

Header Text: c4591001

Visit: COHORT_SELECTION

Form: COHORT SELECTION

Form Version: 10-Dec-2020 02:31

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1044

Site Name: (1044) Virginia Research Center

Subject No: 10441373

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 06-Apr-2021 15:36

[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	01 DEC 2020
2.	Select appropriate response - What cohort does the subject belong to?	STAGE 3 COHORTS

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: 10441373

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 06-Apr-2021 15:36

[eCRF Audit Trail History](#)

Informed Consent

1.	Consent Was:	OBTAINED Date Written Consent Obtained Jan/12/2021
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Header Text: c4591001

Visit: COHORT_SELECTION

Form: DEMOGRAPHY

Form Version: 10-Dec-2020 02:26

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1044

Site Name: (1044) Virginia Research Center

Subject No: 10441373

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 06-Apr-2021 15:36

[eCRF Audit Trail History](#)

Demography

1.	Subject ID	[10441373]
2.	Birth Date:	(b) (6) 2006
3.	Sex:	FEMALE
4.	Ethnicity:	NOT HISPANIC OR LATINO(A) OR OF SPANISH ORIGIN
5.	Race: (Check X all that apply):	WHITE
6.	Racial Designation:	

090177e196b72784\Final\Final On: 06-Apr-2021 19:11 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:02

Site No: 1044

Subject No: 10441373

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): 06-Apr-2021 15:36

eCRF Audit Trail History

Date of Visit

1.	Date of Visit	Jan/12/2021
2.	Erroneous Visit	

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 10-Oct-2020 16:00

Site No: 1044

Subject No: 10441373

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): 06-Apr-2021 15:36

Form Comments

Inclusion Criteria Not Met

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

Exclusion Criteria Met

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

090177e196b72784\Final\Final On: 06-Apr-2021 19:11 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 15-Sep-2020 21:52

Site No: 1044

Subject No: 10441373

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): 06-Apr-2021 15:36

[eCRF Audit Trail History](#)

Disposition - Screening

1.	Date of Completion/Discontinuation/Death	Jan/12/2021
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: 10441373

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): 06-Apr-2021 15:36

[eCRF Audit Trail History](#)

Medical History Details

1.a	Line/MH Number:	[1]
	Disease/Syndrome /Surgery/Non-Drug Allergies/Drug Allergies:	[Obsessive-compulsive disorder]
	Start Date:	UNK/UNK/2020
	Ongoing:	YES
1.b	Line/MH Number:	[2]
	Disease/Syndrome /Surgery/Non-Drug Allergies/Drug Allergies:	[anxiety]
	Start Date:	UNK/UNK/2018
	Ongoing:	YES
1.c	Line/MH Number:	[3]
	Disease/Syndrome /Surgery/Non-Drug Allergies/Drug Allergies:	[GERD]
	Start Date:	UNK/UNK/2006
	Ongoing:	YES

090177e196b72784\Final\Final On: 06-Apr-2021 19:11 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1044

Subject No: 10441373

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): 06-Apr-2021 15:36

1.d

Line/MH Number:	[4]
Disease/Syndrome /Surgery/Non-Drug Allergies/Drug Allergies:	[Allergic Rhinitis]
Start Date:	UNK/UNK/2011
Ongoing:	YES

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 15-Sep-2020 21:57

Site No: 1044

Subject No: 10441373

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): 06-Apr-2021 15:36

[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:** 10-Dec-2020 02:29**Site No:** 1044**Subject No:** 10441373**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):** 06-Apr-2021 15:36[eCRF Audit Trail History](#)**Vital Signs**

1.	Date:	Jan/12/2021
2.	Weight:	[43.9]
3.	Unit:	kg
4.	Height:	[156.2]
5.	Unit:	cm
6.	Body Mass Index:	[18.0]

Vital Signs Details

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

Header Text: c4591001**Visit:** V1_DAY1_VAX1_L**Form Version:** 10-Dec-2020 02:23**Site No:** 1044**Subject No:** 10441373**Generated By:** (b) (4)**Form:** LAB URINALYSIS - PREGNANCY TEST**Form Status:** Data Complete, Locked, Frozen, Verified**Site Name:** (1044) Virginia Research Center**Subject Initials:** ---**Generated Time (GMT):** 06-Apr-2021 15:36**eCRF Audit Trail History****Lab Urinalysis**

1.	Lab Panel:	URINALYSIS
2.	Lab Sub-Panel:	PREGNANCY
3.	Collection Date:	Jan/12/2021
4.	Laboratory Name and Address (Derived)	[STUDY SITE]
5.	Specimen Type:	URINE

Lab Result

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

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1044

Subject No: 10441373

Generated By: (b) (4)

Form: RANDOMIZATION

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1044) Virginia Research Center

Subject Initials: ---

Generated Time (GMT): 06-Apr-2021 15:36

[eCRF Audit Trail History](#)

Disposition

1.	Randomization Date :	Jan/12/2021
2.	Randomization Number:	[26782]
3.	Randomization Group:	[]

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1044

Subject No: 10441373

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING -
IMMUNOGENICITY

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1044) Virginia Research Center

Subject Initials: ---

Generated Time (GMT): 06-Apr-2021 15:36

[eCRF Audit Trail History](#)

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	SERUM
3.	Sample Collected?	YES Date of Collection: Jan/12/2021
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[]

Aliquot

Please enter barcode for each aliquot.

5.a	Sample ID	[BS8KCH]
5.b	Sample ID	[BK9BD1]
5.c	Sample ID	[BRF4TG]

090177e196b72784\Final\Final On: 06-Apr-2021 19:11 (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:** 10441373**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 06-Apr-2021 15:36[eCRF Audit Trail History](#)**Electronic Sample Tracking**

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Jan/12/2021
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[]

Aliquot

Please enter barcode for each aliquot.

5.a	Sample ID	[BRJZG7]
-----	-----------	----------

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 10-Dec-2020 02:26

Site No: 1044

Subject No: 10441373

Generated By: (b) (4)

Form: VACCINATION

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1044) Virginia Research Center

Subject Initials: ---

Generated Time (GMT): 06-Apr-2021 15:36

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:	Jan/12/2021 10:33
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

090177e196b72784\Final\Final On: 06-Apr-2021 19:11 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 06-Jul-2020 21:53

Site No: 1044

Subject No: 10441373

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): 06-Apr-2021 15:36

[eCRF Audit Trail History](#)

Reactogenicity Diary

1.	Select appropriate response - Reactogenicity diary collection	YES - REACTOGENICITY E-DIARY COLLECTED FOR THIS SUBJECT
----	---	--

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: 10441373

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 06-Apr-2021 15:36

eCRF Audit Trail History

Date of Visit

1.	Date of Visit	Feb/4/2021
2.	Erroneous Visit	

090177e196b72784\Final\Final On: 06-Apr-2021 19:11 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form: VACCINATION SYMPTOMS DIARY -
SYMPTOM RESOLVED DATES

Form Version: 10-Dec-2020 02:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1044

Site Name: (1044) Virginia Research Center

Subject No: 10441373

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 06-Apr-2021 15:36

[eCRF Audit Trail History](#)

Vaccination Symptoms Diary - Symptom Resolved Dates

1.	Were medications to treat fever/pain given on the last day the Subject Diary was completed?	NO
2.a	Symptom:	FEVER
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO
2.b	Symptom:	FATIGUE
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO
2.c	Symptom:	HEADACHE
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO

090177e196b72784\Final\Final On: 06-Apr-2021 19:11 (GMT)

Header Text: c4591001**Visit:** V2_VAX2_L**Form:** VACCINATION SYMPTOMS DIARY -
SYMPTOM RESOLVED DATES**Form Version:** 10-Dec-2020 02:30**Form Status:** Data Complete, Locked, Frozen, Verified**Site No:** 1044**Site Name:** (1044) Virginia Research Center**Subject No:** 10441373**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 06-Apr-2021 15:36

2.d	Symptom:	CHILLS
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO
2.e	Symptom:	VOMITING
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO
2.f	Symptom:	DIARRHEA
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO
2.g	Symptom:	NEW OR WORSENERED MUSCLE PAIN
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO
2.h	Symptom:	NEW OR WORSENERED JOINT PAIN
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO
3.	Injection Site Location:	DELTOID MUSCLE

Header Text: c4591001

Visit: V2_VAX2_L

Form: VACCINATION SYMPTOMS DIARY -
SYMPTOM RESOLVED DATES

Form Version: 10-Dec-2020 02:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1044

Site Name: (1044) Virginia Research Center

Subject No: 10441373

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 06-Apr-2021 15:36

4.	Injection Site Body Side:	LEFT
5.a	Injection Site Reaction:	REDNESS
	Were injection site reactions present on the last day the Subject Diary was completed?	NO
5.b	Injection Site Reaction:	SWELLING
	Were injection site reactions present on the last day the Subject Diary was completed?	NO
5.c	Injection Site Reaction:	PAIN AT INJECTION SITE
	Were injection site reactions present on the last day the Subject Diary was completed?	NO

090177e196b72784\Final\Final On: 06-Apr-2021 19:11 (GMT)

Header Text: c4591001**Visit:** V2_VAX2_L**Form Version:** 14-Jan-2021 02:22**Site No:** 1044**Subject No:** 10441373**Generated By:** (b) (4)**Form:** VITAL SIGNS - TEMP**Form Status:** Data Complete, Locked, Frozen, Verified**Site Name:** (1044) Virginia Research Center**Subject Initials:** ---**Generated Time (GMT):** 06-Apr-2021 15:36[eCRF Audit Trail History](#)**Vital Signs**

1.	Date:	Feb/4/2021
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Vital Signs Details

2.a	Record Identifier:	1
	Temperature:	[97.2]
	Unit:	F
	Temperature Location:	ORAL CAVITY

Header Text: c4591001**Visit:** V2_VAX2_L**Form Version:** 10-Dec-2020 02:23**Site No:** 1044**Subject No:** 10441373**Generated By:** (b) (4)**Form:** LAB URINALYSIS - PREGNANCY TEST**Form Status:** Data Complete, Locked, Frozen, Verified**Site Name:** (1044) Virginia Research Center**Subject Initials:** ---**Generated Time (GMT):** 06-Apr-2021 15:36[eCRF Audit Trail History](#)**Lab Urinalysis**

1.	Lab Panel:	URINALYSIS
2.	Lab Sub-Panel:	PREGNANCY
3.	Collection Date:	Feb/4/2021
4.	Laboratory Name and Address (Derived)	[STUDY SITE]
5.	Specimen Type:	URINE

Lab Result

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

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:** 10441373**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 06-Apr-2021 15:36[eCRF Audit Trail History](#)**Electronic Sample Tracking**

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

Aliquot

Please enter barcode for each aliquot.

5.a	Sample ID	[BRJZKK]
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Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 10-Dec-2020 02:26

Site No: 1044

Subject No: 10441373

Generated By: (b) (4)

Form: VACCINATION

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1044) Virginia Research Center

Subject Initials: ---

Generated Time (GMT): 06-Apr-2021 15:36

[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:	Feb/4/2021 10:04
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

090177e196b72784\Final\Final On: 06-Apr-2021 19:11 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L **Form:** DATE OF VISIT

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

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

Subject No: 10441373 **Subject Initials:** ---

Generated By: (b) (4) **Generated Time (GMT):** 06-Apr-2021 15:36

[eCRF Audit Trail History](#)

Date of Visit

1.	Date of Visit	Mar/9/2021
2.	Erroneous Visit	

090177e196b72784\Final\Final On: 06-Apr-2021 19:11 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L **Form:** VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES

Form Version: 10-Dec-2020 02:30 **Form Status:** Data Complete, Frozen, Verified

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

Subject No: 10441373 **Subject Initials:** ---

Generated By: (b) (4) **Generated Time (GMT):** 06-Apr-2021 15:36

[eCRF Audit Trail History](#)

Vaccination Symptoms Diary - Symptom Resolved Dates

1.	Were medications to treat fever/pain given on the last day the Subject Diary was completed?	NO
2.a	Symptom:	FEVER
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO
2.b	Symptom:	FATIGUE
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO
2.c	Symptom:	HEADACHE
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO

090177e196b72784\Final\Final On: 06-Apr-2021 19:11 (GMT)

Header Text: c4591001**Visit:** V3_MONTH1_POSTVAX2_L **Form:** VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES**Form Version:** 10-Dec-2020 02:30 **Form Status:** Data Complete, Frozen, Verified**Site No:** 1044**Site Name:** (1044) Virginia Research Center**Subject No:** 10441373**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 06-Apr-2021 15:36

2.d	Symptom:	CHILLS
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO
2.e	Symptom:	VOMITING
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO
2.f	Symptom:	DIARRHEA
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO
2.g	Symptom:	NEW OR WORSENERED MUSCLE PAIN
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO
2.h	Symptom:	NEW OR WORSENERED JOINT PAIN
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO
3.	Injection Site Location:	DELTOID MUSCLE

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L **Form:** VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES

Form Version: 10-Dec-2020 02:30 **Form Status:** Data Complete, Frozen, Verified

Site No: 1044

Site Name: (1044) Virginia Research Center

Subject No: 10441373

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 06-Apr-2021 15:36

4.	Injection Site Body Side:	LEFT
5.a	Injection Site Reaction:	REDNESS
	Were injection site reactions present on the last day the Subject Diary was completed?	NO
5.b	Injection Site Reaction:	SWELLING
	Were injection site reactions present on the last day the Subject Diary was completed?	NO
5.c	Injection Site Reaction:	PAIN AT INJECTION SITE
	Were injection site reactions present on the last day the Subject Diary was completed?	NO

090177e196b72784\Final\Final On: 06-Apr-2021 19:11 (GMT)

Header Text: c4591001**Visit:** V3_MONTH1_POSTVAX2_L **Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY**Form Version:** 22-Apr-2020 21:03 **Form Status:** Data Complete, Frozen, Verified**Site No:** 1044**Site Name:** (1044) Virginia Research Center**Subject No:** 10441373**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 06-Apr-2021 15:36[eCRF Audit Trail History](#)**Electronic Sample Tracking**

1.	Data Origin	SITE
2.	Sample Type	SERUM
3.	Sample Collected?	YES Date of Collection: Mar/9/2021
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[]

Aliquot

Please enter barcode for each aliquot.

5.a	Sample ID	[BRF4VL]
5.b	Sample ID	[BSD1XF]
5.c	Sample ID	[BSD1X9]

Header Text: c4591001

Visit: V4_MONTH6_L

Form Version: 22-Apr-2020 21:02

Site No: 1044

Subject No: 10441373

Generated By: (b) (4)

Form: DATE OF VISIT

Form Status: Not Started

Site Name: (1044) Virginia Research Center

Subject Initials: ---

Generated Time (GMT): 06-Apr-2021 15:36

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

Header Text: c4591001**Visit:** V4_MONTH6_L**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:** 10441373**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 06-Apr-2021 15:36**Electronic Sample Tracking**

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

Aliquot

Please enter barcode for each aliquot.

5.	Sample ID	[]
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Header Text: c4591001

Visit: V5_MONTH12_L

Form Version: 22-Apr-2020 21:02

Site No: 1044

Subject No: 10441373

Generated By: (b) (4)

Form: DATE OF VISIT

Form Status: Not Started

Site Name: (1044) Virginia Research Center

Subject Initials: ---

Generated Time (GMT): 06-Apr-2021 15:36

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

Header Text: c4591001**Visit:** V5_MONTH12_L**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:** 10441373**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 06-Apr-2021 15:36**Electronic Sample Tracking**

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

Aliquot

Please enter barcode for each aliquot.

5.	Sample ID	[]
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Header Text: c4591001

Visit: V6_MONTH24_L

Form Version: 22-Apr-2020 21:02

Site No: 1044

Subject No: 10441373

Generated By: (b) (4)

Form: DATE OF VISIT

Form Status: Not Started

Site Name: (1044) Virginia Research Center

Subject Initials: ---

Generated Time (GMT): 06-Apr-2021 15:36

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

Header Text: c4591001**Visit:** V6_MONTH24_L**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:** 10441373**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 06-Apr-2021 15:36**Electronic Sample Tracking**

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

Aliquot

Please enter barcode for each aliquot.

5.	Sample ID	[]
----	-----------	-----

Header Text: c4591001

Visit: POT_COVID_ILL - New
Unscheduled Visit

Form: 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: 10441373

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 06-Apr-2021 15:36

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

COVID-19 Illness Visit

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

Header Text: c4591001**Visit:** POT_COVID_ILL - New
Unscheduled Visit**Form Version:** 20-Feb-2021 02:17**Site No:** 1044**Subject No:** 10441373**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):** 06-Apr-2021 15:36**Signs and Symptoms**

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

Symptoms

4.	Symptoms:	
	Was symptom present?	

Symptoms - Other

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

Header Text: c4591001**Visit:** POT_COVID_ILL - New
Unscheduled Visit**Form Version:** 22-Apr-2020 21:03**Site No:** 1044**Subject No:** 10441373**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):** 06-Apr-2021 15:36**Electronic Sample Tracking**

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

Aliquot

Please enter barcode for each aliquot.

5.	Sample ID	[]
----	-----------	-----

Header Text: c4591001**Visit:** POT_COVID_ILL - New
Unscheduled Visit**Form Version:** 22-Apr-2020 21:03**Site No:** 1044**Subject No:** 10441373**Generated By:** (b) (4)**Form:** ELECTRONIC SAMPLE TRACKING - NASAL
SWAB**Form Status:** Not Started**Site Name:** (1044) Virginia Research Center**Subject Initials:** ---**Generated Time (GMT):** 06-Apr-2021 15:36**Electronic Sample Tracking**

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

Aliquot

Please enter barcode for each aliquot.

5.	Sample ID	[]
----	-----------	-----

Header Text: c4591001**Visit:** POT_COVID_ILL - New
Unscheduled Visit**Form:** 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:** 10441373**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 06-Apr-2021 15:36**Health Care Utilization**

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

Health Care Utilization Other

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

Health Care Utilization

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

Header Text: c4591001

Visit: POT_COVID_ILL - New
Unscheduled Visit

Form Version: 06-Jul-2020 21:52

Site No: 1044

Subject No: 10441373

Generated By: (b) (4)

Form: ILLNESS DETAILS

Form Status: Not Started

Site Name: (1044) Virginia Research Center

Subject Initials: ---

Generated Time (GMT): 06-Apr-2021 15:36

Illness Details

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

090177e196b72784\Final\Final On: 06-Apr-2021 19:11 (GMT)

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: 10441373

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 06-Apr-2021 15:36

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

COVID-19 Illness Visit

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

Header Text: c4591001**Visit:** POT_COVID_CONVA - New
Unscheduled Visit**Form:** ELECTRONIC SAMPLE TRACKING -
IMMUNOGENICITY**Form Version:** 22-Apr-2020 21:03**Form Status:** Not Started**Site No:** 1044**Site Name:** (1044) Virginia Research Center**Subject No:** 10441373**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 06-Apr-2021 15:36**Electronic Sample Tracking**

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

Aliquot

Please enter barcode for each aliquot.

5.	Sample ID	[]
----	-----------	-----

Header Text: c4591001

Visit: POT_COVID_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: 10441373

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 06-Apr-2021 15:36

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

COVID-19 Repeat Swab

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

Header Text: c4591001**Visit:** POT_COVID_REPEAT_SWAB - New Unscheduled Visit **Form:** ELECTRONIC SAMPLE TRACKING - REPEAT SWAB**Form Version:** 10-Oct-2020 15:57 **Form Status:** Not Started**Site No:** 1044**Site Name:** (1044) Virginia Research Center**Subject No:** 10441373**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 06-Apr-2021 15:36**Electronic Sample Tracking**

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

Aliquot

Please enter barcode for each aliquot.

5.	Sample ID	[]
----	-----------	-----

Header Text: c4591001

Visit: Logs

Form: ADVERSE EVENT REPORT

Form Version: 22-Apr-2020 21:02

Site No: 1044

Site Name: (1044) Virginia Research Center

Subject No: 10441373

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 06-Apr-2021 15:36

#	Category	AE Identifier	Adverse Event	Start Date	Is the Adverse Event Still Ongoing	Form Instance
1.	ADVERSE EVENT	1	hives forehead	Jan/12/2021 11:29	NO End Date Time: Jan/12/2021 UNK: UNK	Repeating Pages
2.	ADVERSE EVENT	2	Worsening of Anxiety	Mar/5/2021 UNK:UNK	YES	Repeating Pages

090177e196b72784\Final\Final On: 06-Apr-2021 19:11 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1044

Subject No: 10441373

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Frozen

Site Name: (1044) Virginia Research Center

Subject Initials: ---

Generated Time (GMT): 06-Apr-2021 15:36

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[Form Audit Trail](#)

Adverse Event Report

1.	Category:	ADVERSE EVENT
2.	AE ID:	[1]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[hives forehead]
4.	Start Date Time:	Jan/12/2021 11:29
5.	Is the adverse event still ongoing?	NO End Date Time: Jan/12/2021 UNK:UNK
6.	Toxicity Grade:	1

090177e196b72784\Final\Final On: 06-Apr-2021 19:11 (GMT)

Header Text: c4591001**Visit:** Logs - Unscheduled**Form Version:** 22-Apr-2020 21:02**Site No:** 1044**Subject No:** 10441373**Generated By:** (b) (4)**Form:** ADVERSE EVENT REPORT**Form Status:** Data Complete, Frozen**Site Name:** (1044) Virginia Research Center**Subject Initials:** ---**Generated Time (GMT):** 06-Apr-2021 15:36

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

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen

Site No: 1044

Site Name: (1044) Virginia Research Center

Subject No: 10441373

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 06-Apr-2021 15:36

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

Header Text: c4591001**Visit:** Logs - Unscheduled**Form Version:** 22-Apr-2020 21:02**Site No:** 1044**Subject No:** 10441373**Generated By:** (b) (4)**Form:** ADVERSE EVENT REPORT**Form Status:** Data Complete**Site Name:** (1044) Virginia Research Center**Subject Initials:** ---**Generated Time (GMT):** 06-Apr-2021 15:36[Back to Form](#)[eCRF Audit Trail History](#)[Form Audit Trail](#)**Adverse Event Report**

1.	Category:	ADVERSE EVENT
2.	AE ID:	[2]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[Worsening of Anxiety]
4.	Start Date Time:	Mar/5/2021 UNK:UNK
5.	Is the adverse event still ongoing?	YES
6.	Toxicity Grade:	2

Header Text: c4591001**Visit:** Logs - Unscheduled**Form Version:** 22-Apr-2020 21:02**Site No:** 1044**Subject No:** 10441373**Generated By:** (b) (4)**Form:** ADVERSE EVENT REPORT**Form Status:** Data Complete**Site Name:** (1044) Virginia Research Center**Subject Initials:** ---**Generated Time (GMT):** 06-Apr-2021 15:36

7.	<p>Is the adverse event serious?</p> <p>If Yes, NOTIFY PFIZER IMMEDIATELY.</p> <p>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).</p>	NO
8.	<p>Is this adverse event the result of a study Medication Error?</p> <p>If Yes, record the type of medication error on the Medication Error Log.</p>	NO
9.	<p>Is this event related to study treatment:</p>	<p>NOT RELATED</p> <p>If Not Related to study treatment(s), this event is due to: OTHER</p> <p>If Other, specify: [medication dosage adjustment]</p>
10.	<p>Latest Action Taken with Study Treatment:</p>	NOT APPLICABLE

Header Text: c4591001**Visit:** Logs - Unscheduled**Form:** ADVERSE EVENT REPORT**Form Version:** 22-Apr-2020 21:02**Form Status:** Data Complete**Site No:** 1044**Site Name:** (1044) Virginia Research Center**Subject No:** 10441373**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 06-Apr-2021 15:36

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

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: 10441373

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 06-Apr-2021 15:36

#	Category	Medication Error	Start Date	Is the medication error Still Ongoing	Study Medication Errors Action	Form Instance
1.						Repeating Pages

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 17-Jul-2020 21:54

Site No: 1044

Subject No: 10441373

Generated By: (b) (4)

Form: MEDICATION ERROR

Form Status: Not Started

Site Name: (1044) Virginia Research Center

Subject Initials: ---

Generated Time (GMT): 06-Apr-2021 15:36

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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	[]

090177e196b72784\Final\Final On: 06-Apr-2021 19:11 (GMT)

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: 10441373

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 06-Apr-2021 15:36

#	Sponsor-Defined Identifier	Category for Medication	Concomitant Medications Pre-specified	Name of Medication	Start Date	Form Instance
1.						Repeating Pages

Header Text: c4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - NON
STUDY VACCINATIONS

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1044

Site Name: (1044) Virginia Research Center

Subject No: 10441373

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 06-Apr-2021 15:36

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Concomitant Medications

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

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: 10441373

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 06-Apr-2021 15:36

#	Sponsor-Defined Identifier	Category for Medication	Concomitant Medications Pre-specified	Name of Medication	Dose Description	Form Instance
1.						Repeating Pages

Header Text: c4591001

Visit: Logs - Unscheduled

Form: 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: 10441373

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 06-Apr-2021 15:36

[Back to Form](#)

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?	

090177e196b72784\Final\On: 06-Apr-2021 19:11 (GMT)

Header Text: c4591001

Visit: Logs

Form: RADIATION TREATMENT

Form Version: 22-Apr-2020 21:02

Site No: 1044

Site Name: (1044) Virginia Research Center

Subject No: 10441373

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 06-Apr-2021 15:36

#	Category	Treatment Identifier	Con Non-Drug Treatments Pre-specified	Treatment	Start Date	Form Instance
1.						Repeating Pages

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: 10441373

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 06-Apr-2021 15:36

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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?	

Header Text: c4591001

Visit: Logs

Form: TRANSFUSIONS

Form Version: 22-Apr-2020 21:03

Site No: 1044

Site Name: (1044) Virginia Research Center

Subject No: 10441373

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 06-Apr-2021 15:36

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

Header Text: c4591001

Visit: Logs - Unscheduled

Form: TRANSFUSIONS

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1044

Site Name: (1044) Virginia Research Center

Subject No: 10441373

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 06-Apr-2021 15:36

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

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: 10441373

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 06-Apr-2021 15:36

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: 10441373 **Subject Initials:** ---

Generated By: (b) (4) **Generated Time (GMT):** 06-Apr-2021 15:36

Unplanned Assessments

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

Header Text: c4591001

Visit: Unplanned Vaccination -
Unscheduled

Form: DATE OF VISIT

Form Version: 22-Apr-2020 21:02

Form Status: Not Started

Site No: 1044

Site Name: (1044) Virginia Research Center

Subject No: 10441373

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 06-Apr-2021 15:36

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:** 10441373**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 06-Apr-2021 15:36**Vital Signs**

1. Date: //

Vital Signs Details

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

Header Text: c4591001**Visit:** Unplanned Vaccination -
Unscheduled**Form:** LAB URINALYSIS - PREGNANCY TEST**Form Version:** 20-Feb-2021 02:14**Form Status:** Not Started**Site No:** 1044**Site Name:** (1044) Virginia Research Center**Subject No:** 10441373**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 06-Apr-2021 15:36**Lab Urinalysis**

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

Lab Result

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

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:** 10441373**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 06-Apr-2021 15:36**Vaccination**

1.	Was there a temporary delay of vaccination?	
2.	Treatment Name	[]
3.	Formulation:	
4.	Dose Date Time:	//
5.	Anatomical Location:	
6.	Body Side:	
7.	Route:	
8.	Actual Dose:	[]
9.	Unit:	
10.	Timeframe Subject Was Observed	
11.	Was the subject observed for at least the protocol specified observation period after investigational product administration?	

Header Text: c4591001

Visit: Unplanned Vaccination -
Unscheduled

Form: CONTACT OUTCOME - MONTH 1

Form Version: 10-Oct-2020 15:57

Form Status: Not Started

Site No: 1044

Site Name: (1044) Virginia Research Center

Subject No: 10441373

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 06-Apr-2021 15:36

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: 10441373

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 06-Apr-2021 15:36

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: 10441373

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 06-Apr-2021 15:36

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: 10441373

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 06-Apr-2021 15:36

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:** 10441373**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 06-Apr-2021 15:36**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:** 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:** 10441373**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 06-Apr-2021 15:36**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: End of Treatment - Unscheduled **Form:** DISPOSITION - TREATMENT

Form Version: 20-Feb-2021 02:26 **Form Status:** Data Complete, Frozen, Verified

Site No: 1044

Site Name: (1044) Virginia Research Center

Subject No: 10441373

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 06-Apr-2021 15:36

[eCRF Audit Trail History](#)

Disposition - Treatment

1.	Date of Completion/Discontinuation /Death :	Mar/9/2021
2.	Phase of Disposition:	VACCINATION
3.	Status:	COMPLETED
4.	Specify Status:	[]

090177e196b72784\Final\Final On: 06-Apr-2021 19:11 (GMT)

Header Text: c4591001

Visit: Potential ReVax Initial Contact - **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: 10441373

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 06-Apr-2021 15:36

Date of Visit		
1.	Date of Visit	//
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:** Not Started

Site No: 1044

Site Name: (1044) Virginia Research Center

Subject No: 10441373

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 06-Apr-2021 15:36

Further Vaccination Confirmation

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

Header Text: c4591001

Visit: Disposition - Unscheduled

Form: TREATMENT UNBLINDED

Form Version: 10-Dec-2020 02:27

Form Status: Not Started

Site No: 1044

Site Name: (1044) Virginia Research Center

Subject No: 10441373

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 06-Apr-2021 15:36

Treatment Unblinded

1.	Date Treatment Unblinded :	//
2.	Primary Reason for Unblinding:	

Header Text: c4591001

Visit: Disposition - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1044

Subject No: 10441373

Generated By: (b) (4)

Form: WITHDRAWAL OF CONSENT

Form Status: Not Started

Site Name: (1044) Virginia Research Center

Subject Initials: ---

Generated Time (GMT): 06-Apr-2021 15:36

Withdrawal Of Consent

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

Header Text: c4591001

Visit: Disposition - Unscheduled

Form: DEATH DETAILS CODED

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1044

Site Name: (1044) Virginia Research Center

Subject No: 10441373

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 06-Apr-2021 15:36

Death Details

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

Cause of Death

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

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: 10441373

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 06-Apr-2021 15:36

Disposition - Follow-Up

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

Header Text: c4591001

Visit: Subject Status - Unscheduled

Form: SUBJECT STATUS

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Verified

Site No: 1044

Site Name: (1044) Virginia Research Center

Subject No: 10441373

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 06-Apr-2021 15:36

[eCRF Audit Trail History](#)

Subject Status

1.	Subject Status	FOLLOW-UP
2.	Subject Status Date	Mar/9/2021

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: 10441373

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 06-Apr-2021 15:36

[eCRF Audit Trail History](#)

Casebook Signature Form

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

Header Text: c4591001

Visit: Investigator Signature -
Unscheduled

Form Version: 22-Apr-2020 21:04

Site No: 1044

Subject No: 10441373

Generated By: (b) (4)

Form: CASEBOOK SIGNATURE FORM

Form Status: Data Complete, Signed, Verified

Site Name: (1044) Virginia Research Center

Subject Initials: ---

Generated Time (GMT): 06-Apr-2021 15:36

[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-11-2021 15:36:40 (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.

090177e196b72784\Final\Final On: 06-Apr-2021 19:11 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 10-Oct-2020 16:00

Site No: 1044

Subject No: 10441373

Generated By: (b) (4)

Form: INCLUSION/EXCLUSION CRITERIA -
Comments

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1044) Virginia Research Center

Subject Initials: ---

Generated Time (GMT): 06-Apr-2021 15:36

[Back to Form](#)

Item	Date	User	Comment
Form	Jan-12-2021 16:19:20 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6) [REDACTED]	Not Applicable

Header Text: c4591001

Visit: Investigator Signature -
Unscheduled

Form Version: 22-Apr-2020 21:04

Site No: 1044

Subject No: 10441373

Generated By: (b) (4)

Form: CASEBOOK SIGNATURE FORM - Signature
History

Form Status: Data Complete, Signed, Verified

Site Name: (1044) Virginia Research Center

Subject Initials: ---

Generated Time (GMT): 06-Apr-2021 15:36

[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-11-2021 15:36:40 (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) [REDACTED]	N/A	Mar-11-2021 13:39:14 (UTC-05:00) Eastern Time (US & Canada)		Edit - All signatures invalidated
-----------------------	-----	--	--	---

Affidavit:

N/A

Aaron Hartman	Approved	Mar-10-2021 14:16:49 (UTC-05:00) Eastern Time (US & Canada)	BOOK	Signed
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090177e196b72784\Final\Final On: 06-Apr-2021 19:11 (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:** 10441373**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 06-Apr-2021 15:36**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) [REDACTED]	N/A	Mar-09-2021 14:37:22 (UTC-05:00) Eastern Time (US & Canada)		Edit - All signatures invalidated
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Affidavit:

N/A

Aaron Hartman	Approved	Mar-03-2021 14:48:47 (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.

Header Text: c4591001

Visit: COHORT_SELECTION

Form: COHORT SELECTION - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:31

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1044

Site Name: (1044) Virginia Research Center

Subject No: 10441373

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 06-Apr-2021 15:36

[Back to Form](#)

1. Select appropriate response - Protocol version

Date	Location	User	Value	Reason
Jan-12-2021 16:18:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 01 DEC 2020	Initial Entry

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

Date	Location	User	Value	Reason
Jan-12-2021 16:18:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: STAGE 3 COHORT S	Initial Entry

Header Text: c4591001

Visit: COHORT_SELECTION

Form Version: 22-Apr-2020 21:02

Site No: 1044

Subject No: 10441373

Generated By: (b) (4)

Form: MAIN INFORMED CONSENT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1044) Virginia Research Center

Subject Initials: ---

Generated Time (GMT): 06-Apr-2021 15:36

[Back to Form](#)

1. Consent Was:

Date	Location	User	Value	Reason
Jan-12-2021 16:18:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: OBTAINED Date Written Cons ent Obtained Jan/12/2021	Initial Entry

090177e196b72784\Final\Final On: 06-Apr-2021 19:11 (GMT)

Header Text: c4591001

Visit: COHORT_SELECTION

Form Version: 10-Dec-2020 02:26

Site No: 1044

Subject No: 10441373

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): 06-Apr-2021 15:36

[Back to Form](#)

1. Subject ID

Date	Location	User	Value	Reason
Jan-12-2021 16:18:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 10441373	Item copied from previous form

2. Birth Date:

Date	Location	User	Value	Reason
Jan-12-2021 16:18:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: (b) (6) 2006	Enrollment Entry

3. Sex:

Date	Location	User	Value	Reason
Jan-12-2021 16:18:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: FEMALE	Initial Entry

4. Ethnicity:

Date	Location	User	Value	Reason
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090177e196b72784\Final\Final On: 06-Apr-2021 19:11 (GMT)

Header Text: c4591001

Visit: COHORT_SELECTION

Form: DEMOGRAPHY - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:26

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1044

Site Name: (1044) Virginia Research Center

Subject No: 10441373

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 06-Apr-2021 15:36

Jan-12-2021 16:18:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 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
Jan-12-2021 16:18:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: WHITE	Initial Entry

090177e196b72784\Final\Final On: 06-Apr-2021 19:11 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:02

Site No: 1044

Subject No: 10441373

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): 06-Apr-2021 15:36

[Back to Form](#)

1. Date of Visit

Date	Location	User	Value	Reason
Jan-12-2021 16:19:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Jan/12/2021	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 15-Sep-2020 21:52

Site No: 1044

Subject No: 10441373

Generated By: (b) (4)

Form: DISPOSITION - SCREENING - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1044) Virginia Research Center

Subject Initials: ---

Generated Time (GMT): 06-Apr-2021 15:36

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1. Date of Completion/Discontinuation/Death

Date	Location	User	Value	Reason
Jan-12-2021 16:19:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Jan/12/2021	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Jan-12-2021 16:19:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SCREENING	Initial Entry

3. Status:

Date	Location	User	Value	Reason
Jan-12-2021 16:19:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: COMPLETED	Initial Entry

090177e196b72784\Final\On: 06-Apr-2021 19:11 (GMT)

Header Text: c4591001**Visit:** V1_DAY1_VAX1_L**Form:** GENERAL MEDICAL HISTORY - eCRF Audit Trail History**Form Version:** 22-Apr-2020 21:03**Form Status:** Data Complete, Locked, Frozen, Verified**Site No:** 1044**Site Name:** (1044) Virginia Research Center**Subject No:** 10441373**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 06-Apr-2021 15:36[Back to Form](#)**1.a**

Date	Location	User	Value	Reason
Jan-12-2021 16:21:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH 1 Number: Medical History Obsessive-c ompulsive Term: disorder Start Date: UNK/UNK /2020 Ongoing: YES	Initial Entry

1.a Line/MH Number:

Date	Location	User	Value	Reason
Jan-12-2021 16:21:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 1	Initial Entry

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

Date	Location	User	Value	Reason
Jan-12-2021 16:21:11 (UTC-05:00) Eastern Time (US	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Obsessive-compulsi ve disorder	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1044

Site Name: (1044) Virginia Research Center

Subject No: 10441373

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 06-Apr-2021 15:36

& Canada)

1.a Start Date:

Date	Location	User	Value	Reason
Jan-12-2021 16:21:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNK/UNK/2020	Initial Entry

1.a Ongoing:

Date	Location	User	Value	Reason
Jan-12-2021 16:21:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

1.b

Date	Location	User	Value	Reason
Jan-12-2021 16:21:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH N 2 umber: Medical His anxiety tory Term: Start Date: UNK/U NK/201 8 Ongoing: YES	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1044

Subject No: 10441373

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1044) Virginia Research Center

Subject Initials: ---

Generated Time (GMT): 06-Apr-2021 15:36

1.b Line/MH Number:

Date	Location	User	Value	Reason
Jan-12-2021 16:21:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 2	Initial Entry

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

Date	Location	User	Value	Reason
Jan-12-2021 16:21:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: anxiety	Initial Entry

1.b Start Date:

Date	Location	User	Value	Reason
Jan-12-2021 16:21:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNK/UNK/2018	Initial Entry

1.b Ongoing:

Date	Location	User	Value	Reason
Jan-12-2021 16:21:42	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

090177e196b72784\Final\Final On: 06-Apr-2021 19:11 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1044

Subject No: 10441373

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1044) Virginia Research Center

Subject Initials: ---

Generated Time (GMT): 06-Apr-2021 15:36

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

(b) (4), (b) (6)

I.c

Date	Location	User	Value	Reason
Jan-12-2021 16:22:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH N 3 umber: Medical His GERD tory Term: Start Date: UNK/U NK/200 6 Ongoing: YES	Initial Entry

090177e196b72784\Final\Final On: 06-Apr-2021 19:11 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1044

Subject No: 10441373

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1044) Virginia Research Center

Subject Initials: ---

Generated Time (GMT): 06-Apr-2021 15:36

1.c Line/MH Number:

Date	Location	User	Value	Reason
Jan-12-2021 16:22:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 3	Initial Entry

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

Date	Location	User	Value	Reason
Jan-12-2021 16:22:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: GERD	Initial Entry

1.c Start Date:

Date	Location	User	Value	Reason
Jan-12-2021 16:22:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNK/UNK/2006	Initial Entry

1.c Ongoing:

Date	Location	User	Value	Reason
Jan-12-2021 16:22:14	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

090177e196b72784\Final\Final On: 06-Apr-2021 19:11 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1044

Subject No: 10441373

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1044) Virginia Research Center

Subject Initials: ---

Generated Time (GMT): 06-Apr-2021 15:36

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

(b) (4), (b) (6)

1.d

Date	Location	User	Value	Reason
Jan-12-2021 16:23:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH N 4 umber: Medical His Allergic tory Term: Rhinitis Start Date: UNK/U NK/2011 Ongoing: YES	Initial Entry

090177e196b72784\Final\Final On: 06-Apr-2021 19:11 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1044

Subject No: 10441373

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1044) Virginia Research Center

Subject Initials: ---

Generated Time (GMT): 06-Apr-2021 15:36

1.d Line/MH Number:

Date	Location	User	Value	Reason
Jan-12-2021 16:23:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 4	Initial Entry

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

Date	Location	User	Value	Reason
Jan-12-2021 16:23:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Allergic Rhinitis	Initial Entry

1.d Start Date:

Date	Location	User	Value	Reason
Jan-12-2021 16:23:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNK/UNK/2011	Initial Entry

1.d Ongoing:

Date	Location	User	Value	Reason
Jan-12-2021 16:23:03	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

090177e196b72784\Final\Final On: 06-Apr-2021 19:11 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1044

Subject No: 10441373

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1044) Virginia Research Center

Subject Initials: ---

Generated Time (GMT): 06-Apr-2021 15:36

(UTC-05:00)

Eastern Time (US
& Canada)

(b) (4), (b) (6)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 15-Sep-2020 21:57

Site No: 1044

Subject No: 10441373

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): 06-Apr-2021 15:36

[Back to Form](#)

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

Date	Location	User	Value	Reason
Jan-12-2021 16:22:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 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:** 10-Dec-2020 02:29**Form Status:** Data Complete, Locked, Frozen, Verified**Site No:** 1044**Site Name:** (1044) Virginia Research Center**Subject No:** 10441373**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 06-Apr-2021 15:36[Back to Form](#)**1. Date:**

Date	Location	User	Value	Reason
Jan-12-2021 16:25:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Jan/12/2021	Initial Entry

2. Weight:

Date	Location	User	Value	Reason
Jan-12-2021 16:25:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 43.9	Initial Entry

3. Unit:

Date	Location	User	Value	Reason
Jan-12-2021 16:25:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: kg	Initial Entry

4. Height:

Date	Location	User	Value	Reason
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Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: VITAL SIGNS - BASELINE - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:29

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1044

Site Name: (1044) Virginia Research Center

Subject No: 10441373

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 06-Apr-2021 15:36

Jan-12-2021 16:25:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 156.2	Initial Entry
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5. Unit:

Date	Location	User	Value	Reason
Jan-12-2021 16:25:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: cm	Initial Entry

6. Body Mass Index:

Date	Location	User	Value	Reason
Jan-12-2021 16:25:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 18.0	Initial Entry

7.a

Date	Location	User	Value	Reason
Jan-12-2021 16:25:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Record Id 1 entifier:: Temperat 98.3 ure:	Initial Entry

090177e196b72784\Final\Final On: 06-Apr-2021 19:11 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 10-Dec-2020 02:29

Site No: 1044

Subject No: 10441373

Generated By: (b) (4)

Form: VITAL SIGNS - BASELINE - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1044) Virginia Research Center

Subject Initials: ---

Generated Time (GMT): 06-Apr-2021 15:36

			Temperature Unit: Temperature Location: on:: Y	
--	--	--	---	--

7.a Record Identifier:

Date	Location	User	Value	Reason
Jan-12-2021 16:25:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 1	Initial Entry

7.a Temperature:

Date	Location	User	Value	Reason
Jan-12-2021 16:25:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 98.3	Initial Entry

7.a Unit:

Date	Location	User	Value	Reason
Jan-12-2021 16:25:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: F	Initial Entry

090177e196b72784\Final\On: 06-Apr-2021 19:11 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: VITAL SIGNS - BASELINE - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:29

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1044

Site Name: (1044) Virginia Research Center

Subject No: 10441373

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 06-Apr-2021 15:36

7.a Temperature Location:

Date	Location	User	Value	Reason
Jan-12-2021 16:25:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: ORAL CAVITY	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 10-Dec-2020 02:23

Site No: 1044

Subject No: 10441373

Generated By: (b) (4)

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

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1044) Virginia Research Center

Subject Initials: ---

Generated Time (GMT): 06-Apr-2021 15:36

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1. Lab Panel:

Date	Location	User	Value	Reason
Jan-12-2021 16:25:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: URINALYSIS	Initial Entry

2. Lab Sub-Panel:

Date	Location	User	Value	Reason
Jan-12-2021 16:25:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: PREGNANCY	Initial Entry

3. Collection Date:

Date	Location	User	Value	Reason
Jan-12-2021 16:25:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Jan/12/2021	Initial Entry

4. Laboratory Name and Address (Derived)

Date	Location	User	Value	Reason
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090177e196b72784\Final\On: 06-Apr-2021 19:11 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 10-Dec-2020 02:23

Site No: 1044

Subject No: 10441373

Generated By: (b) (4)

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

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1044) Virginia Research Center

Subject Initials: ---

Generated Time (GMT): 06-Apr-2021 15:36

Jan-12-2021 16:25:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: STUDY SITE	Initial Entry
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5. Specimen Type:

Date	Location	User	Value	Reason
Jan-12-2021 16:25:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: URINE	Initial Entry

6.a

Date	Location	User	Value	Reason
Jan-12-2021 16:25:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sponsor- 113 Defined I dentifier: Test:: Choriogon adotropin Beta_PX11 3 Result:: NEGATIV E Not Done ::	Initial Entry

6.a Sponsor ID:

090177e196b72784\Final\Final On: 06-Apr-2021 19:11 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 10-Dec-2020 02:23

Site No: 1044

Subject No: 10441373

Generated By: (b) (4)

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

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1044) Virginia Research Center

Subject Initials: ---

Generated Time (GMT): 06-Apr-2021 15:36

Date	Location	User	Value	Reason
Jan-12-2021 16:25:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 113	Initial Entry

6.a Test:

Date	Location	User	Value	Reason
Jan-12-2021 16:25:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Choriogonadotropin Beta_PX113	Initial Entry

6.a Result:

Date	Location	User	Value	Reason
Jan-12-2021 16:25:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NEGATIVE	Initial Entry

090177e196b72784\Final\Final On: 06-Apr-2021 19:11 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1044

Subject No: 10441373

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): 06-Apr-2021 15:36

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1. Randomization Date :

Date	Location	User	Value	Reason
Jan-12-2021 16:26:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Jan/12/2021	Initial Entry

2. Randomization Number:

Date	Location	User	Value	Reason
Jan-12-2021 16:26:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 26782	Initial Entry

090177e196b72784\Final\Final On: 06-Apr-2021 19:11 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1044

Subject No: 10441373

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): 06-Apr-2021 15:36

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1. Data Origin

Date	Location	User	Value	Reason
Jan-12-2021 16:26:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Jan-12-2021 16:26:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SERUM	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Jan-12-2021 16:27:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Jan-12-2021 16:26:23 (UTC-05:00)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1044

Subject No: 10441373

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): 06-Apr-2021 15:36

Eastern Time (US & Canada)				no barcodes are entered. Please review and correct as appropriate.
Jan-12-2021 16:26:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Collection: Jan/12/2021	Initial Entry

5.a

Date	Location	User	Value	Reason
Jan-12-2021 16:27:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample I BS8KC D: H	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Jan-12-2021 16:27:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BS8KCH	Initial Entry

5.b

090177e196b72784\Final\Final On: 06-Apr-2021 19:11 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1044

Subject No: 10441373

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): 06-Apr-2021 15:36

Date	Location	User	Value	Reason
Jan-12-2021 16:27:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample I BK9BD D: 1	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Jan-12-2021 16:27:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BK9BD1	Initial Entry

5.c

Date	Location	User	Value	Reason
Jan-12-2021 16:27:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample I BRF4T D: G	Initial Entry

090177e196b72784\Final\Final On: 06-Apr-2021 19:11 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1044

Subject No: 10441373

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): 06-Apr-2021 15:36

5.c Sample ID

Date	Location	User	Value	Reason
Jan-12-2021 16:27:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BRF4TG	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1044

Subject No: 10441373

Generated By: (b) (4)

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

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1044) Virginia Research Center

Subject Initials: ---

Generated Time (GMT): 06-Apr-2021 15:36

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1. Data Origin

Date	Location	User	Value	Reason
Jan-12-2021 16:28:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Jan-12-2021 16:28:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: NASAL_SWAB	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Jan-12-2021 16:28:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Jan-12-2021 16:28:13 (UTC-05:00)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however

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:** 10441373**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 06-Apr-2021 15:36

Eastern Time (US & Canada)				no barcodes are entered. Please review and correct as appropriate.
Jan-12-2021 16:28:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Collection: Jan/12/2021	Initial Entry

5.a

Date	Location	User	Value	Reason
Jan-12-2021 16:28:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample I BRJZG D: 7	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Jan-12-2021 16:28:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BRJZG7	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 10-Dec-2020 02:26

Site No: 1044

Subject No: 10441373

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): 06-Apr-2021 15:36

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1. Was there a temporary delay of vaccination?

Date	Location	User	Value	Reason
Jan-12-2021 16:29:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2. Treatment Name

Date	Location	User	Value	Reason
Jan-12-2021 16:29:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: BLINDED THERAPY	Initial Entry

3. Formulation:

Date	Location	User	Value	Reason
Jan-12-2021 16:29:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INJECTION	Initial Entry

4. Dose Date Time:

Date	Location	User	Value	Reason
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090177e196b72784\Final\Final On: 06-Apr-2021 19:11 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 10-Dec-2020 02:26

Site No: 1044

Subject No: 10441373

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): 06-Apr-2021 15:36

Jan-12-2021 16:29:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Jan/12/2021 10:33	Initial Entry
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5. Anatomical Location:

Date	Location	User	Value	Reason
Jan-12-2021 16:29:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: DELTOID MUSCLE	Initial Entry

6. Body Side:

Date	Location	User	Value	Reason
Jan-12-2021 16:29:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: LEFT	Initial Entry

7. Route:

Date	Location	User	Value	Reason
Jan-12-2021 16:29:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INTRAMUSCULAR	Initial Entry

090177e196b72784\Final\Final On: 06-Apr-2021 19:11 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 10-Dec-2020 02:26

Site No: 1044

Subject No: 10441373

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): 06-Apr-2021 15:36

10. Timeframe Subject Was Observed

Date	Location	User	Value	Reason
Jan-12-2021 16:29:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 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
Jan-12-2021 16:29:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

090177e196b72784\Final\Final On: 06-Apr-2021 19:11 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 06-Jul-2020 21:53

Site No: 1044

Subject No: 10441373

Generated By: (b) (4)

Form: REACTOGENICITY DIARY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1044) Virginia Research Center

Subject Initials: ---

Generated Time (GMT): 06-Apr-2021 15:36

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1. Select appropriate response - Reactogenicity diary collection

Date	Location	User	Value	Reason
Jan-12-2021 16:29:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES - REACTOGE NICITY E-DIARY COLLECTED FOR THIS SUBJECT	Initial Entry

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 1044

Subject No: 10441373

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): 06-Apr-2021 15:36

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1. Date of Visit

Date	Location	User	Value	Reason
Feb-04-2021 16:46:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Feb/4/2021	Initial Entry

090177e196b72784\Final\Final On: 06-Apr-2021 19:11 (GMT)

Header Text: c4591001**Visit:** V2_VAX2_L**Form:** VACCINATION SYMPTOMS DIARY -
SYMPTOM RESOLVED DATES - eCRF Audit Trail
History**Form Version:** 10-Dec-2020 02:30**Form Status:** Data Complete, Locked, Frozen, Verified**Site No:** 1044**Site Name:** (1044) Virginia Research Center**Subject No:** 10441373**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 06-Apr-2021 15:36[Back to Form](#)**1. Were medications to treat fever/pain given on the last day the Subject Diary was completed?**

Date	Location	User	Value	Reason
Feb-04-2021 16:46:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2.a

Date	Location	User	Value	Reason
Feb-04-2021 16:46:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom:: F E V E R Were fever or s N ystemic sympt O oms present on the last day the Subject Diary was completed ?:	Initial Entry

2.a Symptom:

Date	Location	User	Value	Reason
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Header Text: c4591001

Visit: V2_VAX2_L

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

Form Version: 10-Dec-2020 02:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1044

Site Name: (1044) Virginia Research Center

Subject No: 10441373

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 06-Apr-2021 15:36

Feb-04-2021 16:46:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: FEVER	Initial Entry
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2.a Were fever or systemic symptoms present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Feb-04-2021 16:46:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2.b

Date	Location	User	Value	Reason
Feb-04-2021 16:46:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom:: FA TI G U E Were fever or N systemic symp O toms present o n the last day t he Subject Dia ry was comple ted?:	Initial Entry

090177e196b72784\Final\Final On: 06-Apr-2021 19:11 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

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

Form Version: 10-Dec-2020 02:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1044

Site Name: (1044) Virginia Research Center

Subject No: 10441373

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 06-Apr-2021 15:36

2.b Symptom:

Date	Location	User	Value	Reason
Feb-04-2021 16:46:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: FATIGUE	Initial Entry

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

Date	Location	User	Value	Reason
Feb-04-2021 16:46:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2.c

Date	Location	User	Value	Reason
Feb-04-2021 16:46:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom:: HE A D A C HE	Initial Entry

090177e196b72784\Final\On: 06-Apr-2021 19:11 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

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

Form Version: 10-Dec-2020 02:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1044

Site Name: (1044) Virginia Research Center

Subject No: 10441373

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 06-Apr-2021 15:36

			Were fever or N systemic symp O toms present o n the last day the Subject Di ary was compl eted?:	
--	--	--	--	--

2.c Symptom:

Date	Location	User	Value	Reason
Feb-04-2021 16:46:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: HEADACHE	Initial Entry

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

Date	Location	User	Value	Reason
Feb-04-2021 16:46:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2.d

Date	Location	User	Value	Reason
Feb-04-2021 16:46:36	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom:: C	Initial Entry

090177e196b72784\Final\Final On: 06-Apr-2021 19:11 (GMT)

Header Text: c4591001**Visit:** V2_VAX2_L**Form:** VACCINATION SYMPTOMS DIARY -
SYMPTOM RESOLVED DATES - eCRF Audit Trail
History**Form Version:** 10-Dec-2020 02:30**Form Status:** Data Complete, Locked, Frozen, Verified**Site No:** 1044**Site Name:** (1044) Virginia Research Center**Subject No:** 10441373**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 06-Apr-2021 15:36

(UTC-05:00) Eastern Time (US & Canada)		(b) (4), (b) (6)	HI L L S N O N O ms present on the last day the Subject Diary was completed ?:	
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2.d Symptom:

Date	Location	User	Value	Reason
Feb-04-2021 16:46:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: CHILLS	Initial Entry

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

Date	Location	User	Value	Reason
Feb-04-2021 16:46:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2.e

Header Text: c4591001

Visit: V2_VAX2_L

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

Form Version: 10-Dec-2020 02:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1044

Site Name: (1044) Virginia Research Center

Subject No: 10441373

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 06-Apr-2021 15:36

Date	Location	User	Value	Reason
Feb-04-2021 16:46:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom:: VO MI TI NG Were fever or NO systemic symp toms present on the last da y the Subject Diary was co mpleted?:	Initial Entry

2.e Symptom:

Date	Location	User	Value	Reason
Feb-04-2021 16:46:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: VOMITING	Initial Entry

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

Date	Location	User	Value	Reason
Feb-04-2021 16:46:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

090177e196b72784\Final\Final On: 06-Apr-2021 19:11 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

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

Form Version: 10-Dec-2020 02:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1044

Site Name: (1044) Virginia Research Center

Subject No: 10441373

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 06-Apr-2021 15:36

2.f

Date	Location	User	Value	Reason
Feb-04-2021 16:46:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom:: DI A RR HE A Were fever or N systemic symp O toms present o n the last day the Subject Di ary was compl eted?:	Initial Entry

Header Text: c4591001

Visit: V2_VAX2_L

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

Form Version: 10-Dec-2020 02:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1044

Site Name: (1044) Virginia Research Center

Subject No: 10441373

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 06-Apr-2021 15:36

2.f Symptom:

Date	Location	User	Value	Reason
Feb-04-2021 16:46:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: DIARRHEA	Initial Entry

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

Date	Location	User	Value	Reason
Feb-04-2021 16:46:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2.g

Date	Location	User	Value	Reason
Feb-04-2021 16:46:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom:: NEW OR W ORSE NED MUS CLE P AIN	Initial Entry

Header Text: c4591001

Visit: V2_VAX2_L

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

Form Version: 10-Dec-2020 02:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1044

Site Name: (1044) Virginia Research Center

Subject No: 10441373

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 06-Apr-2021 15:36

			Were fever NO or systemic symptoms present on the last day the Subject Diary was c ompleted?:	
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2.g Symptom:

Date	Location	User	Value	Reason
Feb-04-2021 16:46:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NEW OR WORSE NED MUSCLE PAI N	Initial Entry

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

Date	Location	User	Value	Reason
Feb-04-2021 16:46:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2.h

Date	Location	User	Value	Reason
Feb-04-2021	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Initial Entry

090177e196b72784\Final\On: 06-Apr-2021 19:11 (GMT)

Header Text: c4591001**Visit:** V2_VAX2_L**Form:** VACCINATION SYMPTOMS DIARY -
SYMPTOM RESOLVED DATES - eCRF Audit Trail
History**Form Version:** 10-Dec-2020 02:30**Form Status:** Data Complete, Locked, Frozen, Verified**Site No:** 1044**Site Name:** (1044) Virginia Research Center**Subject No:** 10441373**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 06-Apr-2021 15:36

16:46:36 (UTC-05:00) Eastern Time (US & Canada)		(b) (4), (b) (6) [REDACTED]	Symptom:: NEW OR WOR SENE D JOI NT P AIN Were fever NO or systemic symptoms present on t he last day the Subject Diary was c ompleted?:	
--	--	--------------------------------	--	--

Header Text: c4591001

Visit: V2_VAX2_L

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

Form Version: 10-Dec-2020 02:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1044

Site Name: (1044) Virginia Research Center

Subject No: 10441373

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 06-Apr-2021 15:36

2.h Symptom:

Date	Location	User	Value	Reason
Feb-04-2021 16:46:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NEW OR WORSE NED JOINT PAIN	Initial Entry

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

Date	Location	User	Value	Reason
Feb-04-2021 16:46:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

3. Injection Site Location:

Date	Location	User	Value	Reason
Feb-04-2021 16:46:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: DELTOID MUSCLE	Initial Entry

4. Injection Site Body Side:

Date	Location	User	Value	Reason
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090177e196b72784\Final On: 06-Apr-2021 19:11 (GMT)

Header Text: c4591001**Visit:** V2_VAX2_L**Form:** VACCINATION SYMPTOMS DIARY -
SYMPTOM RESOLVED DATES - eCRF Audit Trail
History**Form Version:** 10-Dec-2020 02:30**Form Status:** Data Complete, Locked, Frozen, Verified**Site No:** 1044**Site Name:** (1044) Virginia Research Center**Subject No:** 10441373**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 06-Apr-2021 15:36

Feb-04-2021 16:46:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: LEFT	Initial Entry
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5.a

Date	Location	User	Value	Reason
Feb-04-2021 16:46:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Injection Site RE Reaction:: D N ES S Were injection N site reactions O present on the last day the Su bject Diary wa s completed?:	Initial Entry

5.a Injection Site Reaction:

Date	Location	User	Value	Reason
Feb-04-2021 16:46:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: REDNESS	Initial Entry

Header Text: c4591001

Visit: V2_VAX2_L

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

Form Version: 10-Dec-2020 02:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1044

Site Name: (1044) Virginia Research Center

Subject No: 10441373

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 06-Apr-2021 15:36

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

Date	Location	User	Value	Reason
Feb-04-2021 16:46:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

5.b

Date	Location	User	Value	Reason
Feb-04-2021 16:46:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Injection Site SW Reaction:: EL LI NG Were injection site reactions present on the last day the Subject Diary was completed?: NO	Initial Entry

Header Text: c4591001

Visit: V2_VAX2_L

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

Form Version: 10-Dec-2020 02:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1044

Site Name: (1044) Virginia Research Center

Subject No: 10441373

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 06-Apr-2021 15:36

5.b Injection Site Reaction:

Date	Location	User	Value	Reason
Feb-04-2021 16:46:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: SWELLING	Initial Entry

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

Date	Location	User	Value	Reason
Feb-04-2021 16:46:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

5.c

Date	Location	User	Value	Reason
Feb-04-2021 16:46:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Injection Site Reaction: PAI N A T IN JEC TIO N SI TE	Initial Entry

Header Text: c4591001

Visit: V2_VAX2_L

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

Form Version: 10-Dec-2020 02:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1044

Site Name: (1044) Virginia Research Center

Subject No: 10441373

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 06-Apr-2021 15:36

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

Date	Location	User	Value	Reason
Feb-04-2021 16:46:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: PAIN AT INJECTION SITE	Initial Entry

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

Date	Location	User	Value	Reason
Feb-04-2021 16:46:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

090177e196b72784\Final\On: 06-Apr-2021 19:11 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 14-Jan-2021 02:22

Site No: 1044

Subject No: 10441373

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): 06-Apr-2021 15:36

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1. Date:

Date	Location	User	Value	Reason
Feb-04-2021 16:47:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Feb/4/2021	Initial Entry

2.a

Date	Location	User	Value	Reason
Feb-04-2021 16:47:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Record Id 1 entifier:: Temperat 97.2 ure: Temperat F ure Unit: Temperat ORAL ure Locati CAVIT on:: Y	Initial Entry

2.a Record Identifier:

Date	Location	User	Value	Reason
Feb-04-2021 16:47:26 (UTC-05:00) Eastern Time (US	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 1	Initial Entry

090177e196b72784\Final\Final On: 06-Apr-2021 19:11 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 14-Jan-2021 02:22

Site No: 1044

Subject No: 10441373

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): 06-Apr-2021 15:36

& Canada)

2.a Temperature:

Date	Location	User	Value	Reason
Feb-04-2021 16:47:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 97.2	Initial Entry

2.a Unit:

Date	Location	User	Value	Reason
Feb-04-2021 16:47:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: F	Initial Entry

2.a Temperature Location:

Date	Location	User	Value	Reason
Feb-04-2021 16:47:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: ORAL CAVITY	Initial Entry

090177e196b72784\Final\On: 06-Apr-2021 19:11 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 10-Dec-2020 02:23

Site No: 1044

Subject No: 10441373

Generated By: (b) (4)

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

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1044) Virginia Research Center

Subject Initials: ---

Generated Time (GMT): 06-Apr-2021 15:36

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1. Lab Panel:

Date	Location	User	Value	Reason
Feb-04-2021 16:47:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: URINALYSIS	Initial Entry

2. Lab Sub-Panel:

Date	Location	User	Value	Reason
Feb-04-2021 16:47:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: PREGNANCY	Initial Entry

3. Collection Date:

Date	Location	User	Value	Reason
Feb-04-2021 16:47:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Feb/4/2021	Initial Entry

4. Laboratory Name and Address (Derived)

Date	Location	User	Value	Reason
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090177e196b72784\Final\On: 06-Apr-2021 19:11 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

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

Form Version: 10-Dec-2020 02:23

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1044

Site Name: (1044) Virginia Research Center

Subject No: 10441373

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 06-Apr-2021 15:36

Feb-04-2021 16:47:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: STUDY SITE	Initial Entry
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5. Specimen Type:

Date	Location	User	Value	Reason
Feb-04-2021 16:47:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: URINE	Initial Entry

6.a

Date	Location	User	Value	Reason
Feb-04-2021 16:47:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sponsor- 113 Defined I dentifier: Test:: Choriogon adotropin Beta_PX11 3 Result:: NEGATIV E Not Done ::	Initial Entry

6.a Sponsor ID:

090177e196b72784\Final\Final On: 06-Apr-2021 19:11 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

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

Form Version: 10-Dec-2020 02:23

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1044

Site Name: (1044) Virginia Research Center

Subject No: 10441373

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 06-Apr-2021 15:36

Date	Location	User	Value	Reason
Feb-04-2021 16:47:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 113	Initial Entry

6.a Test:

Date	Location	User	Value	Reason
Feb-04-2021 16:47:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Choriogonadotropin Beta_PX113	Initial Entry

6.a Result:

Date	Location	User	Value	Reason
Feb-04-2021 16:47:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NEGATIVE	Initial Entry

090177e196b72784\Final\Final On: 06-Apr-2021 19:11 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:03

Site No: 1044

Subject No: 10441373

Generated By: (b) (4)

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

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1044) Virginia Research Center

Subject Initials: ---

Generated Time (GMT): 06-Apr-2021 15:36

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1. Data Origin

Date	Location	User	Value	Reason
Feb-04-2021 16:47:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Feb-04-2021 16:47:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: NASAL_SWAB	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Feb-04-2021 16:48:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Feb-04-2021 16:47:52 (UTC-05:00)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however

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: 10441373

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 06-Apr-2021 15:36

Eastern Time (US & Canada)				no barcodes are entered. Please review and correct as appropriate.
Feb-04-2021 16:47:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Collection: Feb/4/2021	Initial Entry

5.a

Date	Location	User	Value	Reason
Feb-04-2021 16:48:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample I BRJZK D: K	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Feb-04-2021 16:48:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BRJZKK	Initial Entry

090177e196b72784\Final\On: 06-Apr-2021 19:11 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 10-Dec-2020 02:26

Site No: 1044

Subject No: 10441373

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): 06-Apr-2021 15:36

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1. Was there a temporary delay of vaccination?

Date	Location	User	Value	Reason
Feb-04-2021 16:48:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2. Treatment Name

Date	Location	User	Value	Reason
Feb-04-2021 16:48:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: BLINDED THERAPY	Initial Entry

3. Formulation:

Date	Location	User	Value	Reason
Feb-04-2021 16:48:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INJECTION	Initial Entry

4. Dose Date Time:

Date	Location	User	Value	Reason
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090177e196b72784\Final\Final On: 06-Apr-2021 19:11 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 10-Dec-2020 02:26

Site No: 1044

Subject No: 10441373

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): 06-Apr-2021 15:36

Feb-04-2021 16:48:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Feb/4/2021 10:04	Initial Entry
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5. Anatomical Location:

Date	Location	User	Value	Reason
Feb-04-2021 16:48:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: DELTOID MUSCLE	Initial Entry

6. Body Side:

Date	Location	User	Value	Reason
Feb-04-2021 16:48:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: LEFT	Initial Entry

7. Route:

Date	Location	User	Value	Reason
Feb-04-2021 16:48:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INTRAMUSCULAR	Initial Entry

090177e196b72784\Final\Final On: 06-Apr-2021 19:11 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 10-Dec-2020 02:26

Site No: 1044

Subject No: 10441373

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): 06-Apr-2021 15:36

10. Timeframe Subject Was Observed

Date	Location	User	Value	Reason
Feb-04-2021 16:48:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 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
Feb-04-2021 16:48:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

090177e196b72784\Final\Final On: 06-Apr-2021 19:11 (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, Frozen, Verified

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

Subject No: 10441373 **Subject Initials:** ---

Generated By: (b) (4) **Generated Time (GMT):** 06-Apr-2021 15:36

[Back to Form](#)

1. Date of Visit

Date	Location	User	Value	Reason
Mar-09-2021 14:37:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Mar/9/2021	Initial Entry

090177e196b72784\Final\Final On: 06-Apr-2021 19:11 (GMT)

Header Text: c4591001**Visit:** V3_MONTH1_POSTVAX2_L **Form:** VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History**Form Version:** 10-Dec-2020 02:30**Form Status:** Data Complete, Frozen, Verified**Site No:** 1044**Site Name:** (1044) Virginia Research Center**Subject No:** 10441373**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 06-Apr-2021 15:36[Back to Form](#)**1. Were medications to treat fever/pain given on the last day the Subject Diary was completed?**

Date	Location	User	Value	Reason
Mar-09-2021 14:38:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2.a

Date	Location	User	Value	Reason
Mar-09-2021 14:38:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom:: F E V E R Were fever or s N ystemic sympt O oms present on the last day the Subject Diary was completed ?:	Initial Entry

2.a Symptom:

Date	Location	User	Value	Reason
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Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L **Form:** VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:30 **Form Status:** Data Complete, Frozen, Verified

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

Subject No: 10441373 **Subject Initials:** ---

Generated By: (b) (4) **Generated Time (GMT):** 06-Apr-2021 15:36

Mar-09-2021 14:38:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: FEVER	Initial Entry
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2.a Were fever or systemic symptoms present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Mar-09-2021 14:38:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2.b

Date	Location	User	Value	Reason
Mar-09-2021 14:38:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom:: FA TI G U E Were fever or N systemic symp O toms present o n the last day t he Subject Dia ry was comple ted?:	Initial Entry

090177e196b72784\Final\Final On: 06-Apr-2021 19:11 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L **Form:** VACCINATION SYMPTOMS DIARY -
SYMPTOM RESOLVED DATES - eCRF Audit Trail
History

Form Version: 10-Dec-2020 02:30 **Form Status:** Data Complete, Frozen, Verified

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

Subject No: 10441373 **Subject Initials:** ---

Generated By: (b) (4) **Generated Time (GMT):** 06-Apr-2021 15:36

2.b Symptom:

Date	Location	User	Value	Reason
Mar-09-2021 14:38:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: FATIGUE	Initial Entry

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

Date	Location	User	Value	Reason
Mar-09-2021 14:38:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2.c

Date	Location	User	Value	Reason
Mar-09-2021 14:38:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom:: HE A D A C HE	Initial Entry

090177e196b72784\Final\On: 06-Apr-2021 19:11 (GMT)

Header Text: c4591001**Visit:** V3_MONTH1_POSTVAX2_L **Form:** VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History**Form Version:** 10-Dec-2020 02:30**Form Status:** Data Complete, Frozen, Verified**Site No:** 1044**Site Name:** (1044) Virginia Research Center**Subject No:** 10441373**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 06-Apr-2021 15:36

			Were fever or N systemic symp O toms present o n the last day the Subject Di ary was compl eted?:	
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2.c Symptom:

Date	Location	User	Value	Reason
Mar-09-2021 14:38:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: HEADACHE	Initial Entry

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

Date	Location	User	Value	Reason
Mar-09-2021 14:38:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2.d

Date	Location	User	Value	Reason
Mar-09-2021 14:38:21	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom:: C	Initial Entry

Header Text: c4591001**Visit:** V3_MONTH1_POSTVAX2_L **Form:** VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History**Form Version:** 10-Dec-2020 02:30**Form Status:** Data Complete, Frozen, Verified**Site No:** 1044**Site Name:** (1044) Virginia Research Center**Subject No:** 10441373**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 06-Apr-2021 15:36(UTC-05:00)
Eastern Time (US
& Canada)

(b) (4), (b) (6)

HI
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SWere fever or
systemic sympt
oms present on
the last day the
Subject Diary
was completed
?:**2.d Symptom:**

Date	Location	User	Value	Reason
Mar-09-2021 14:38:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: CHILLS	Initial Entry

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

Date	Location	User	Value	Reason
Mar-09-2021 14:38:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2.e

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L **Form:** VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:30 **Form Status:** Data Complete, Frozen, Verified

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

Subject No: 10441373 **Subject Initials:** ---

Generated By: (b) (4) **Generated Time (GMT):** 06-Apr-2021 15:36

Date	Location	User	Value	Reason
Mar-09-2021 14:38:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom:: VO MI TI NG Were fever or NO systemic symp toms present on the last da y the Subject Diary was co mpleted?:	Initial Entry

2.e Symptom:

Date	Location	User	Value	Reason
Mar-09-2021 14:38:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: VOMITING	Initial Entry

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

Date	Location	User	Value	Reason
Mar-09-2021 14:38:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L **Form:** VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:30 **Form Status:** Data Complete, Frozen, Verified

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

Subject No: 10441373 **Subject Initials:** ---

Generated By: (b) (4) **Generated Time (GMT):** 06-Apr-2021 15:36

2.f

Date	Location	User	Value	Reason
Mar-09-2021 14:38:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom:: DI A RR HE A Were fever or N systemic symp O toms present o n the last day the Subject Di ary was compl eted?:	Initial Entry

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L **Form:** VACCINATION SYMPTOMS DIARY -
SYMPTOM RESOLVED DATES - eCRF Audit Trail
History

Form Version: 10-Dec-2020 02:30 **Form Status:** Data Complete, Frozen, Verified

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

Subject No: 10441373 **Subject Initials:** ---

Generated By: (b) (4) **Generated Time (GMT):** 06-Apr-2021 15:36

2.f Symptom:

Date	Location	User	Value	Reason
Mar-09-2021 14:38:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: DIARRHEA	Initial Entry

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

Date	Location	User	Value	Reason
Mar-09-2021 14:38:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2.g

Date	Location	User	Value	Reason
Mar-09-2021 14:38:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom:: NEW OR W ORSE NED MUS CLE P AIN	Initial Entry

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L **Form:** VACCINATION SYMPTOMS DIARY -
SYMPTOM RESOLVED DATES - eCRF Audit Trail
History

Form Version: 10-Dec-2020 02:30

Form Status: Data Complete, Frozen, Verified

Site No: 1044

Site Name: (1044) Virginia Research Center

Subject No: 10441373

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 06-Apr-2021 15:36

			Were fever NO or systemic symptoms present on the last day the Subject Diary was c ompleted?:	
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2.g Symptom:

Date	Location	User	Value	Reason
Mar-09-2021 14:38:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NEW OR WORSE NED MUSCLE PAI N	Initial Entry

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

Date	Location	User	Value	Reason
Mar-09-2021 14:38:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2.h

Date	Location	User	Value	Reason
Mar-09-2021	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Initial Entry

090177e196b72784\Final\Final On: 06-Apr-2021 19:11 (GMT)

Header Text: c4591001**Visit:** V3_MONTH1_POSTVAX2_L **Form:** VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History**Form Version:** 10-Dec-2020 02:30**Form Status:** Data Complete, Frozen, Verified**Site No:** 1044**Site Name:** (1044) Virginia Research Center**Subject No:** 10441373**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 06-Apr-2021 15:3614:38:21
(UTC-05:00)
Eastern Time (US
& Canada)

(b) (4), (b) (6)

Symptom:: NEW
OR
WOR
SENE
D JOI
NT P
AIN**Were fever NO**
or systemic
symptoms
present on t
he last day
the Subject
Diary was c
ompleted?:

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L **Form:** VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:30 **Form Status:** Data Complete, Frozen, Verified

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

Subject No: 10441373 **Subject Initials:** ---

Generated By: (b) (4) **Generated Time (GMT):** 06-Apr-2021 15:36

2.h Symptom:

Date	Location	User	Value	Reason
Mar-09-2021 14:38:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NEW OR WORSE NED JOINT PAIN	Initial Entry

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

Date	Location	User	Value	Reason
Mar-09-2021 14:38:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

3. Injection Site Location:

Date	Location	User	Value	Reason
Mar-09-2021 14:38:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: DELTOID MUSCLE	Initial Entry

4. Injection Site Body Side:

Date	Location	User	Value	Reason
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090177e196b72784\Final\On: 06-Apr-2021 19:11 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L **Form:** VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:30 **Form Status:** Data Complete, Frozen, Verified

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

Subject No: 10441373 **Subject Initials:** ---

Generated By: (b) (4) **Generated Time (GMT):** 06-Apr-2021 15:36

Mar-09-2021 14:38:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: LEFT	Initial Entry
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5.a

Date	Location	User	Value	Reason
Mar-09-2021 14:38:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Injection Site RE Reaction:: D N ES S Were injection N site reactions O present on the last day the Su bject Diary wa s completed?:	Initial Entry

5.a Injection Site Reaction:

Date	Location	User	Value	Reason
Mar-09-2021 14:38:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: REDNESS	Initial Entry

090177e196b72784\Final\Final On: 06-Apr-2021 19:11 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L **Form:** VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:30 **Form Status:** Data Complete, Frozen, Verified

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

Subject No: 10441373 **Subject Initials:** ---

Generated By: (b) (4) **Generated Time (GMT):** 06-Apr-2021 15:36

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

Date	Location	User	Value	Reason
Mar-09-2021 14:38:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

5.b

Date	Location	User	Value	Reason
Mar-09-2021 14:38:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Injection Site SW Reaction:: EL LI NG Were injection site reactions present on the last day the Subject Diary was completed?: NO	Initial Entry

090177e196b72784\Final\Final On: 06-Apr-2021 19:11 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L **Form:** VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:30 **Form Status:** Data Complete, Frozen, Verified

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

Subject No: 10441373 **Subject Initials:** ---

Generated By: (b) (4) **Generated Time (GMT):** 06-Apr-2021 15:36

5.b Injection Site Reaction:

Date	Location	User	Value	Reason
Mar-09-2021 14:38:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: SWELLING	Initial Entry

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

Date	Location	User	Value	Reason
Mar-09-2021 14:38:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

5.c

Date	Location	User	Value	Reason
Mar-09-2021 14:38:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Injection Site Reaction: PAI N A T IN JEC TIO N SI TE	Initial Entry

Header Text: c4591001**Visit:** V3_MONTH1_POSTVAX2_L **Form:** VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History**Form Version:** 10-Dec-2020 02:30**Form Status:** Data Complete, Frozen, Verified**Site No:** 1044**Site Name:** (1044) Virginia Research Center**Subject No:** 10441373**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 06-Apr-2021 15:36

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

Date	Location	User	Value	Reason
Mar-09-2021 14:38:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: PAIN AT INJECTION SITE	Initial Entry

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

Date	Location	User	Value	Reason
Mar-09-2021 14:38:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L **Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF Audit Trail History

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

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

Subject No: 10441373 **Subject Initials:** ---

Generated By: (b) (4) **Generated Time (GMT):** 06-Apr-2021 15:36

[Back to Form](#)

1. Data Origin

Date	Location	User	Value	Reason
Mar-09-2021 14:38:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Mar-09-2021 14:38:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SERUM	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Mar-09-2021 14:38:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Mar-09-2021 14:38:40 (UTC-05:00)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however

Header Text: c4591001**Visit:** V3_MONTH1_POSTVAX2_L **Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF Audit Trail History**Form Version:** 22-Apr-2020 21:03 **Form Status:** Data Complete, Frozen, Verified**Site No:** 1044**Site Name:** (1044) Virginia Research Center**Subject No:** 10441373**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 06-Apr-2021 15:36

Eastern Time (US & Canada)				no barcodes are entered. Please review and correct as appropriate.
Mar-09-2021 14:38:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Collection: Mar/9/2021	Initial Entry

5.a

Date	Location	User	Value	Reason
Mar-09-2021 14:38:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample I BRF4V D: L	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Mar-09-2021 14:38:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BRF4VL	Initial Entry

5.b

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L **Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF Audit Trail History

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

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

Subject No: 10441373 **Subject Initials:** ---

Generated By: (b) (4) **Generated Time (GMT):** 06-Apr-2021 15:36

Date	Location	User	Value	Reason
Mar-09-2021 14:39:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample I BSD1X D: F	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Mar-09-2021 14:39:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BSD1XF	Initial Entry

5.c

Date	Location	User	Value	Reason
Mar-09-2021 14:39:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample I BSD1X D: 9	Initial Entry

090177e196b72784\Final\Final On: 06-Apr-2021 19:11 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L **Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF Audit Trail History

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

Site No: 1044

Site Name: (1044) Virginia Research Center

Subject No: 10441373

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 06-Apr-2021 15:36

5.c Sample ID

Date	Location	User	Value	Reason
Mar-09-2021 14:39:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BSD1X9	Initial Entry

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1044

Subject No: 10441373

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - Audit Trail

Form Status:

Site Name: (1044) Virginia Research Center

Subject Initials: ---

Generated Time (GMT): 06-Apr-2021 15:36

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Date	Location	User	Value	Reason
Jan-12-2021 16:34:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

090177e196b72784\Final\Final On: 06-Apr-2021 19:11 (GMT)

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: 10441373

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 06-Apr-2021 15:36

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Date	Location	User	Value	Reason
Mar-09-2021 14:41:15 (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, Frozen

Site No: 1044

Site Name: (1044) Virginia Research Center

Subject No: 10441373

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 06-Apr-2021 15:36

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1. Category:

Date	Location	User	Value	Reason
Jan-12-2021 16:34:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: ADVERSE EVENT	Initial Entry

2. AE ID:

Date	Location	User	Value	Reason
Jan-12-2021 16:34:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 1	Initial Entry

3. Adverse Event:

(If possible specify diagnosis, not individual symptoms)

Date	Location	User	Value	Reason
Jan-14-2021 16:58:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Query 1: Closed	Response satisfies query
Jan-13-2021 19:18:27 (UTC-05:00)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Query 1: Answered	no precipitant noted

Header Text: c4591001**Visit:** Logs - Unscheduled**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History**Form Version:** 22-Apr-2020 21:02**Form Status:** Data Complete, Frozen**Site No:** 1044**Site Name:** (1044) Virginia Research Center**Subject No:** 10441373**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 06-Apr-2021 15:36

Eastern Time (US & Canada)				
Jan-13-2021 10:36:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Query 1: Opened	GPD Clin: given history of allergies, please confirm if participant has had an allergic exposure as a precipitant to hives. Thank you
Jan-12-2021 16:34:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry: hives forehead	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason
Jan-12-2021 16:34:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry: Jan/12/2021 11:29	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
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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, Frozen

Site No: 1044

Site Name: (1044) Virginia Research Center

Subject No: 10441373

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 06-Apr-2021 15:36

Feb-04-2021 16:49:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO End Date Time: Jan/12/2021 U NK:UNK	Changed Information
Jan-12-2021 16:34:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
Jan-12-2021 16:34:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 1	Initial Entry

7. Is the adverse event serious?

If Yes, NOTIFY PFIZER IMMEDIATELY.

Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).

Date	Location	User	Value	Reason
Jan-12-2021	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Initial Entry

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: 10441373

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 06-Apr-2021 15:36

16:34:49
(UTC-05:00)
Eastern Time (US
& Canada)

(b) (4), (b) (6)

NO

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

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

Date	Location	User	Value	Reason
Jan-12-2021 16:34:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Jan-12-2021 16:34:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: RELATED	Initial Entry

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Jan-12-2021 16:34:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NOT APPLICABLE	Initial Entry

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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, Frozen

Site No: 1044

Site Name: (1044) Virginia Research Center

Subject No: 10441373

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 06-Apr-2021 15:36

11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
Jan-12-2021 16:34:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Jan-12-2021 16:34:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

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

Date	Location	User	Value	Reason
Feb-04-2021 16:49:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Clo sed	Close Auto Query
Feb-04-2021 16:49:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: RECOVERE D/RESOLV ED	Transcription Error

090177e196b72784\Final\Final On: 06-Apr-2021 19:11 (GMT)

Header Text: c4591001**Visit:** Logs - Unscheduled**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History**Form Version:** 22-Apr-2020 21:02**Form Status:** Data Complete, Frozen**Site No:** 1044**Site Name:** (1044) Virginia Research Center**Subject No:** 10441373**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 06-Apr-2021 15:36

Feb-04-2021 16:49:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	For AE hives forehead: Response to "What was the outcome of this adverse event?" is 'Recovering/Resolving' but AE End Date/Time is present.
Jan-12-2021 16:34:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: RECOVERING/RESOLVING	Initial Entry

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

Date	Location	User	Value	Reason
Jan-12-2021 16:34:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

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Form Status: Data Complete

Site No: 1044

Site Name: (1044) Virginia Research Center

Subject No: 10441373

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 06-Apr-2021 15:36

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1. Category:

Date	Location	User	Value	Reason
Mar-09-2021 14:41:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: ADVERSE EVENT	Initial Entry

2. AE ID:

Date	Location	User	Value	Reason
Mar-09-2021 14:41:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 2	Initial Entry

3. Adverse Event:

(If possible specify diagnosis, not individual symptoms)

Date	Location	User	Value	Reason
Mar-09-2021 14:41:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Worsening of Anxiety	Initial Entry

4. Start Date Time:

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Header Text: c4591001

Visit: Logs - Unscheduled

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Form Status: Data Complete

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Site Name: (1044) Virginia Research Center

Subject No: 10441373

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 06-Apr-2021 15:36

Date	Location	User	Value	Reason
Mar-09-2021 14:41:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Mar/5/2021 UNK:U NK	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Mar-09-2021 14:41:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
Mar-09-2021 14:41:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 2	Initial Entry

7. Is the adverse event serious?

If Yes, NOTIFY PFIZER IMMEDIATELY.

Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to

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Header Text: c4591001

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Subject No: 10441373

Subject Initials: ---

Generated By: (b) (4)

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prevent above outcomes).

Date	Location	User	Value	Reason
Mar-09-2021 14:41:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

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

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

Date	Location	User	Value	Reason
Mar-09-2021 14:41:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Mar-11-2021 14:35:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Mar-11-2021 13:39:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	New Information

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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**Site No:** 1044**Site Name:** (1044) Virginia Research Center**Subject No:** 10441373**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 06-Apr-2021 15:36

Mar-11-2021 13:39:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NOT RELATED If Not Related to study treatment(s) , this event is due to: OTHER <i>If Other, specify:</i> medication dosage adjustment	New Information
Mar-10-2021 18:17:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued: Opened	GPD Clin: please consider amending Item 9. alternative causality to reflect medication changes if this is felt to be a precipitating factor. Thank you
Mar-10-2021 17:02:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	subject is adjusting medication strength

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**Site No:** 1044**Site Name:** (1044) Virginia Research Center**Subject No:** 10441373**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 06-Apr-2021 15:36

Mar-10-2021 15:11:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	GPD Clin: Did patient have any precipitating factors such as new social stressors? Please review and update alternative causality as appropriate to indicate precipitating factors.
Mar-09-2021 14:41:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<p>Data Entry: NOT RELATED</p> <p>If Not Related to study treatment(s), this event is due to:</p> <p>OTHER</p> <p><i>If Other, specify:</i></p> <p>med history</p>	Initial Entry

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
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Header Text: c4591001

Visit: Logs - Unscheduled

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Form Status: Data Complete

Site No: 1044

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Generated By: (b) (4)

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Mar-09-2021 14:41:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NOT APPLICABLE	Initial Entry
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11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
Mar-09-2021 14:41:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Mar-09-2021 14:41:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

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

Date	Location	User	Value	Reason
Mar-09-2021 14:41:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: RECOVERING/RESOLVING	Initial Entry

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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

Site No: 1044

Site Name: (1044) Virginia Research Center

Subject No: 10441373

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 06-Apr-2021 15:36

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

Date	Location	User	Value	Reason
Mar-09-2021 14:41:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

Header Text: c4591001

Visit: End of Treatment - Unscheduled **Form:** DISPOSITION - TREATMENT - eCRF Audit Trail History

Form Version: 20-Feb-2021 02:26

Form Status: Data Complete, Frozen, Verified

Site No: 1044

Site Name: (1044) Virginia Research Center

Subject No: 10441373

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 06-Apr-2021 15:36

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1. Date of Completion/Discontinuation/Death :

Date	Location	User	Value	Reason
Mar-09-2021 14:39:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Mar/9/2021	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Mar-09-2021 14:39:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: VACCINATION	Initial Entry

3. Status:

Date	Location	User	Value	Reason
Mar-09-2021 14:39:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: COMPLETED	Initial Entry

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Header Text: c4591001

Visit: Subject Status - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1044

Subject No: 10441373

Generated By: (b) (4)

Form: SUBJECT STATUS - eCRF Audit Trail History

Form Status: Data Complete, Verified

Site Name: (1044) Virginia Research Center

Subject Initials: ---

Generated Time (GMT): 06-Apr-2021 15:36

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1. Subject Status

Date	Location	User	Value	Reason
Mar-09-2021 14:39:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: FOLLOW-UP	Initial Entry
Jan-12-2021 16:26:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: ENROLLED/RANDO MIZED	Initial Entry
Jan-12-2021 16:19:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SCREENED	Initial Entry

2. Subject Status Date

Date	Location	User	Value	Reason
Mar-09-2021 14:39:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Mar/9/2021	Initial Entry
Jan-12-2021 16:26:08	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Jan/12/2021	Initial Entry

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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: 10441373

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 06-Apr-2021 15:36

(UTC-05:00) Eastern Time (US & Canada)				
Jan-12-2021 16:19:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Jan/12/2021	Initial Entry

Header Text: c4591001

Visit: Investigator Signature -
Unscheduled

Form Version: 22-Apr-2020 21:04

Site No: 1044

Subject No: 10441373

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): 06-Apr-2021 15:36

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1. Casebook Signature

Date	Location	User	Value	Reason
Feb-25-2021 14:23:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Click Here to Enabl e	Initial Entry

090177e196b72784\Final\Final On: 06-Apr-2021 19:11 (GMT)