</b> BPW0H <b>D:</b> K	Initial Entry

**5.a Sample ID**

Date	Location	User	Value	Reason
Nov-11-2020 09:49:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BPW0HK	Initial Entry

**5.b**

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**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:** 1044 **Site Name:** (1044) Virginia Research Center

**Subject No:** 10441139 **Subject Initials:** ---

**Generated By:** (b) (4) **Generated Time (GMT):** 21-Apr-2021 18:02

Date	Location	User	Value	Reason
Nov-11-2020 09:50:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample I</b> BRVK <b>D:</b> RJ	Initial Entry

**5.b Sample ID**

Date	Location	User	Value	Reason
Nov-11-2020 09:50:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BRVKRJ	Initial Entry

**5.c**

Date	Location	User	Value	Reason
Nov-11-2020 09:50:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample I</b> BRVKS <b>D:</b> D	Initial Entry

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**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:** 1044 **Site Name:** (1044) Virginia Research Center

**Subject No:** 10441139 **Subject Initials:** ---

**Generated By:** (b) (4) **Generated Time (GMT):** 21-Apr-2021 18:02

*5.c Sample ID*

Date	Location	User	Value	Reason
Nov-11-2020 09:50:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BRVKSD	Initial Entry

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

**Form:** ADVERSE EVENT REPORT - Audit Trail

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

**Form Status:**

**Site No:** 1044

**Site Name:** (1044) Virginia Research Center

**Subject No:** 10441139

**Subject Initials:** ---

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

**Generated Time (GMT):** 21-Apr-2021 18:02

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Date	Location	User	Value	Reason
Oct-17-2020 11:00:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

**Form:** ADVERSE EVENT REPORT - Audit Trail

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

**Form Status:**

**Site No:** 1044

**Site Name:** (1044) Virginia Research Center

**Subject No:** 10441139

**Subject Initials:** ---

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

**Generated Time (GMT):** 21-Apr-2021 18:02

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Date	Location	User	Value	Reason
Oct-17-2020 11:01:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

**Form:** ADVERSE EVENT REPORT - Audit Trail

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

**Form Status:**

**Site No:** 1044

**Site Name:** (1044) Virginia Research Center

**Subject No:** 10441139

**Subject Initials:** ---

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

**Generated Time (GMT):** 21-Apr-2021 18:02

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Date	Location	User	Value	Reason
Oct-17-2020 11:02:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

**Form:** ADVERSE EVENT REPORT - Audit Trail

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

**Form Status:**

**Site No:** 1044

**Site Name:** (1044) Virginia Research Center

**Subject No:** 10441139

**Subject Initials:** ---

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

**Generated Time (GMT):** 21-Apr-2021 18:02

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Date	Location	User	Value	Reason
Nov-11-2020 09:53:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

**Form:** ADVERSE EVENT REPORT - Audit Trail

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

**Form Status:**

**Site No:** 1044

**Site Name:** (1044) Virginia Research Center

**Subject No:** 10441139

**Subject Initials:** ---

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

**Generated Time (GMT):** 21-Apr-2021 18:02

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Date	Location	User	Value	Reason
Nov-11-2020 09:54:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

**Form:** ADVERSE EVENT REPORT - Audit Trail

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

**Form Status:**

**Site No:** 1044

**Site Name:** (1044) Virginia Research Center

**Subject No:** 10441139

**Subject Initials:** ---

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

**Generated Time (GMT):** 21-Apr-2021 18:02

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Date	Location	User	Value	Reason
Nov-11-2020 09:56:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History

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

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

**Site No:** 1044

**Site Name:** (1044) Virginia Research Center

**Subject No:** 10441139

**Subject Initials:** ---

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

**Generated Time (GMT):** 21-Apr-2021 18:02

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**1. Category:**

Date	Location	User	Value	Reason
Oct-17-2020 11:00:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> ADVERSE EVENT	Initial Entry

**2. AE ID:**

Date	Location	User	Value	Reason
Oct-17-2020 11:00:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 1	Initial Entry

**3. Adverse Event:**

*(If possible specify diagnosis, not individual symptoms)*

Date	Location	User	Value	Reason
Oct-17-2020 11:00:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> chills	Initial Entry

**4. Start Date Time:**

Date	Location	User	Value	Reason
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090177e196d89032\Final\Final On: 22-Apr-2021 02:14 (GMT)



**Header Text:** c4591001

**Visit:** Logs - Unscheduled

**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History

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

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

**Site No:** 1044

**Site Name:** (1044) Virginia Research Center

**Subject No:** 10441139

**Subject Initials:** ---

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

**Generated Time (GMT):** 21-Apr-2021 18:02

Oct-17-2020 11:00:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Oct/15/2020 UNK: UNK	Initial Entry
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**5. Is the adverse event still ongoing?**

Date	Location	User	Value	Reason
Oct-17-2020 11:00:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO End Date Time:  Oct/15/2020 UN K:UNK	Initial Entry

**6. Toxicity Grade:**

Date	Location	User	Value	Reason
Oct-17-2020 11:00:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 1	Initial Entry

**7. Is the adverse event serious?**

**If Yes, NOTIFY PFIZER IMMEDIATELY.**

**Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).**

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**Header Text:** c4591001

**Visit:** Logs - Unscheduled

**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History

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

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

**Site No:** 1044

**Site Name:** (1044) Virginia Research Center

**Subject No:** 10441139

**Subject Initials:** ---

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

**Generated Time (GMT):** 21-Apr-2021 18:02

Date	Location	User	Value	Reason
Oct-17-2020 11:00:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

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

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

Date	Location	User	Value	Reason
Oct-17-2020 11:00:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**9. Is this event related to study treatment:**

Date	Location	User	Value	Reason
Oct-17-2020 11:00:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> RELATED	Initial Entry

**10. Latest Action Taken with Study Treatment:**

Date	Location	User	Value	Reason
Oct-17-2020 11:00:48 (UTC-05:00)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NOT APPLICABLE	Initial Entry

090177e196d89032\Final\Final On: 22-Apr-2021 02:14 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History

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

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

**Site No:** 1044

**Site Name:** (1044) Virginia Research Center

**Subject No:** 10441139

**Subject Initials:** ---

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

**Generated Time (GMT):** 21-Apr-2021 18:02

Eastern Time (US & Canada)

**11. Was a Concomitant Medication given?**

Date	Location	User	Value	Reason
Oct-17-2020 11:00:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**12. Was a Non-Drug Treatment given?**

Date	Location	User	Value	Reason
Oct-17-2020 11:00:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

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

Date	Location	User	Value	Reason
Oct-17-2020 11:00:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> RECOVERED/RESOLVED	Initial Entry

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

090177e196d89032\Final\Final On: 22-Apr-2021 02:14 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History

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

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

**Site No:** 1044

**Site Name:** (1044) Virginia Research Center

**Subject No:** 10441139

**Subject Initials:** ---

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

**Generated Time (GMT):** 21-Apr-2021 18:02

Date	Location	User	Value	Reason
Oct-17-2020 11:00:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History

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

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

**Site No:** 1044

**Site Name:** (1044) Virginia Research Center

**Subject No:** 10441139

**Subject Initials:** ---

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

**Generated Time (GMT):** 21-Apr-2021 18:02

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**1. Category:**

Date	Location	User	Value	Reason
Oct-17-2020 11:01:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> ADVERSE EVENT	Initial Entry

**2. AE ID:**

Date	Location	User	Value	Reason
Oct-17-2020 11:01:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 2	Initial Entry

**3. Adverse Event:**

*(If possible specify diagnosis, not individual symptoms)*

Date	Location	User	Value	Reason
Oct-17-2020 11:01:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> fever	Initial Entry

**4. Start Date Time:**

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**Header Text:** c4591001

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**Subject No:** 10441139

**Subject Initials:** ---

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

**Generated Time (GMT):** 21-Apr-2021 18:02

Date	Location	User	Value	Reason
Oct-17-2020 11:01:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Oct/15/2020 UNK: UNK	Initial Entry

**5. Is the adverse event still ongoing?**

Date	Location	User	Value	Reason
Nov-11-2020 09:57:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO End Date Time:  Oct/16/2020 U NK:UNK	Transcription Error
Oct-21-2020 10:22:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Oct-19-2020 10:35:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	will be updated when subject presents for visit 3
Oct-17-2020 13:08:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	Please confirm if event has resolved?

090177e196d89032\Final\Final On: 22-Apr-2021 02:14 (GMT)

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**Site Name:** (1044) Virginia Research Center

**Subject No:** 10441139

**Subject Initials:** ---

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

**Generated Time (GMT):** 21-Apr-2021 18:02

Oct-17-2020 11:01:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry
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**6. Toxicity Grade:**

Date	Location	User	Value	Reason
Oct-17-2020 11:01:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 1	Initial Entry

**7. Is the adverse event serious?**

***If Yes, NOTIFY PFIZER IMMEDIATELY.***

***Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).***

Date	Location	User	Value	Reason
Oct-17-2020 11:01:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

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

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

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

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Date	Location	User	Value	Reason
Oct-17-2020 11:01:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**9. Is this event related to study treatment:**

Date	Location	User	Value	Reason
Oct-17-2020 11:01:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> RELATED	Initial Entry

**10. Latest Action Taken with Study Treatment:**

Date	Location	User	Value	Reason
Oct-17-2020 11:01:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NOT APPLICABLE	Initial Entry

**11. Was a Concomitant Medication given?**

Date	Location	User	Value	Reason
Oct-17-2020 11:01:32 (UTC-05:00) Eastern Time (US	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

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

**Generated Time (GMT):** 21-Apr-2021 18:02

& Canada)

**12. Was a Non-Drug Treatment given?**

Date	Location	User	Value	Reason
Oct-17-2020 11:01:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

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

Date	Location	User	Value	Reason
Nov-11-2020 09:58:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Clo sed	Close Auto Query
Nov-11-2020 09:58:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> RECOVERE D/RESOLV ED	Changed Information
Nov-11-2020 09:57:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Op ened	For AE fever: Response to "What was the outcome of this adverse event?" is 'Recovering/Resolving' but AE End Date/Time is present.

090177e196d89032\Final\Final On: 22-Apr-2021 02:14 (GMT)

**Header Text:** c4591001

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**Subject No:** 10441139

**Subject Initials:** ---

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

**Generated Time (GMT):** 21-Apr-2021 18:02

Oct-17-2020 11:01:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> RECOVERI NG/RESOL VING	Initial Entry
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**14. Did the adverse event cause the subject to be discontinued from the study?**

Date	Location	User	Value	Reason
Oct-17-2020 11:01:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

090177e196d89032\Final\Final On: 22-Apr-2021 02:14 (GMT)

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**Subject No:** 10441139

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

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**1. Category:**

Date	Location	User	Value	Reason
Oct-17-2020 11:02:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> ADVERSE EVENT	Initial Entry

**2. AE ID:**

Date	Location	User	Value	Reason
Oct-17-2020 11:02:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 3	Initial Entry

**3. Adverse Event:**

*(If possible specify diagnosis, not individual symptoms)*

Date	Location	User	Value	Reason
Oct-17-2020 11:02:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> injection site pain	Initial Entry

**4. Start Date Time:**

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**Header Text:** c4591001

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

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Date	Location	User	Value	Reason
Oct-20-2020 08:16:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Oct-19-2020 07:57:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	after vaccination
Oct-19-2020 02:24:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued:Opened	DM: Thank you for the response. Vaccination date is same as event date. Please confirm if event occur prior to vaccination or after the vaccination. Else clarify.
Oct-17-2020 18:00:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Original value is correct
Oct-17-2020 13:09:56 (UTC-05:00) Eastern Time	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued:Opened	Please confirm if start time should be the same as IP

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**Header Text:** c4591001

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

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(US & Canada)				administration?
Oct-17-2020 11:02:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Original value is correct
Oct-17-2020 11:02:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	For AE injection site pain: Start Date is the same as a Vaccination Date, but time is not provided. Please review and update as appropriate.
Oct-17-2020 11:02:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Oct/14/2020 UN K:UNK	Initial Entry

**5. Is the adverse event still ongoing?**

Date	Location	User	Value	Reason
Nov-11-2020 09:58:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO End Date Time: Oct/15/2020 UN NK:UNK	Changed Information

090177e196d89032\Final\Final On: 22-Apr-2021 02:14 (GMT)

**Header Text:** c4591001

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**Site Name:** (1044) Virginia Research Center

**Subject No:** 10441139

**Subject Initials:** ---

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

**Generated Time (GMT):** 21-Apr-2021 18:02

Oct-21-2020 10:24:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Oct-19-2020 10:35:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	will be updated when subject presents for visit 3
Oct-17-2020 13:08:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	Please confirm if event has resolved?
Oct-17-2020 11:02:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

**6. Toxicity Grade:**

Date	Location	User	Value	Reason
Oct-17-2020 11:02:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 1	Initial Entry

**7. Is the adverse event serious?**

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**Site Name:** (1044) Virginia Research Center

**Subject No:** 10441139

**Subject Initials:** ---

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

**Generated Time (GMT):** 21-Apr-2021 18:02

*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
Oct-17-2020 11:02:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

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

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

Date	Location	User	Value	Reason
Oct-17-2020 11:02:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**9. Is this event related to study treatment:**

Date	Location	User	Value	Reason
Oct-17-2020 11:02:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> RELATED	Initial Entry

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

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**10. Latest Action Taken with Study Treatment:**

Date	Location	User	Value	Reason
Oct-17-2020 11:02:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NOT APPLICABLE	Initial Entry

**11. Was a Concomitant Medication given?**

Date	Location	User	Value	Reason
Oct-17-2020 11:02:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**12. Was a Non-Drug Treatment given?**

Date	Location	User	Value	Reason
Oct-17-2020 11:02:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

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

Date	Location	User	Value	Reason
Nov-11-2020 09:59:00	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query

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**Subject No:** 10441139

**Subject Initials:** ---

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

**Generated Time (GMT):** 21-Apr-2021 18:02

(UTC-05:00) Eastern Time (US & Canada)				
Nov-11-2020 09:59:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> RECOVERE D/RESOLV ED	Changed Information
Nov-11-2020 09:58:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Op ened	For AE injection site pain: Response to "What was the outcome of this adverse event?" is 'Recovering/Resolving' but AE End Date/Time is present.
Oct-17-2020 11:02:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> RECOVERI NG/RESOL VING	Initial Entry

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

Date	Location	User	Value	Reason
Oct-17-2020 11:02:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

090177e196d89032\Final\Final On: 22-Apr-2021 02:14 (GMT)

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**1. Category:**

Date	Location	User	Value	Reason
Nov-11-2020 09:53:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> ADVERSE EVENT	Initial Entry

**2. AE ID:**

Date	Location	User	Value	Reason
Nov-11-2020 09:53:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 4	Initial Entry

**3. Adverse Event:**

*(If possible specify diagnosis, not individual symptoms)*

Date	Location	User	Value	Reason
Nov-11-2020 09:53:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> fatigue	Initial Entry

**4. Start Date Time:**

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

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Date	Location	User	Value	Reason
Nov-12-2020 01:20:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Closed as data updated.
Nov-11-2020 15:07:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Answer Auto Query
Nov-11-2020 15:07:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Oct/14/2020 18:00	Changed Information
Nov-11-2020 14:19:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued :Opened	DM: Thank you for response, however please provide a approximate time for after vaccination.
Nov-11-2020 09:53:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	after vaccination

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**Generated Time (GMT):** 21-Apr-2021 18:02

Nov-11-2020 09:53:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	For AE fatigue: Start Date is the same as a Vaccination Date, but time is not provided. Please review and update as appropriate.
Nov-11-2020 09:53:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Oct/14/2020 UNK :UNK	Initial Entry

**5. Is the adverse event still ongoing?**

Date	Location	User	Value	Reason
Nov-11-2020 09:53:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO End Date Time:  Oct/16/2020 UN K:UNK	Initial Entry

**6. Toxicity Grade:**

Date	Location	User	Value	Reason
Nov-11-2020 09:53:03	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 1	Initial Entry

090177e196d89032\Final\Final On: 22-Apr-2021 02:14 (GMT)

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

**Generated Time (GMT):** 21-Apr-2021 18:02

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

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

**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
Nov-11-2020 09:53:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

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

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

Date	Location	User	Value	Reason
Nov-11-2020 09:53:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**9. Is this event related to study treatment:**

Date	Location	User	Value	Reason
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090177e196d89032\Final\Final On: 22-Apr-2021 02:14 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History

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

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

**Site No:** 1044

**Site Name:** (1044) Virginia Research Center

**Subject No:** 10441139

**Subject Initials:** ---

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

**Generated Time (GMT):** 21-Apr-2021 18:02

Nov-11-2020 09:53:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> RELATED	Initial Entry
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**10. Latest Action Taken with Study Treatment:**

Date	Location	User	Value	Reason
Nov-11-2020 09:53:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NOT APPLICABLE	Initial Entry

**11. Was a Concomitant Medication given?**

Date	Location	User	Value	Reason
Nov-11-2020 09:53:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**12. Was a Non-Drug Treatment given?**

Date	Location	User	Value	Reason
Nov-11-2020 09:53:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

090177e196d89032\Final\Final On: 22-Apr-2021 02:14 (GMT)

**Header Text:** c4591001

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**Site No:** 1044

**Site Name:** (1044) Virginia Research Center

**Subject No:** 10441139

**Subject Initials:** ---

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

**Generated Time (GMT):** 21-Apr-2021 18:02

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

Date	Location	User	Value	Reason
Nov-11-2020 09:53:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> RECOVERED/RES OLVED	Initial Entry

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

Date	Location	User	Value	Reason
Nov-11-2020 09:53:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

090177e196d89032\Final\Final On: 22-Apr-2021 02:14 (GMT)

**Header Text:** c4591001

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

**Site No:** 1044

**Site Name:** (1044) Virginia Research Center

**Subject No:** 10441139

**Subject Initials:** ---

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

**Generated Time (GMT):** 21-Apr-2021 18:02

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**1. Category:**

Date	Location	User	Value	Reason
Nov-11-2020 09:54:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> ADVERSE EVENT	Initial Entry

**2. AE ID:**

Date	Location	User	Value	Reason
Nov-11-2020 09:54:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 5	Initial Entry

**3. Adverse Event:**

*(If possible specify diagnosis, not individual symptoms)*

Date	Location	User	Value	Reason
Nov-11-2020 09:54:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> headache	Initial Entry

**4. Start Date Time:**

090177e196d89032\Final\Final On: 22-Apr-2021 02:14 (GMT)



**Header Text:** c4591001

**Visit:** Logs - Unscheduled

**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History

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**Site No:** 1044

**Site Name:** (1044) Virginia Research Center

**Subject No:** 10441139

**Subject Initials:** ---

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

**Generated Time (GMT):** 21-Apr-2021 18:02

Date	Location	User	Value	Reason
Nov-12-2020 01:20:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Closed as data updated.
Nov-11-2020 15:07:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Answer Auto Query
Nov-11-2020 15:07:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Oct/14/2020 18:00	New Information
Nov-11-2020 14:19:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued :Opened	DM: Thank you for response, however please provide a approximate time for after vaccination.
Nov-11-2020 09:54:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	after vaccination

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

**Generated Time (GMT):** 21-Apr-2021 18:02

Nov-11-2020 09:54:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	For AE headache: Start Date is the same as a Vaccination Date, but time is not provided. Please review and update as appropriate.
Nov-11-2020 09:54:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Oct/14/2020 UNK :UNK	Initial Entry

**5. Is the adverse event still ongoing?**

Date	Location	User	Value	Reason
Nov-11-2020 09:54:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO End Date Time:  Oct/16/2020 UNK:UNK	Initial Entry

**6. Toxicity Grade:**

Date	Location	User	Value	Reason
Nov-11-2020 09:54:44	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 1	Initial Entry

090177e196d89032\Final\Final On: 22-Apr-2021 02:14 (GMT)

**Header Text:** c4591001

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**Subject No:** 10441139

**Subject Initials:** ---

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

**Generated Time (GMT):** 21-Apr-2021 18:02

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

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

**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
Nov-11-2020 09:54:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

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

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

Date	Location	User	Value	Reason
Nov-11-2020 09:54:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**9. Is this event related to study treatment:**

Date	Location	User	Value	Reason
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090177e196d89032\Final\Final On: 22-Apr-2021 02:14 (GMT)

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**Subject Initials:** ---

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

**Generated Time (GMT):** 21-Apr-2021 18:02

Nov-11-2020 09:54:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> RELATED	Initial Entry
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**10. Latest Action Taken with Study Treatment:**

Date	Location	User	Value	Reason
Nov-11-2020 09:55:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NOT APPLICABLE	Initial Entry

**11. Was a Concomitant Medication given?**

Date	Location	User	Value	Reason
Nov-11-2020 09:54:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**12. Was a Non-Drug Treatment given?**

Date	Location	User	Value	Reason
Nov-11-2020 09:54:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

090177e196d89032\Final\Final On: 22-Apr-2021 02:14 (GMT)

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**Site Name:** (1044) Virginia Research Center

**Subject No:** 10441139

**Subject Initials:** ---

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

**Generated Time (GMT):** 21-Apr-2021 18:02

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

Date	Location	User	Value	Reason
Nov-11-2020 09:54:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> RECOVERED/RES OLVED	Initial Entry

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

Date	Location	User	Value	Reason
Nov-11-2020 09:54:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

090177e196d89032\Final\Final On: 22-Apr-2021 02:14 (GMT)

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**Site No:** 1044

**Site Name:** (1044) Virginia Research Center

**Subject No:** 10441139

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

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**1. Category:**

Date	Location	User	Value	Reason
Nov-11-2020 09:56:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> ADVERSE EVENT	Initial Entry

**2. AE ID:**

Date	Location	User	Value	Reason
Nov-11-2020 09:56:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 6	Initial Entry

**3. Adverse Event:**

*(If possible specify diagnosis, not individual symptoms)*

Date	Location	User	Value	Reason
Nov-14-2020 08:02:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Nov-13-2020	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Closed	Response

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**Form Status:** Data Complete, Locked, Frozen, Not Complete

**Site No:** 1044

**Site Name:** (1044) Virginia Research Center

**Subject No:** 10441139

**Subject Initials:** ---

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

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14:11:38 (UTC-05:00) Eastern Time (US & Canada)		(b) (4), (b) (6)		satisfies query
Nov-13-2020 13:36:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Answered	unknown
Nov-13-2020 10:35:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Opened	clinical: Pls advise if AE is considered an allergic reaction, and if so pls add separate AE of allergic reaction on CRF. Thanks
Nov-12-2020 16:52:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	New Information
Nov-12-2020 16:52:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Angioedema face	New Information
Nov-12-2020 15:58:07 (UTC-05:00)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	ClinQuery:Please specify location of AE in the

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**Header Text:** c4591001

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**Site No:** 1044

**Site Name:** (1044) Virginia Research Center

**Subject No:** 10441139

**Subject Initials:** ---

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

**Generated Time (GMT):** 21-Apr-2021 18:02

Eastern Time (US & Canada)				verbatim term. Thank you.
Nov-11-2020 09:56:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Angioedema	Initial Entry

**4. Start Date Time:**

Date	Location	User	Value	Reason
Nov-11-2020 09:56:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Oct/16/2020 UNK: UNK	Initial Entry

**5. Is the adverse event still ongoing?**

Date	Location	User	Value	Reason
Nov-11-2020 09:56:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO End Date Time: Oct/17/2020 UNK:UNK	Initial Entry

**6. Toxicity Grade:**

Date	Location	User	Value	Reason
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**Subject No:** 10441139

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

**Generated Time (GMT):** 21-Apr-2021 18:02

Nov-11-2020 09:56:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 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
Nov-11-2020 09:56:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

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

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

Date	Location	User	Value	Reason
Nov-11-2020 09:56:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

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**Site Name:** (1044) Virginia Research Center

**Subject No:** 10441139

**Subject Initials:** ---

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

**Generated Time (GMT):** 21-Apr-2021 18:02

**9. Is this event related to study treatment:**

Date	Location	User	Value	Reason
Nov-11-2020 09:56:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> RELATED	Initial Entry

**10. Latest Action Taken with Study Treatment:**

Date	Location	User	Value	Reason
Nov-11-2020 09:56:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NOT APPLICABLE	Initial Entry

**11. Was a Concomitant Medication given?**

Date	Location	User	Value	Reason
Nov-11-2020 09:56:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**12. Was a Non-Drug Treatment given?**

Date	Location	User	Value	Reason
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**Site No:** 1044

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

**Generated Time (GMT):** 21-Apr-2021 18:02

Nov-11-2020 09:56:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry
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**13. What was the outcome of this adverse event?:**

Date	Location	User	Value	Reason
Nov-11-2020 09:56:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> RECOVERED/RES OLVED	Initial Entry

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

Date	Location	User	Value	Reason
Nov-11-2020 09:56:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

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**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

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

**Form Status:**

**Site No:** 1044

**Site Name:** (1044) Virginia Research Center

**Subject No:** 10441139

**Subject Initials:** ---

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

**Generated Time (GMT):** 21-Apr-2021 18:02

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Date	Location	User	Value	Reason
Nov-12-2020 14:51:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

**Form:** CONCOMITANT MEDICATIONS - NON STUDY VACCINATIONS - eCRF Audit Trail History

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

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

**Site No:** 1044

**Site Name:** (1044) Virginia Research Center

**Subject No:** 10441139

**Subject Initials:** ---

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

**Generated Time (GMT):** 21-Apr-2021 18:02

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**1. What is the medication identifier?**

Date	Location	User	Value	Reason
Nov-12-2020 14:51:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 1	Initial Entry

**2. Category:**

Date	Location	User	Value	Reason
Nov-12-2020 14:51:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> VACCINATIONS	Initial Entry

**3. Concomitant Medications Pre-specified:**

Date	Location	User	Value	Reason
Nov-12-2020 14:51:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> NO	Initial Entry

**4. Medication:**

*Provide the complete generic drug name (including salt form, where applicable). Where generic name is unknown, enter the full trade or proprietary name. Include clarifying information in*

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**Header Text:** c4591001

**Visit:** Logs - Unscheduled

**Form:** CONCOMITANT MEDICATIONS - NON STUDY VACCINATIONS - eCRF Audit Trail History

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

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

**Site No:** 1044

**Site Name:** (1044) Virginia Research Center

**Subject No:** 10441139

**Subject Initials:** ---

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

**Generated Time (GMT):** 21-Apr-2021 18:02

*the Medication text (e.g., Ingredient(s), route, use, formulation).*

Date	Location	User	Value	Reason
Nov-12-2020 15:34:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Nov-12-2020 14:51:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Initial Entry
Nov-12-2020 14:51:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Influenza Vaccine	Initial Entry
Nov-12-2020 14:46:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	Per Source subject reported receiving the Influenza Vax on 9Nov2020. Please review and reconcile.

**5. Date:**

Date	Location	User	Value	Reason
Nov-12-2020	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	Initial Entry

090177e196d89032\Final\Final On: 22-Apr-2021 02:14 (GMT)

**Header Text:** c4591001

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STUDY VACCINATIONS - eCRF Audit Trail History

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

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

**Site No:** 1044

**Site Name:** (1044) Virginia Research Center

**Subject No:** 10441139

**Subject Initials:** ---

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

**Generated Time (GMT):** 21-Apr-2021 18:02

14:51:06 (UTC-05:00) Eastern Time (US & Canada)		(b) (4), (b) (6)	Nov/9/2020	
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**Header Text:** c4591001

**Visit:** End of Treatment - Unscheduled **Form:** DISPOSITION - TREATMENT - eCRF Audit Trail History

**Form Version:** 15-Sep-2020 21:55 **Form Status:** Data Complete, Locked, Frozen, Verified

**Site No:** 1044

**Site Name:** (1044) Virginia Research Center

**Subject No:** 10441139

**Subject Initials:** ---

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

**Generated Time (GMT):** 21-Apr-2021 18:02

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

Date	Location	User	Value	Reason
Nov-11-2020 09:51:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Nov/11/2020	Initial Entry

**2. Phase of Disposition:**

Date	Location	User	Value	Reason
Nov-11-2020 09:51:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> VACCINATION	Initial Entry

**3. Status:**

Date	Location	User	Value	Reason
Nov-11-2020 09:51:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> COMPLETED	Initial Entry

090177e196d89032\Final\Final On: 22-Apr-2021 02:14 (GMT)



**Header Text:** c4591001

**Visit:** Potential ReVax Initial Contact - **Form:** DATE OF VISIT - eCRF Audit Trail History  
Unscheduled

**Form Version:** 22-Apr-2020 21:02      **Form Status:** Data Complete, Frozen, Verified

**Site No:** 1044      **Site Name:** (1044) Virginia Research Center

**Subject No:** 10441139      **Subject Initials:** ---

**Generated By:** (b) (4)      **Generated Time (GMT):** 21-Apr-2021 18:02

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*1. Date of Visit*

Date	Location	User	Value	Reason
Jan-20-2021 08:02:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Jan/8/2021	Initial Entry

090177e196d89032\Final\Final On: 22-Apr-2021 02:14 (GMT)

**Header Text:** c4591001

**Visit:** Potential ReVax Initial Contact - **Form:** FURTHER VACCINATION CONFIRMATION -  
Unscheduled eCRF Audit Trail History

**Form Version:** 10-Dec-2020 02:25 **Form Status:** Data Complete, Frozen

**Site No:** 1044 **Site Name:** (1044) Virginia Research Center

**Subject No:** 10441139 **Subject Initials:** ---

**Generated By:** (b) (4) **Generated Time (GMT):** 21-Apr-2021 18:02

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

Date	Location	User	Value	Reason
Feb-16-2021 11:18:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Participant is willing to return for Vaccination 3 Participant is:  eligible and NOT confirmed to have received only placebo at Vaccination 1/2	Transcription Error
Jan-20-2021 08:02:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Participant is NOT willing to return for Vaccination 3 OR otherwise not eligible	Initial Entry

090177e196d89032\Final\Final On: 22-Apr-2021 02:14 (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, Frozen, Verified

**Site No:** 1044

**Site Name:** (1044) Virginia Research Center

**Subject No:** 10441139

**Subject Initials:** ---

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

**Generated Time (GMT):** 21-Apr-2021 18:02

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**1. Date Treatment Unblinded :**

Date	Location	User	Value	Reason
Jan-20-2021 08:02:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Jan/8/2021	Initial Entry

**2. Primary Reason for Unblinding:**

Date	Location	User	Value	Reason
Jan-20-2021 08:02:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> ASSESS ELIGIBIL ITY FOR ADDITI ONAL VACCINAT ION	Initial Entry

090177e196d89032\Final\Final On: 22-Apr-2021 02:14 (GMT)

**Header Text:** c4591001

**Visit:** Disposition - Unscheduled

**Form:** WITHDRAWAL OF CONSENT - eCRF Audit Trail History

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

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

**Site No:** 1044

**Site Name:** (1044) Virginia Research Center

**Subject No:** 10441139

**Subject Initials:** ---

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

**Generated Time (GMT):** 21-Apr-2021 18:02

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**1. Withdrawal of Consent Date :**

Date	Location	User	Value	Reason
Jan-20-2021 08:02:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**Header Text:** c4591001

**Visit:** Disposition - Unscheduled

**Form:** DEATH DETAILS CODED - eCRF Audit Trail History

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

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

**Site No:** 1044

**Site Name:** (1044) Virginia Research Center

**Subject No:** 10441139

**Subject Initials:** ---

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

**Generated Time (GMT):** 21-Apr-2021 18:02

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

Date	Location	User	Value	Reason
Jan-20-2021 08:02:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

090177e196d89032\Final\Final On: 22-Apr-2021 02:14 (GMT)

**Header Text:** c4591001

**Visit:** Subject Status - Unscheduled

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

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

**Form Status:** Data Complete, Verified

**Site No:** 1044

**Site Name:** (1044) Virginia Research Center

**Subject No:** 10441139

**Subject Initials:** ---

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

**Generated Time (GMT):** 21-Apr-2021 18:02

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**1. Subject Status**

Date	Location	User	Value	Reason
Nov-11-2020 09:51:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> FOLLOW-UP	Initial Entry
Sep-24-2020 07:57:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> ENROLLED/RANDOMIZED	Initial Entry
Sep-24-2020 07:55:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SCREENED	Initial Entry

**2. Subject Status Date**

Date	Location	User	Value	Reason
Nov-11-2020 09:51:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> Nov/11/2020	Initial Entry
Sep-24-2020 07:57:18	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> Sep/23/2020	Initial Entry

090177e196d89032\Final\Final On: 22-Apr-2021 02:14 (GMT)

**Header Text:** c4591001

**Visit:** Subject Status - Unscheduled

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

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

**Form Status:** Data Complete, Verified

**Site No:** 1044

**Site Name:** (1044) Virginia Research Center

**Subject No:** 10441139

**Subject Initials:** ---

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

**Generated Time (GMT):** 21-Apr-2021 18:02

(UTC-05:00) Eastern Time (US & Canada)				
Sep-24-2020 07:55:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> Sep/23/2020	Initial Entry

090177e196d89032\Final\Final On: 22-Apr-2021 02:14 (GMT)

**Header Text:** c4591001

**Visit:** Investigator Signature -  
Unscheduled

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

**Site No:** 1044

**Subject No:** 10441139

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

**Form:** CASEBOOK SIGNATURE FORM - eCRF Audit  
Trail History

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

**Site Name:** (1044) Virginia Research Center

**Subject Initials:** ---

**Generated Time (GMT):** 21-Apr-2021 18:02

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*1. Casebook Signature*

Date	Location	User	Value	Reason
Nov-10-2020 14:36:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Click Here to Enabl e	Initial Entry