

**Header Text:** c4591001

**Visit:** COHORT\_SELECTION

**Form:** COHORT\_SELECTION

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

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

**Site No:** 1047

**Site Name:** (1047) Medical Affiliated Research Center

**Subject No:** 10471318

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 04:44

[eCRF Audit Trail History](#)

**Cohort Selection**

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

1.	Select appropriate response - Protocol version	06 OCT 2020
2.	Select appropriate response - What cohort does the subject belong to?	STAGE 3 COHORTS

090177e196ae3083\Final\Final On: 01-Apr-2021 04:08 (GMT)

**Header Text:** c4591001

**Visit:** COHORT\_SELECTION

**Form:** MAIN INFORMED CONSENT

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

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

**Site No:** 1047

**Site Name:** (1047) Medical Affiliated Research Center

**Subject No:** 10471318

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 04:44

[eCRF Audit Trail History](#)

**Informed Consent**

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

**Visit:** COHORT\_SELECTION

**Form:** DEMOGRAPHY

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

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

**Site No:** 1047

**Site Name:** (1047) Medical Affiliated Research Center

**Subject No:** 10471318

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 04:44

[eCRF Audit Trail History](#)

**Demography**

1.	Subject ID	[10471318]
2.	Birth Date:	(b) (6) /1991
3.	Sex:	FEMALE
4.	Ethnicity:	NOT HISPANIC OR LATINO(A) OR OF SPANISH ORIGIN
5.	Race: (Check X all that apply):	BLACK OR AFRICAN AMERICAN
6.	Racial Designation:	

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**Header Text:** c4591001

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

**Form:** DATE OF VISIT

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

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

**Site No:** 1047

**Site Name:** (1047) Medical Affiliated Research Center

**Subject No:** 10471318

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 04:44

[eCRF Audit Trail History](#)

**Date of Visit**

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

**Header Text:** c4591001

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

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

**Site No:** 1047

**Subject No:** 10471318

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

**Form:** INCLUSION/EXCLUSION CRITERIA

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

**Site Name:** (1047) Medical Affiliated Research Center

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:44

**Form Comments**

**Inclusion Criteria Not Met**

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

2.	Description of Exclusion Criterion Met	Not Applicable _____
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**Header Text:** c4591001

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

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

**Site No:** 1047

**Subject No:** 10471318

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

**Form:** DISPOSITION - SCREENING

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

**Site Name:** (1047) Medical Affiliated Research Center

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:44

[eCRF Audit Trail History](#)

**Disposition - Screening**

1.	Date of Completion/Discontinuation /Death	Oct/14/2020
2.	Phase of Disposition:	SCREENING
3.	Status:	COMPLETED
4.	Specify Status:	[ ]

**Header Text:** c4591001

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

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

**Site No:** 1047

**Subject No:** 10471318

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

**Form:** GENERAL MEDICAL HISTORY

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

**Site Name:** (1047) Medical Affiliated Research Center

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:44

[eCRF Audit Trail History](#)

**Medical History Details**

1.a	Line/MH Number:	[1]
	Disease/Syndrome /Surgery/Non-Drug Allergies/Drug Allergies:	[c section]
	Start Date:	UNK/UNK/2009
	Ongoing:	NO End Date: UNK/UNK/2009
1.b	Line/MH Number:	[2]
	Disease/Syndrome /Surgery/Non-Drug Allergies/Drug Allergies:	[c section]
	Start Date:	UNK/UNK/2010
	Ongoing:	NO End Date: UNK/UNK/2010

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**Header Text:** c4591001

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

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

**Site No:** 1047

**Subject No:** 10471318

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

**Form:** HIV STATUS

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

**Site Name:** (1047) Medical Affiliated Research Center

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:44

[eCRF Audit Trail History](#)

**HIV Status**

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

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

**Form:** VITAL SIGNS - BASELINE

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

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

**Site No:** 1047

**Site Name:** (1047) Medical Affiliated Research Center

**Subject No:** 10471318

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 04:44

[eCRF Audit Trail History](#)

**Vital Signs**

1.	Date:	Oct/14/2020
2.	Weight:	[240.0]
3.	Unit:	LB
4.	Height:	[72.0]
5.	Unit:	in
6.	Body Mass Index:	[32.5]

**Vital Signs Details**

7.a	Record Identifier:	1
	Temperature:	[97.7]
	Unit:	F
	Temperature Location:	FOREHEAD

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**Header Text:** c4591001

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

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

**Site No:** 1047

**Subject No:** 10471318

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

**Form:** LAB URINALYSIS - PREGNANCY TEST

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

**Site Name:** (1047) Medical Affiliated Research Center

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:44

[eCRF Audit Trail History](#)

**Lab Urinalysis**

1.	Lab Panel:	URINALYSIS
2.	Lab Sub-Panel:	PREGNANCY
3.	Collection Date:	Oct/14/2020
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:	

090177e196ae3083\Final\Final On: 01-Apr-2021 04:08 (GMT)

**Header Text:** c4591001

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

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

**Site No:** 1047

**Subject No:** 10471318

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

**Form:** RANDOMIZATION

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

**Site Name:** (1047) Medical Affiliated Research Center

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:44

[eCRF Audit Trail History](#)

**Disposition**

1.	Randomization Date :	Oct/14/2020
2.	Randomization Number:	[107233]
3.	Randomization Group:	[ ]

**Header Text:** c4591001

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

**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

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

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

**Site No:** 1047

**Site Name:** (1047) Medical Affiliated Research Center

**Subject No:** 10471318

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 04:44

[eCRF Audit Trail History](#)

**Electronic Sample Tracking**

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

**Aliquot**

Please enter barcode for each aliquot.

5.a	Sample ID	[BR8FNF]
5.b	Sample ID	[BR8FNG]
5.c	Sample ID	[BR8FNH]
5.d	Sample ID	[BSHNW1]

090177e196ae3083\Final\Final On: 01-Apr-2021 04:08 (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, Frozen, Verified

**Site No:** 1047

**Site Name:** (1047) Medical Affiliated Research Center

**Subject No:** 10471318

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 04:44

[eCRF Audit Trail History](#)

**Electronic Sample Tracking**

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

**Aliquot**

Please enter barcode for each aliquot.

5.a	Sample ID	[BR8FMW]
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090177e196ae3083\Final\Final On: 01-Apr-2021 04:08 (GMT)

**Header Text:** c4591001

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

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

**Site No:** 1047

**Subject No:** 10471318

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

**Form:** VACCINATION

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

**Site Name:** (1047) Medical Affiliated Research Center

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:44

[eCRF Audit Trail History](#)

**Vaccination**

1.	Was there a temporary delay of vaccination?	NO
2.	Treatment Name	[BLINDED THERAPY]
3.	Formulation:	INJECTION
4.	Dose Date Time:	Oct/14/2020 10:42
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

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**Header Text:** c4591001

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

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

**Site No:** 1047

**Subject No:** 10471318

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

**Form:** REACTOGENICITY DIARY

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

**Site Name:** (1047) Medical Affiliated Research Center

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:44

[eCRF Audit Trail History](#)

**Reactogenicity Diary**

1.	Select appropriate response - Reactogenicity diary collection	NO - REACTOGENICITY E-DIARY NOT COLLECTED FOR THIS SUBJECT
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090177e196ae3083\Final\Final On: 01-Apr-2021 04:08 (GMT)

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

**Form:** DATE OF VISIT

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

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

**Site No:** 1047

**Site Name:** (1047) Medical Affiliated Research Center

**Subject No:** 10471318

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 04:44

[eCRF Audit Trail History](#)

**Date of Visit**

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



**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1047

**Subject No:** 10471318

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

**Form:** VITAL SIGNS - TEMP

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

**Site Name:** (1047) Medical Affiliated Research Center

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:44

[eCRF Audit Trail History](#)

**Vital Signs**

1.	Date:	Nov/2/2020
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**Vital Signs Details**

2.a	Record Identifier:	1
	Temperature:	[98.1]
	Unit:	F
	Temperature Location:	FOREHEAD

090177e196ae3083\Final\Final On: 01-Apr-2021 04:08 (GMT)

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1047

**Subject No:** 10471318

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

**Form:** LAB URINALYSIS - PREGNANCY TEST

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

**Site Name:** (1047) Medical Affiliated Research Center

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:44

[eCRF Audit Trail History](#)

**Lab Urinalysis**

1.	Lab Panel:	URINALYSIS
2.	Lab Sub-Panel:	PREGNANCY
3.	Collection Date:	Nov/2/2020
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:	

090177e196ae3083\Final\Final On: 01-Apr-2021 04:08 (GMT)

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

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

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

**Site No:** 1047

**Site Name:** (1047) Medical Affiliated Research Center

**Subject No:** 10471318

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 04:44

[eCRF Audit Trail History](#)

**Electronic Sample Tracking**

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

**Aliquot**

Please enter barcode for each aliquot.

5.a	Sample ID	[BR8F9J]
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090177e196ae3083\Final\Final On: 01-Apr-2021 04:08 (GMT)

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

**Form:** VACCINATION

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

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

**Site No:** 1047

**Site Name:** (1047) Medical Affiliated Research Center

**Subject No:** 10471318

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 04:44

[eCRF Audit Trail History](#)

**Vaccination**

1.	Was there a temporary delay of vaccination?	NO
2.	Treatment Name	[BLINDED THERAPY]
3.	Formulation:	INJECTION
4.	Dose Date Time:	Nov/2/2020 09:05
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

090177e196ae3083\Final\Final On: 01-Apr-2021 04:08 (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:** 1047 **Site Name:** (1047) Medical Affiliated Research Center

**Subject No:** 10471318 **Subject Initials:** ---

**Generated By:** (b) (4) **Generated Time (GMT):** 29-Mar-2021 04:44

[eCRF Audit Trail History](#)

**Date of Visit**

1.	Date of Visit	Nov/30/2020
2.	Erroneous Visit	

**Header Text:** c4591001

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

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

**Site No:** 1047 **Site Name:** (1047) Medical Affiliated Research Center

**Subject No:** 10471318 **Subject Initials:** ---

**Generated By:** (b) (4) **Generated Time (GMT):** 29-Mar-2021 04:44

[eCRF Audit Trail History](#)

**Electronic Sample Tracking**

1.	Data Origin	SITE
2.	Sample Type	SERUM
3.	Sample Collected?	YES Date of Collection: Nov/30/2020
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[ ]

**Aliquot**

Please enter barcode for each aliquot.

5.a	Sample ID	[BSHP60]
5.b	Sample ID	[BPSY18]
5.c	Sample ID	[BPSY17]
5.d	Sample ID	[BPSY16]

090177e196ae3083\Final\Final On: 01-Apr-2021 04:08 (GMT)

**Header Text:** c4591001

**Visit:** V4\_MONTH6\_L

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

**Site No:** 1047

**Subject No:** 10471318

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

**Form:** DATE OF VISIT

**Form Status:** Not Started

**Site Name:** (1047) Medical Affiliated Research Center

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:44

**Date of Visit**

1.	Date of Visit	//
2.	Erroneous Visit	

**Header Text:** c4591001

**Visit:** V4\_MONTH6\_L

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

**Site No:** 1047

**Subject No:** 10471318

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

**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

**Form Status:** Not Started

**Site Name:** (1047) Medical Affiliated Research Center

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:44

**Electronic Sample Tracking**

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

**Aliquot**

Please enter barcode for each aliquot.

5.	Sample ID	[ ]
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090177e196ae3083\Final\Final On: 01-Apr-2021 04:08 (GMT)



**Header Text:** c4591001

**Visit:** V5\_MONTH12\_L

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

**Site No:** 1047

**Subject No:** 10471318

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

**Form:** DATE OF VISIT

**Form Status:** Not Started

**Site Name:** (1047) Medical Affiliated Research Center

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:44

**Date of Visit**

1.	Date of Visit	//
2.	Erroneous Visit	

**Header Text:** c4591001

**Visit:** V5\_MONTH12\_L

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

**Site No:** 1047

**Subject No:** 10471318

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

**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

**Form Status:** Not Started

**Site Name:** (1047) Medical Affiliated Research Center

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:44

**Electronic Sample Tracking**

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

**Aliquot**

Please enter barcode for each aliquot.

5.	Sample ID	[ ]
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090177e196ae3083\Final\Final On: 01-Apr-2021 04:08 (GMT)

**Header Text:** c4591001

**Visit:** V6\_MONTH24\_L

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

**Site No:** 1047

**Subject No:** 10471318

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

**Form:** DATE OF VISIT

**Form Status:** Not Started

**Site Name:** (1047) Medical Affiliated Research Center

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:44

**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:** 1047

**Site Name:** (1047) Medical Affiliated Research Center

**Subject No:** 10471318

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 04:44

**Electronic Sample Tracking**

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

**Aliquot**

Please enter barcode for each aliquot.

5.	Sample ID	[ ]
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090177e196ae3083\Final\Final On: 01-Apr-2021 04:08 (GMT)

**Header Text:** c4591001

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

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

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

**Form Status:** Not Started

**Site No:** 1047

**Site Name:** (1047) Medical Affiliated Research Center

**Subject No:** 10471318

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 04:44

**Date of Visit**

1.	Date of Visit	//
2.	Erroneous Visit	

**COVID-19 Illness Visit**

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

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

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

**Site No:** 1047

**Subject No:** 10471318

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

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

**Form Status:** Not Started

**Site Name:** (1047) Medical Affiliated Research Center

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:44

**Signs and Symptoms**

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

**Symptoms**

4.	Symptoms:	
	Was symptom present?	

**Symptoms - Other**

5.	Symptoms - Other Text:	[ ]
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090177e196ae3083\Final\Final On: 01-Apr-2021 04:08 (GMT)

**Header Text:** c4591001

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

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

**Site No:** 1047

**Subject No:** 10471318

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

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

**Form Status:** Not Started

**Site Name:** (1047) Medical Affiliated Research Center

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:44

**Electronic Sample Tracking**

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

**Aliquot**

Please enter barcode for each aliquot.

5.	Sample ID	[ ]
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090177e196ae3083\Final\Final On: 01-Apr-2021 04:08 (GMT)

**Header Text:** c4591001

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

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

**Site No:** 1047

**Subject No:** 10471318

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

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

**Form Status:** Not Started

**Site Name:** (1047) Medical Affiliated Research Center

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:44

**Electronic Sample Tracking**

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

**Aliquot**

Please enter barcode for each aliquot.

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

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

**Form:** HEALTH CARE UTILIZATION

**Form Version:** 20-Feb-2021 02:19

**Form Status:** Not Started

**Site No:** 1047

**Site Name:** (1047) Medical Affiliated Research Center

**Subject No:** 10471318

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 04:44

**Health Care Utilization**

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

**Health Care Utilization Other**

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

**Health Care Utilization**

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

090177e196ae3083\Final\Final On: 01-Apr-2021 04:08 (GMT)

**Header Text:** c4591001

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

**Form:** ILLNESS DETAILS

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

**Form Status:** Not Started

**Site No:** 1047

**Site Name:** (1047) Medical Affiliated Research Center

**Subject No:** 10471318

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 04:44

**Illness Details**

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

**Header Text:** c4591001

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

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

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

**Form Status:** Not Started

**Site No:** 1047

**Site Name:** (1047) Medical Affiliated Research Center

**Subject No:** 10471318

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 04:44

**Date of Visit**

1.	Date of Visit	//
2.	Erroneous Visit	

**COVID-19 Illness Visit**

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

**Header Text:** c4591001

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

**Form:** ELECTRONIC SAMPLE TRACKING -  
IMMUNOGENICITY

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

**Form Status:** Not Started

**Site No:** 1047

**Site Name:** (1047) Medical Affiliated Research Center

**Subject No:** 10471318

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 04:44

**Electronic Sample Tracking**

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

**Aliquot**

Please enter barcode for each aliquot.

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

**Header Text:** c4591001

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

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

**Site No:** 1047

**Site Name:** (1047) Medical Affiliated Research Center

**Subject No:** 10471318

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 04:44

**Date of Visit**

1.	Date of Visit	//
2.	Erroneous Visit	

**COVID-19 Repeat Swab**

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

**Header Text:** c4591001

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

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

**Site No:** 1047 **Site Name:** (1047) Medical Affiliated Research Center

**Subject No:** 10471318 **Subject Initials:** ---

**Generated By:** (b) (4) **Generated Time (GMT):** 29-Mar-2021 04:44

**Electronic Sample Tracking**

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

**Aliquot**

Please enter barcode for each aliquot.

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

090177e196ae3083\Final\Final On: 01-Apr-2021 04:08 (GMT)

**Header Text:** c4591001

**Visit:** Logs

**Form:** ADVERSE EVENT REPORT

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

**Site No:** 1047

**Site Name:** (1047) Medical Affiliated Research Center

**Subject No:** 10471318

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 04:44

#	Category	AE Identifier	Adverse Event	Start Date	Is the Adverse Event Still Ongoing	Form Instance
1.	ADVERSE EVENT	1	Exposure during pregnancy	Dec/UNK/2020 UNK:UNK	YES	<a href="#">Repeating Pages</a>

090177e196ae3083\Final\Final On: 01-Apr-2021 04:08 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

**Form:** ADVERSE EVENT REPORT

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

**Form Status:** Data Complete

**Site No:** 1047

**Site Name:** (1047) Medical Affiliated Research Center

**Subject No:** 10471318

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 04:44

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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)	[Exposure during pregnancy]	
4.	Start Date Time:	Dec/UNK/2020 UNK:UNK	
5.	Is the adverse event still ongoing?	YES	
6.	Toxicity Grade:	Not Applicable	<a href="#">Comments</a>

090177e196ae3083\Final\Final On: 01-Apr-2021 04:08 (GMT)



**Header Text:** c4591001

**Visit:** Logs - Unscheduled

**Form:** ADVERSE EVENT REPORT

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

**Form Status:** Data Complete

**Site No:** 1047

**Site Name:** (1047) Medical Affiliated Research Center

**Subject No:** 10471318

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 04:44

7.	Is the adverse event serious?  If Yes, NOTIFY PFIZER IMMEDIATELY.  Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).	NO
8.	Is this adverse event the result of a study Medication Error? If Yes, record the type of medication error on the Medication Error Log.	NO
9.	Is this event related to study treatment:	NOT RELATED If Not Related to study treatment(s), this event is due to: OTHER If Other, specify: [pregnancy]
10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE

090177e196ae3083\Final\Final On: 01-Apr-2021 04:08 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

**Form:** ADVERSE EVENT REPORT

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

**Form Status:** Data Complete

**Site No:** 1047

**Site Name:** (1047) Medical Affiliated Research Center

**Subject No:** 10471318

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 04:44

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

090177e196ae3083\Final\Final On: 01-Apr-2021 04:08 (GMT)

**Header Text:** c4591001

**Visit:** Logs

**Form:** MEDICATION ERROR

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

**Site No:** 1047

**Site Name:** (1047) Medical Affiliated Research Center

**Subject No:** 10471318

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 04:44

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

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

**Form:** MEDICATION ERROR

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

**Form Status:** Not Started

**Site No:** 1047

**Site Name:** (1047) Medical Affiliated Research Center

**Subject No:** 10471318

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 04:44

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**Medication Error**

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

090177e196ae3083\Final\Final On: 01-Apr-2021 04:08 (GMT)

**Header Text:** c4591001

**Visit:** Logs

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

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

**Site No:** 1047

**Site Name:** (1047) Medical Affiliated Research Center

**Subject No:** 10471318

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 04:44

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

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

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

**Form Status:** Not Started

**Site No:** 1047

**Site Name:** (1047) Medical Affiliated Research Center

**Subject No:** 10471318

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 04:44

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**Concomitant Medications**

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

090177e196ae3083\Final\Final On: 01-Apr-2021 04:08 (GMT)

**Header Text:** c4591001

**Visit:** Logs

**Form:** CONCOMITANT MEDICATIONS - PROHIBITED

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

**Site No:** 1047

**Site Name:** (1047) Medical Affiliated Research Center

**Subject No:** 10471318

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 04:44

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

090177e196ae3083\Final\Final On: 01-Apr-2021 04:08 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

**Form:** CONCOMITANT MEDICATIONS - PROHIBITED

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

**Form Status:** Not Started

**Site No:** 1047

**Site Name:** (1047) Medical Affiliated Research Center

**Subject No:** 10471318

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 04:44

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**Concomitant Medications**

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

090177e196ae3083\Final\Final On: 01-Apr-2021 04:08 (GMT)



**Header Text:** c4591001

**Visit:** Logs

**Form:** RADIATION TREATMENT

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

**Site No:** 1047

**Site Name:** (1047) Medical Affiliated Research Center

**Subject No:** 10471318

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 04:44

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

090177e196ae3083\Final\Final On: 01-Apr-2021 04:08 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

**Form:** RADIATION TREATMENT

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

**Form Status:** Not Started

**Site No:** 1047

**Site Name:** (1047) Medical Affiliated Research Center

**Subject No:** 10471318

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 04:44

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**Radiation Treatment**

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

**Header Text:** c4591001

**Visit:** Logs

**Form:** TRANSFUSIONS

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

**Site No:** 1047

**Site Name:** (1047) Medical Affiliated Research Center

**Subject No:** 10471318

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 04:44

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

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

**Form:** TRANSFUSIONS

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

**Form Status:** Not Started

**Site No:** 1047

**Site Name:** (1047) Medical Affiliated Research Center

**Subject No:** 10471318

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 04:44

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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:** 1047 **Site Name:** (1047) Medical Affiliated Research Center

**Subject No:** 10471318 **Subject Initials:** ---

**Generated By:** (b) (4) **Generated Time (GMT):** 29-Mar-2021 04:44

**Date of Visit**

1.	Date of Visit	//
2.	Erroneous Visit	

**Header Text:** c4591001

**Visit:** Unplanned - New Unscheduled Visit    **Form:** UNPLANNED VISIT

**Form Version:** 22-Apr-2020 21:04    **Form Status:** Not Started

**Site No:** 1047    **Site Name:** (1047) Medical Affiliated Research Center

**Subject No:** 10471318    **Subject Initials:** ---

**Generated By:** (b) (4)    **Generated Time (GMT):** 29-Mar-2021 04:44

**Unplanned Assessments**

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

**Header Text:** c4591001

**Visit:** Unplanned Vaccination -  
Unscheduled

**Form:** DATE OF VISIT

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

**Form Status:** Not Started

**Site No:** 1047

**Site Name:** (1047) Medical Affiliated Research Center

**Subject No:** 10471318

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 04:44

**Date of Visit**

1.	Date of Visit	//
2.	Erroneous Visit	

**Header Text:** c4591001

**Visit:** Unplanned Vaccination -  
Unscheduled

**Form:** VITAL SIGNS - TEMP

**Form Version:** 20-Feb-2021 02:16

**Form Status:** Not Started

**Site No:** 1047

**Site Name:** (1047) Medical Affiliated Research Center

**Subject No:** 10471318

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 04:44

**Vital Signs**

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

**Vital Signs Details**

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



**Header Text:** c4591001

**Visit:** Unplanned Vaccination -  
Unscheduled

**Form:** LAB URINALYSIS - PREGNANCY TEST

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

**Form Status:** Not Started

**Site No:** 1047

**Site Name:** (1047) Medical Affiliated Research Center

**Subject No:** 10471318

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 04:44

**Lab Urinalysis**

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

**Lab Result**

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

090177e196ae3083\Final\Final On: 01-Apr-2021 04:08 (GMT)

**Header Text:** c4591001

**Visit:** Unplanned Vaccination -  
Unscheduled

**Form:** VACCINATION

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

**Form Status:** Not Started

**Site No:** 1047

**Site Name:** (1047) Medical Affiliated Research Center

**Subject No:** 10471318

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 04:44

**Vaccination**

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

090177e196ae3083\Final\Final On: 01-Apr-2021 04:08 (GMT)

**Header Text:** c4591001

**Visit:** Unplanned Vaccination -  
Unscheduled

**Form:** CONTACT OUTCOME - MONTH 1

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

**Form Status:** Not Started

**Site No:** 1047

**Site Name:** (1047) Medical Affiliated Research Center

**Subject No:** 10471318

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 04:44

**Contact Outcome**

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

**Header Text:** c4591001

**Visit:** Unplanned Vaccination -  
Unscheduled

**Form:** CONTACT OUTCOME - MONTH 6

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

**Form Status:** Not Started

**Site No:** 1047

**Site Name:** (1047) Medical Affiliated Research Center

**Subject No:** 10471318

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 04:44

**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:** 1047

**Site Name:** (1047) Medical Affiliated Research Center

**Subject No:** 10471318

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 04:44

**Date of Visit**

1.	Date of Visit	//
2.	Erroneous Visit	

**Header Text:** c4591001

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

**Form:** INFORMED CONSENT - ASYMPTOMATIC  
SURVEILLANCE

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

**Form Status:** Not Started

**Site No:** 1047

**Site Name:** (1047) Medical Affiliated Research Center

**Subject No:** 10471318

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 04:44

**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:** 1047

**Site Name:** (1047) Medical Affiliated Research Center

**Subject No:** 10471318

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 04:44

**Electronic Sample Tracking**

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

**Aliquot**

Please enter barcode for each aliquot.

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

090177e196ae3083\Final\Final On: 01-Apr-2021 04:08 (GMT)

**Header Text:** c4591001

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

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

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

**Form Status:** Not Started

**Site No:** 1047

**Site Name:** (1047) Medical Affiliated Research Center

**Subject No:** 10471318

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 04:44

**Electronic Sample Tracking**

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

**Aliquot**

Please enter barcode for each aliquot.

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

090177e196ae3083\Final\Final On: 01-Apr-2021 04:08 (GMT)



**Header Text:** c4591001

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

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

**Site No:** 1047

**Site Name:** (1047) Medical Affiliated Research Center

**Subject No:** 10471318

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 04:44

[eCRF Audit Trail History](#)

**Disposition - Treatment**

1.	Date of Completion/Discontinuation/Death :	Nov/30/2020
2.	Phase of Disposition:	VACCINATION
3.	Status:	COMPLETED
4.	Specify Status:	[ ]

**Header Text:** c4591001

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

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

**Site No:** 1047      **Site Name:** (1047) Medical Affiliated Research Center

**Subject No:** 10471318      **Subject Initials:** ---

**Generated By:** (b) (4)      **Generated Time (GMT):** 29-Mar-2021 04:44

[eCRF Audit Trail History](#)

Date of Visit		
1.	Date of Visit	Feb/5/2021
2.	Erroneous Visit	

**Header Text:** c4591001

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

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

**Site No:** 1047      **Site Name:** (1047) Medical Affiliated Research Center

**Subject No:** 10471318      **Subject Initials:** ---

**Generated By:** (b) (4)      **Generated Time (GMT):** 29-Mar-2021 04:44

[eCRF Audit Trail History](#)

**Further Vaccination Confirmation**

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

**Header Text:** c4591001

**Visit:** Follow-Up - Unscheduled

**Form:** DISPOSITION - FOLLOW-UP

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

**Form Status:** Not Started

**Site No:** 1047

**Site Name:** (1047) Medical Affiliated Research Center

**Subject No:** 10471318

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 04:44

**Disposition - Follow-Up**

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

**Header Text:** c4591001

**Visit:** Disposition - Unscheduled

**Form:** TREATMENT UNBLINDED

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

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

**Site No:** 1047

**Site Name:** (1047) Medical Affiliated Research Center

**Subject No:** 10471318

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 04:44

[eCRF Audit Trail History](#)

**Treatment Unblinded**

1.	Date Treatment Unblinded :	Feb/5/2021
2.	Primary Reason for Unblinding:	ASSESS ELIGIBILITY FOR ADDITIONAL VACCINATION

**Header Text:** c4591001

**Visit:** Disposition - Unscheduled

**Form:** WITHDRAWAL OF CONSENT

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

**Form Status:** Not Started

**Site No:** 1047

**Site Name:** (1047) Medical Affiliated Research Center

**Subject No:** 10471318

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 04:44

**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:** 1047

**Site Name:** (1047) Medical Affiliated Research Center

**Subject No:** 10471318

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 04:44

**Death Details**

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

**Cause of Death**

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

**Header Text:** c4591001

**Visit:** Subject Status - Unscheduled

**Form:** SUBJECT STATUS

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

**Form Status:** Data Complete, Verified

**Site No:** 1047

**Site Name:** (1047) Medical Affiliated Research Center

**Subject No:** 10471318

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 04:44

[eCRF Audit Trail History](#)

**Subject Status**

1.	Subject Status	FOLLOW-UP
2.	Subject Status Date	Nov/30/2020



**Header Text:** c4591001

**Visit:** Investigator Signature -  
Unscheduled

**Form:** CASEBOOK SIGNATURE FORM

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

**Form Status:** Data Complete, Verified

**Site No:** 1047

**Site Name:** (1047) Medical Affiliated Research Center

**Subject No:** 10471318

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 04:44

[eCRF Audit Trail History](#)

**Casebook Signature Form**

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

**Header Text:** c4591001

**Visit:** Investigator Signature -  
Unscheduled

**Form:** CASEBOOK SIGNATURE FORM

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

**Form Status:** Data Complete, Verified

**Site No:** 1047

**Site Name:** (1047) Medical Affiliated Research Center

**Subject No:** 10471318

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 04:44

[Audit Trail](#)

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

- CRF\_Sign
- CRF\_Sign\_1

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

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

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

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

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

**Site No:** 1047

**Site Name:** (1047) Medical Affiliated Research Center

**Subject No:** 10471318

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 04:44

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Item	Date	User	Comment
Form	Oct-14-2020 10:42:35 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

**Form:** ADVERSE EVENT REPORT - Comments

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

**Form Status:** Data Complete

**Site No:** 1047

**Site Name:** (1047) Medical Affiliated Research Center

**Subject No:** 10471318

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 04:44

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Item	Date	User	Comment
6	Feb-18-2021 16:30:01 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Pregnancy not an Adverse event <hr/> Not Applicable

**Header Text:** c4591001

**Visit:** Investigator Signature -  
Unscheduled

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

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

**Form Status:** Data Complete, Verified

**Site No:** 1047

**Site Name:** (1047) Medical Affiliated Research Center

**Subject No:** 10471318

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 04:44

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

- CRF\_Sign
- CRF\_Sign\_1

Name	Signature Meaning	Date	Type	Action
(b) (6) (b) (6)	N/A	Feb-11-2021 14:02:51 (UTC-06:00) Central Time (US & Canada)		Edit - All signatures invalidated

**Affidavit:**

N/A

(b) (6) (b) (6)	Approved	Jan-21-2021 09:29:33 (UTC-06:00) Central Time (US & Canada)	BOOK	Signed
--------------------	----------	--	------	--------

**Affidavit:**

By my dated signature below, I, (b) (6) 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.

090177e196ae3083\Final\Final On: 01-Apr-2021 04:08 (GMT)

**Header Text:** c4591001

**Visit:** COHORT\_SELECTION

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

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

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

**Site No:** 1047

**Site Name:** (1047) Medical Affiliated Research Center

**Subject No:** 10471318

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 04:44

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*1. Select appropriate response - Protocol version*

Date	Location	User	Value	Reason
Oct-14-2020 10:41:55 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 06 OCT 2020	Initial Entry

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

Date	Location	User	Value	Reason
Oct-14-2020 10:41:55 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> STAGE 3 COHORT S	Initial Entry

**Header Text:** c4591001

**Visit:** COHORT\_SELECTION

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

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

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

**Site No:** 1047

**Site Name:** (1047) Medical Affiliated Research Center

**Subject No:** 10471318

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 04:44

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**1. Consent Was:**

Date	Location	User	Value	Reason
Oct-14-2020 10:42:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> OBTAINED Date Written Cons ent Obtained  Oct/14/2020	Initial Entry

090177e196ae3083\Final\Final On: 01-Apr-2021 04:08 (GMT)

**Header Text:** c4591001

**Visit:** COHORT\_SELECTION

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

**Site No:** 1047

**Subject No:** 10471318

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

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

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

**Site Name:** (1047) Medical Affiliated Research Center

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:44

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**1. Subject ID**

Date	Location	User	Value	Reason
Oct-14-2020 10:41:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 10471318	Item copied from previous form

**2. Birth Date:**

Date	Location	User	Value	Reason
Oct-14-2020 10:41:46 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> (b) (6) /1991	Enrollment Entry

**3. Sex:**

Date	Location	User	Value	Reason
Oct-14-2020 10:42:17 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> FEMALE	Initial Entry

**4. Ethnicity:**

Date	Location	User	Value	Reason
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090177e196ae3083\Final\Final On: 01-Apr-2021 04:08 (GMT)



**Header Text:** c4591001

**Visit:** COHORT\_SELECTION

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

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

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

**Site No:** 1047

**Site Name:** (1047) Medical Affiliated Research Center

**Subject No:** 10471318

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 04:44

Oct-14-2020 10:42:17 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NOT HISPANIC O R LATINO(A) OR OF SPANISH ORIG IN	Initial Entry
---	-----------------	---------------------	---	---------------

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

Date	Location	User	Value	Reason
Oct-14-2020 10:42:17 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BLACK OR AFRIC AN AMERICAN	Initial Entry

090177e196ae3083\Final\Final On: 01-Apr-2021 04:08 (GMT)

**Header Text:** c4591001

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

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

**Site No:** 1047

**Subject No:** 10471318

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

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

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

**Site Name:** (1047) Medical Affiliated Research Center

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:44

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*1. Date of Visit*

Date	Location	User	Value	Reason
Oct-14-2020 10:42:27 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Oct/14/2020	Initial Entry

090177e196ae3083\Final\Final On: 01-Apr-2021 04:08 (GMT)

**Header Text:** c4591001

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

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

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

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

**Site No:** 1047

**Site Name:** (1047) Medical Affiliated Research Center

**Subject No:** 10471318

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 04:44

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

Date	Location	User	Value	Reason
Oct-14-2020 10:42:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Oct/14/2020	Initial Entry

**2. Phase of Disposition:**

Date	Location	User	Value	Reason
Oct-14-2020 10:42:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SCREENING	Initial Entry

**3. Status:**

Date	Location	User	Value	Reason
Oct-14-2020 10:42:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> COMPLETED	Initial Entry

090177e196ae3083\Final\Final On: 01-Apr-2021 04:08 (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, Frozen, Verified**Site No:** 1047**Site Name:** (1047) Medical Affiliated Research Center**Subject No:** 10471318**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 04:44[Back to Form](#)*1.a*

Date	Location	User	Value	Reason
Oct-14-2020 12:09:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Line/MH</b> 1 <b>Number:</b> <b>Medical H</b> c section <b>istory Ter</b> <b>m:</b> <b>Start Date</b> UNK/UN <b>:</b> K/2009 <b>Ongoing:</b> NO <b>End Date</b> <b>:</b>  UNK/U NK/200 9	Initial Entry

*1.a Line/MH Number:*

Date	Location	User	Value	Reason
Oct-14-2020 12:09:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 1	Initial Entry

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

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, Frozen, Verified

Site No: 1047

Site Name: (1047) Medical Affiliated Research Center

Subject No: 10471318

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

Date	Location	User	Value	Reason
Oct-14-2020 12:09:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> c section	Initial Entry

**1.a Start Date:**

Date	Location	User	Value	Reason
Oct-14-2020 12:09:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> UNK/UNK/2009	Initial Entry

**1.a Ongoing:**

Date	Location	User	Value	Reason
Oct-14-2020 12:09:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO End Date:  UNK/UNK/2009	Initial Entry

**1.b**

Date	Location	User	Value	Reason
Oct-14-2020 12:09:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Line/MH</b> 2 <b>Number:</b>	Initial Entry

090177e196ae3083\Final\Final On: 01-Apr-2021 04:08 (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, Frozen, Verified

**Site No:** 1047

**Site Name:** (1047) Medical Affiliated Research Center

**Subject No:** 10471318

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 04:44

& Canada)			<b>Medical History Term:</b> <b>Start Date:</b> UNK/UNK/2010 <b>Ongoing:</b> NO <b>End Date:</b> UNK/UNK/2010	
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090177e196ae3083\Final\Final On: 01-Apr-2021 04:08 (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, Frozen, Verified

**Site No:** 1047

**Site Name:** (1047) Medical Affiliated Research Center

**Subject No:** 10471318

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 04:44

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

Date	Location	User	Value	Reason
Oct-14-2020 12:09:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 2	Initial Entry

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

Date	Location	User	Value	Reason
Oct-14-2020 12:09:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> c section	Initial Entry

**1.b Start Date:**

Date	Location	User	Value	Reason
Oct-14-2020 12:09:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> UNK/UNK/2010	Initial Entry

**1.b Ongoing:**

Date	Location	User	Value	Reason
Oct-14-2020 12:09:59	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

090177e196ae3083\Final\Final On: 01-Apr-2021 04:08 (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, Frozen, Verified

**Site No:** 1047

**Site Name:** (1047) Medical Affiliated Research Center

**Subject No:** 10471318

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 04:44

(UTC-06:00) Central Time (US & Canada)		(b) (4), (b) (6)	End Date:  UNK/UNK/2010	
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**Header Text:** c4591001

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

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

**Site No:** 1047

**Subject No:** 10471318

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

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

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

**Site Name:** (1047) Medical Affiliated Research Center

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:44

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

Date	Location	User	Value	Reason
Oct-14-2020 12:09:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> The subject is NOT known to be HIV P OSITIVE	Initial Entry

**Header Text:** c4591001

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

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

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

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

**Site No:** 1047

**Site Name:** (1047) Medical Affiliated Research Center

**Subject No:** 10471318

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 04:44

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**1. Date:**

Date	Location	User	Value	Reason
Oct-14-2020 12:08:55 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Oct/14/2020	Initial Entry

**2. Weight:**

Date	Location	User	Value	Reason
Oct-14-2020 12:08:55 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 240.0	Initial Entry

**3. Unit:**

Date	Location	User	Value	Reason
Oct-14-2020 12:08:55 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> LB	Initial Entry

**4. Height:**

Date	Location	User	Value	Reason
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090177e196ae3083\Final\Final On: 01-Apr-2021 04:08 (GMT)

**Header Text:** c4591001

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

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

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

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

**Site No:** 1047

**Site Name:** (1047) Medical Affiliated Research Center

**Subject No:** 10471318

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 04:44

Oct-14-2020 12:08:55 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 72.0	Initial Entry
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**5. Unit:**

Date	Location	User	Value	Reason
Oct-14-2020 12:08:55 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> in	Initial Entry

**6. Body Mass Index:**

Date	Location	User	Value	Reason
Oct-14-2020 12:08:55 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 32.5	Initial Entry

**7.a**

Date	Location	User	Value	Reason
Oct-14-2020 12:08:55 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Record Ide 1</b> <b>ntifier::</b> <b>Temperatu 97.7</b> <b>re:</b>	Initial Entry

090177e196ae3083\Final\Final On: 01-Apr-2021 04:08 (GMT)

**Header Text:** c4591001

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

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

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

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

**Site No:** 1047

**Site Name:** (1047) Medical Affiliated Research Center

**Subject No:** 10471318

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 04:44

			<b>Temperatu F re Unit:</b> <b>Temperatu FORE re Location HEAD ::</b>	
--	--	--	--	--

**7.a Record Identifier:**

Date	Location	User	Value	Reason
Oct-14-2020 12:08:55 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 1	Initial Entry

**7.a Temperature:**

Date	Location	User	Value	Reason
Oct-14-2020 12:08:55 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 97.7	Initial Entry

**7.a Unit:**

Date	Location	User	Value	Reason
Oct-14-2020 12:08:55 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> F	Initial Entry

090177e196ae3083\Final\Final On: 01-Apr-2021 04:08 (GMT)

**Header Text:** c4591001

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

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

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

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

**Site No:** 1047

**Site Name:** (1047) Medical Affiliated Research Center

**Subject No:** 10471318

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 04:44

**7.a Temperature Location:**

Date	Location	User	Value	Reason
Oct-14-2020 12:08:55 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> FOREHEAD	Initial Entry

**Header Text:** c4591001

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

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

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

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

**Site No:** 1047

**Site Name:** (1047) Medical Affiliated Research Center

**Subject No:** 10471318

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 04:44

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**1. Lab Panel:**

Date	Location	User	Value	Reason
Oct-14-2020 12:10:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> URINALYSIS	Initial Entry

**2. Lab Sub-Panel:**

Date	Location	User	Value	Reason
Oct-14-2020 12:10:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> PREGNANCY	Initial Entry

**3. Collection Date:**

Date	Location	User	Value	Reason
Oct-14-2020 12:10:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Oct/14/2020	Initial Entry

**4. Laboratory Name and Address (Derived)**

Date	Location	User	Value	Reason
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090177e196ae3083\Final\Final On: 01-Apr-2021 04:08 (GMT)

**Header Text:** c4591001

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

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

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

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

**Site No:** 1047

**Site Name:** (1047) Medical Affiliated Research Center

**Subject No:** 10471318

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 04:44

Oct-14-2020 12:10:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> STUDY SITE	Initial Entry
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**5. Specimen Type:**

Date	Location	User	Value	Reason
Oct-14-2020 12:10:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> URINE	Initial Entry

**6.a**

Date	Location	User	Value	Reason
Oct-14-2020 12:10:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Sponsor-</b> 113 <b>Defined I</b> <b>dentifier:</b> <b>Test::</b> Choriogon adotropin Beta_PX11 3 <b>Result::</b> NEGATIV E <b>Not Done</b> <b>::</b>	Initial Entry

**6.a Sponsor ID:**

090177e196ae3083\Final\Final On: 01-Apr-2021 04:08 (GMT)

**Header Text:** c4591001

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

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

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

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

**Site No:** 1047

**Site Name:** (1047) Medical Affiliated Research Center

**Subject No:** 10471318

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 04:44

Date	Location	User	Value	Reason
Oct-14-2020 12:10:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 113	Initial Entry

**6.a Test:**

Date	Location	User	Value	Reason
Oct-14-2020 12:10:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Choriogonadotropin Beta_PX113	Initial Entry

**6.a Result:**

Date	Location	User	Value	Reason
Oct-14-2020 12:10:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NEGATIVE	Initial Entry

090177e196ae3083\Final\Final On: 01-Apr-2021 04:08 (GMT)



**Header Text:** c4591001

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

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

**Site No:** 1047

**Subject No:** 10471318

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

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

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

**Site Name:** (1047) Medical Affiliated Research Center

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:44

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**1. Randomization Date :**

Date	Location	User	Value	Reason
Oct-14-2020 12:08:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Oct/14/2020	Initial Entry

**2. Randomization Number:**

Date	Location	User	Value	Reason
Oct-14-2020 12:08:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 107233	Initial Entry

090177e196ae3083\Final\Final On: 01-Apr-2021 04:08 (GMT)

**Header Text:** c4591001

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

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

**Site No:** 1047

**Subject No:** 10471318

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

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

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

**Site Name:** (1047) Medical Affiliated Research Center

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:44

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**1. Data Origin**

Date	Location	User	Value	Reason
Oct-14-2020 15:36:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SITE	Initial Entry

**2. Sample Type**

Date	Location	User	Value	Reason
Oct-14-2020 15:36:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SERUM	Initial Entry

**3. Sample Collected?**

Date	Location	User	Value	Reason
Oct-14-2020 15:36:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Oct-14-2020 15:36:34 (UTC-06:00)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however

090177e196ae3083\Final\Final On: 01-Apr-2021 04:08 (GMT)

**Header Text:** c4591001

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

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

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

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

**Site No:** 1047

**Site Name:** (1047) Medical Affiliated Research Center

**Subject No:** 10471318

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 04:44

Central Time (US & Canada)				no barcodes are entered. Please review and correct as appropriate.
Oct-14-2020 15:36:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES Date of Collection:  Oct/14/2020	Initial Entry

**5.a**

Date	Location	User	Value	Reason
Oct-14-2020 15:36:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample I</b> BR8FN <b>D:</b> F	Initial Entry

**5.a Sample ID**

Date	Location	User	Value	Reason
Oct-14-2020 15:36:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BR8FNF	Initial Entry

**5.b**

090177e196ae3083\Final\Final On: 01-Apr-2021 04:08 (GMT)

**Header Text:** c4591001

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

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

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

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

**Site No:** 1047

**Site Name:** (1047) Medical Affiliated Research Center

**Subject No:** 10471318

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 04:44

Date	Location	User	Value	Reason
Oct-14-2020 15:36:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample I</b> BR8FN <b>D:</b> G	Initial Entry

**5.b Sample ID**

Date	Location	User	Value	Reason
Oct-14-2020 15:36:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BR8FNG	Initial Entry

**5.c**

Date	Location	User	Value	Reason
Oct-14-2020 15:37:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample I</b> BR8FN <b>D:</b> H	Initial Entry

090177e196ae3083\Final\Final On: 01-Apr-2021 04:08 (GMT)

**Header Text:** c4591001

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

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

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

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

**Site No:** 1047

**Site Name:** (1047) Medical Affiliated Research Center

**Subject No:** 10471318

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 04:44

**5.c Sample ID**

Date	Location	User	Value	Reason
Oct-14-2020 15:37:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BR8FNH	Initial Entry

**5.d**

Date	Location	User	Value	Reason
Oct-14-2020 15:37:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sample I BSHN D: W1	Initial Entry

**5.d Sample ID**

Date	Location	User	Value	Reason
Oct-14-2020 15:37:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BSHNW1	Initial Entry

090177e196ae3083\Final\Final On: 01-Apr-2021 04:08 (GMT)

**Header Text:** c4591001

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

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

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

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

**Site No:** 1047

**Site Name:** (1047) Medical Affiliated Research Center

**Subject No:** 10471318

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 04:44

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**1. Data Origin**

Date	Location	User	Value	Reason
Oct-14-2020 11:32:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SITE	Initial Entry

**2. Sample Type**

Date	Location	User	Value	Reason
Oct-14-2020 11:32:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> NASAL_SWAB	Initial Entry

**3. Sample Collected?**

Date	Location	User	Value	Reason
Oct-14-2020 11:32:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Oct-14-2020 11:32:39 (UTC-06:00)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however

090177e196ae3083\Final\Final On: 01-Apr-2021 04:08 (GMT)

**Header Text:** c4591001

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

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

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

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

**Site No:** 1047

**Site Name:** (1047) Medical Affiliated Research Center

**Subject No:** 10471318

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 04:44

Central Time (US & Canada)				no barcodes are entered. Please review and correct as appropriate.
Oct-14-2020 11:32:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	<b>Data Entry:</b> YES Date of Collection : Oct/14/2020	Initial Entry

**5.a**

Date	Location	User	Value	Reason
Oct-14-2020 11:32:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample I</b> BR8FM <b>D:</b> W	Initial Entry

**5.a Sample ID**

Date	Location	User	Value	Reason
Oct-14-2020 11:32:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	<b>Data Entry:</b> BR8FMW	Initial Entry

090177e196ae3083\Final\Final On: 01-Apr-2021 04:08 (GMT)

**Header Text:** c4591001

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

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

**Site No:** 1047

**Subject No:** 10471318

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

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

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

**Site Name:** (1047) Medical Affiliated Research Center

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:44

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

Date	Location	User	Value	Reason
Oct-14-2020 12:07:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**2. Treatment Name**

Date	Location	User	Value	Reason
Oct-14-2020 12:07:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> BLINDED THERAPY	Initial Entry

**3. Formulation:**

Date	Location	User	Value	Reason
Oct-14-2020 12:07:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> INJECTION	Initial Entry

**4. Dose Date Time:**

Date	Location	User	Value	Reason
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090177e196ae3083\Final\Final On: 01-Apr-2021 04:08 (GMT)



**Header Text:** c4591001

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

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

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

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

**Site No:** 1047

**Site Name:** (1047) Medical Affiliated Research Center

**Subject No:** 10471318

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 04:44

Oct-14-2020 12:07:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Oct/14/2020 10:42	Initial Entry
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**5. Anatomical Location:**

Date	Location	User	Value	Reason
Oct-14-2020 12:07:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> DELTOID MUSCLE	Initial Entry

**6. Body Side:**

Date	Location	User	Value	Reason
Oct-14-2020 12:07:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> LEFT	Initial Entry

**7. Route:**

Date	Location	User	Value	Reason
Oct-14-2020 12:07:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> INTRAMUSCULAR	Initial Entry

090177e196ae3083\Final\Final On: 01-Apr-2021 04:08 (GMT)

**Header Text:** c4591001

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

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

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

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

**Site No:** 1047

**Site Name:** (1047) Medical Affiliated Research Center

**Subject No:** 10471318

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 04:44

**10. Timeframe Subject Was Observed**

Date	Location	User	Value	Reason
Oct-14-2020 12:07:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> THE PROTOCOL SPE CIFIED OBSERVATIO N PERIOD	Initial Entry

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

Date	Location	User	Value	Reason
Oct-14-2020 12:07:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

090177e196ae3083\Final\Final On: 01-Apr-2021 04:08 (GMT)

**Header Text:** c4591001

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

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

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

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

**Site No:** 1047

**Site Name:** (1047) Medical Affiliated Research Center

**Subject No:** 10471318

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 04:44

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*1. Select appropriate response - Reactogenicity diary collection*

Date	Location	User	Value	Reason
Oct-14-2020 10:42:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO - REACTOGEN ICITY E-DIARY N OT COLLECTED F OR THIS SUBJECT	Initial Entry

090177e196ae3083\Final\Final On: 01-Apr-2021 04:08 (GMT)

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1047

**Subject No:** 10471318

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

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

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

**Site Name:** (1047) Medical Affiliated Research Center

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:44

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*1. Date of Visit*

Date	Location	User	Value	Reason
Nov-02-2020 10:39:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	<b>Data Entry:</b> Nov/2/2020	Initial Entry

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1047

**Subject No:** 10471318

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

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

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

**Site Name:** (1047) Medical Affiliated Research Center

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:44

[Back to Form](#)

**1. Date:**

Date	Location	User	Value	Reason
Nov-02-2020 10:40:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	<b>Data Entry:</b> Nov/2/2020	Initial Entry

**2.a**

Date	Location	User	Value	Reason
Nov-02-2020 10:40:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	<b>Data Entry:</b> <b>Record Identifier::</b> <b>Temperature:</b> <b>Temperature Unit:</b> <b>Temperature Location::</b> HEAD	Initial Entry

**2.a Record Identifier:**

Date	Location	User	Value	Reason
Nov-02-2020 10:40:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	<b>Data Entry:</b> 1	Initial Entry

090177e196ae3083\Final\Final On: 01-Apr-2021 04:08 (GMT)

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

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

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

**Site No:** 1047

**Site Name:** (1047) Medical Affiliated Research Center

**Subject No:** 10471318

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 04:44

**2.a Temperature:**

Date	Location	User	Value	Reason
Nov-02-2020 10:40:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	<b>Data Entry:</b> 98.1	Initial Entry

**2.a Unit:**

Date	Location	User	Value	Reason
Nov-02-2020 10:40:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	<b>Data Entry:</b> F	Initial Entry

**2.a Temperature Location:**

Date	Location	User	Value	Reason
Nov-02-2020 10:40:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	<b>Data Entry:</b> FOREHEAD	Initial Entry

090177e196ae3083\Final\Final On: 01-Apr-2021 04:08 (GMT)

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

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

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

**Site No:** 1047

**Site Name:** (1047) Medical Affiliated Research Center

**Subject No:** 10471318

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 04:44

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**1. Lab Panel:**

Date	Location	User	Value	Reason
Nov-02-2020 10:40:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> URINALYSIS	Initial Entry

**2. Lab Sub-Panel:**

Date	Location	User	Value	Reason
Nov-02-2020 10:40:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> PREGNANCY	Initial Entry

**3. Collection Date:**

Date	Location	User	Value	Reason
Nov-02-2020 10:40:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	<b>Data Entry:</b> Nov/2/2020	Initial Entry

**4. Laboratory Name and Address (Derived)**

Date	Location	User	Value	Reason
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090177e196ae3083\Final\Final On: 01-Apr-2021 04:08 (GMT)

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

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

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

**Site No:** 1047

**Site Name:** (1047) Medical Affiliated Research Center

**Subject No:** 10471318

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 04:44

Nov-02-2020 10:40:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> STUDY SITE	Initial Entry
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**5. Specimen Type:**

Date	Location	User	Value	Reason
Nov-02-2020 10:40:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> URINE	Initial Entry

**6.a**

Date	Location	User	Value	Reason
Nov-02-2020 10:40:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Sponsor-</b> 113 <b>Defined I</b> <b>dentifier:</b> <b>Test::</b> Choriogon adotropin Beta_PX11 3 <b>Result::</b> NEGATIV E <b>Not Done</b> ::	Initial Entry

**6.a Sponsor ID:**

090177e196ae3083\Final\Final On: 01-Apr-2021 04:08 (GMT)



**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

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

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

**Site No:** 1047

**Site Name:** (1047) Medical Affiliated Research Center

**Subject No:** 10471318

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 04:44

Date	Location	User	Value	Reason
Nov-02-2020 10:40:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 113	Initial Entry

**6.a Test:**

Date	Location	User	Value	Reason
Nov-02-2020 10:40:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	<b>Data Entry:</b> Choriogonadotropin Beta_PX113	Initial Entry

**6.a Result:**

Date	Location	User	Value	Reason
Nov-02-2020 10:40:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	<b>Data Entry:</b> NEGATIVE	Initial Entry

090177e196ae3083\Final\Final On: 01-Apr-2021 04:08 (GMT)

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

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

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

**Site No:** 1047

**Site Name:** (1047) Medical Affiliated Research Center

**Subject No:** 10471318

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 04:44

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**1. Data Origin**

Date	Location	User	Value	Reason
Nov-02-2020 12:01:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SITE	Initial Entry

**2. Sample Type**

Date	Location	User	Value	Reason
Nov-02-2020 12:01:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> NASAL_SWAB	Initial Entry

**3. Sample Collected?**

Date	Location	User	Value	Reason
Nov-02-2020 12:01:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Nov-02-2020 12:01:35 (UTC-06:00)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however

090177e196ae3083\Final\Final On: 01-Apr-2021 04:08 (GMT)

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

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

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

**Site No:** 1047

**Site Name:** (1047) Medical Affiliated Research Center

**Subject No:** 10471318

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 04:44

Central Time (US & Canada)				no barcodes are entered. Please review and correct as appropriate.
Nov-02-2020 12:01:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	<b>Data Entry:</b> YES Date of Collection : Nov/2/2020	Initial Entry

**5.a**

Date	Location	User	Value	Reason
Nov-02-2020 12:01:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample ID</b> BR8F9 : J	Initial Entry

**5.a Sample ID**

Date	Location	User	Value	Reason
Nov-02-2020 12:01:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	<b>Data Entry:</b> BR8F9J	Initial Entry

090177e196ae3083\Final\Final On: 01-Apr-2021 04:08 (GMT)

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1047

**Subject No:** 10471318

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

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

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

**Site Name:** (1047) Medical Affiliated Research Center

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:44

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

Date	Location	User	Value	Reason
Nov-02-2020 10:40:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**2. Treatment Name**

Date	Location	User	Value	Reason
Nov-02-2020 10:40:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> BLINDED THERAPY	Initial Entry

**3. Formulation:**

Date	Location	User	Value	Reason
Nov-02-2020 10:40:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> INJECTION	Initial Entry

**4. Dose Date Time:**

Date	Location	User	Value	Reason
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090177e196ae3083\Final\Final On: 01-Apr-2021 04:08 (GMT)

Header Text: c4591001

Visit: V2\_VAX2\_L

Form: VACCINATION - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Frozen, Verified

Site No: 1047

Site Name: (1047) Medical Affiliated Research Center

Subject No: 10471318

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

Nov-02-2020 10:40:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	<b>Data Entry:</b> Nov/2/2020 09:05	Initial Entry
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**5. Anatomical Location:**

Date	Location	User	Value	Reason
Nov-02-2020 10:40:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> DELTOID MUSCLE	Initial Entry

**6. Body Side:**

Date	Location	User	Value	Reason
Nov-02-2020 10:40:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	<b>Data Entry:</b> LEFT	Initial Entry

**7. Route:**

Date	Location	User	Value	Reason
Nov-02-2020 10:40:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> INTRAMUSCULAR	Initial Entry

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**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

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

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

**Site No:** 1047

**Site Name:** (1047) Medical Affiliated Research Center

**Subject No:** 10471318

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 04:44

**10. Timeframe Subject Was Observed**

Date	Location	User	Value	Reason
Nov-02-2020 10:40:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> THE PROTOCOL SPE CIFIED OBSERVATIO N PERIOD	Initial Entry

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

Date	Location	User	Value	Reason
Nov-02-2020 10:40:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

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**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:** 1047 **Site Name:** (1047) Medical Affiliated Research Center

**Subject No:** 10471318 **Subject Initials:** ---

**Generated By:** (b) (4) **Generated Time (GMT):** 29-Mar-2021 04:44

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*1. Date of Visit*

<b>Date</b>	<b>Location</b>	<b>User</b>	<b>Value</b>	<b>Reason</b>
Nov-30-2020 08:42:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Nov/30/2020	Initial Entry

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**Header Text:** c4591001

**Visit:** V3\_MONTH1\_POSTVAX2\_L **Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF Audit Trail History

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

**Site No:** 1047 **Site Name:** (1047) Medical Affiliated Research Center

**Subject No:** 10471318 **Subject Initials:** ---

**Generated By:** (b) (4) **Generated Time (GMT):** 29-Mar-2021 04:44

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**1. Data Origin**

Date	Location	User	Value	Reason
Nov-30-2020 15:45:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SITE	Initial Entry

**2. Sample Type**

Date	Location	User	Value	Reason
Nov-30-2020 15:45:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SERUM	Initial Entry

**3. Sample Collected?**

Date	Location	User	Value	Reason
Nov-30-2020 15:45:54 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Nov-30-2020 15:45:39 (UTC-06:00)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however

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Header Text: c4591001

Visit: V3\_MONTH1\_POSTVAX2\_L Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF Audit Trail History

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

Site No: 1047 Site Name: (1047) Medical Affiliated Research Center

Subject No: 10471318 Subject Initials: ---

Generated By: (b) (4) Generated Time (GMT): 29-Mar-2021 04:44

Central Time (US & Canada)				no barcodes are entered. Please review and correct as appropriate.
Nov-30-2020 15:45:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	<b>Data Entry:</b> YES Date of Collection : Nov/30/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Nov-30-2020 15:45:54 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample ID</b> BSHP6 : 0	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Nov-30-2020 15:45:54 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	<b>Data Entry:</b> BSHP60	Initial Entry

5.b

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**Header Text:** c4591001

**Visit:** V3\_MONTH1\_POSTVAX2\_L **Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF Audit Trail History

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

**Site No:** 1047 **Site Name:** (1047) Medical Affiliated Research Center

**Subject No:** 10471318 **Subject Initials:** ---

**Generated By:** (b) (4) **Generated Time (GMT):** 29-Mar-2021 04:44

Date	Location	User	Value	Reason
Nov-30-2020 15:46:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample ID BPSY1</b> : 8	Initial Entry

**5.b Sample ID**

Date	Location	User	Value	Reason
Nov-30-2020 15:46:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	<b>Data Entry:</b> BPSY18	Initial Entry

**5.c**

Date	Location	User	Value	Reason
Nov-30-2020 15:47:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample ID BPSY1</b> : 7	Initial Entry

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**Header Text:** c4591001

**Visit:** V3\_MONTH1\_POSTVAX2\_L **Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF Audit Trail History

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

**Site No:** 1047 **Site Name:** (1047) Medical Affiliated Research Center

**Subject No:** 10471318 **Subject Initials:** ---

**Generated By:** (b) (4) **Generated Time (GMT):** 29-Mar-2021 04:44

**5.c Sample ID**

Date	Location	User	Value	Reason
Nov-30-2020 15:47:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	<b>Data Entry:</b> BPSY17	Initial Entry

**5.d**

Date	Location	User	Value	Reason
Nov-30-2020 15:47:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample ID BPSY1</b> : 6	Initial Entry

**5.d Sample ID**

Date	Location	User	Value	Reason
Nov-30-2020 15:47:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	<b>Data Entry:</b> BPSY16	Initial Entry

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**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Form Status:**

**Site No:** 1047

**Site Name:** (1047) Medical Affiliated Research Center

**Subject No:** 10471318

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 04:44

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Date	Location	User	Value	Reason
Feb-18-2021 16:29:26 (UTC-06:00) Central 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

**Site No:** 1047

**Site Name:** (1047) Medical Affiliated Research Center

**Subject No:** 10471318

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 04:44

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**1. Category:**

Date	Location	User	Value	Reason
Feb-18-2021 16:29:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> ADVERSE EVENT	Initial Entry

**2. AE ID:**

Date	Location	User	Value	Reason
Feb-18-2021 16:29:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 1	Initial Entry

**3. Adverse Event:**

*(If possible specify diagnosis, not individual symptoms)*

Date	Location	User	Value	Reason
Mar-12-2021 15:23:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Query 6: Closed	Response satisfies query
Mar-12-2021 08:56:40 (UTC-06:00)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Query 6: Answered	It was updated to Exposure during

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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:** 1047

**Site Name:** (1047) Medical Affiliated Research Center

**Subject No:** 10471318

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 04:44

Central Time (US & Canada)				pregnancy under item 10
Mar-11-2021 20:31:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Query 6: Reissued:Opened	Clinical - the 10Mar21 update did not update the event term, which is still Pregnancy. Please update event term to match AE, per CRF guidelines, as Exposure during Pregnancy.
Mar-11-2021 07:52:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Query 6: Answered	This was submitted yesterday
Mar-10-2021 20:39:02 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Query 6: Reissued:Opened	Clinical - no medical records are required for EDP term, which is already reported on AE CRF per study guidelines. Please simply submit this same updated term in a PG safety

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**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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				update ASAP
Mar-09-2021 08:16:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Query 6: Answered	working on update waiting on medical records
Mar-09-2021 07:44:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Query 4: Closed	Response satisfies query
Mar-09-2021 00:16:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Query 6: Reissued: Opened	Clinical - Please send PG safety update with EDP term ASAP
Mar-09-2021 00:15:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Query 3: Closed	Query closed; will follow for requested Partner information.
Mar-08-2021 11:35:46 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Query 4: Answered	Changed data per query
Mar-08-2021 11:35:23 (UTC-06:00) Central Time	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Query 6: Answered	working on update

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**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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**Form Status:** Data Complete

**Site No:** 1047

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**Subject Initials:** ---

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

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(US & Canada)				
Mar-08-2021 11:33:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Query 3: Answered	working on update
Mar-05-2021 09:40:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Query 5: Closed	reworded
Mar-05-2021 09:39:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Query 6: Opened	Clinical - Event term is EDP; however, PG Safety report (most recent 02Mar21) has event term Pregnancy. Please submit a PG Safety update with EDP term, per reporting guidelines
Mar-05-2021 09:37:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Query 3: Reissued: Opened	Clinical Please try to contact subject/partner for this interview before the data lock in

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**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

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**Site No:** 1047

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

**Generated Time (GMT):** 29-Mar-2021 04:44

				mid March
Mar-04-2021 17:35:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Query 4: Reissued:Opened	Clinical - start date on AE CRF is XX Nov 2020; however, SAE report start date is XX Dec 2020. Please review, harmonize reporting, and update where applicable
Mar-04-2021 17:33:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Query 5: Opened	Clinical Per most recent PG Safety report, event term is still Pregnancy. Please update event to EDP per study guidelines
Mar-04-2021 17:14:27 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Mar-04-2021 07:46:18 (UTC-06:00) Central Time	ACV0PFEINFP6000	auto query (autoquery)	Query 4: Answered	changed per query

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**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

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**Subject Initials:** ---

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**Generated Time (GMT):** 29-Mar-2021 04:44

(US & Canada)				
Mar-04-2021 07:46:18 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 3: Answered	changed per query
Mar-04-2021 07:46:18 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	changed per query
Mar-04-2021 07:46:18 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	<b>Data Entry:</b> Exposure during pregnancy	changed per query
Mar-02-2021 11:18:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Query 2: Closed	Query closed; will follow for requested date of urine PG test information.
Mar-02-2021 11:11:19 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Query 4: Opened	Clinical please try to clarify the PG event start date (XX NOV 2020) if at all possible to clarify if this occurred before / after VAX 2 on 02Nov2020

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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:** 1047

**Site Name:** (1047) Medical Affiliated Research Center

**Subject No:** 10471318

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 04:44

Mar-02-2021 11:09:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Query 3: Reissued:Opened	Clinical Please try to contact subject/partner for this interview before the data lock in mid March
Mar-02-2021 11:07:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Query 1: Reissued:Opened	Clinical - PG safety Event term is Exposure during Pregnancy; however, here the event term is still Pregnancy. Please update to EDP term per study guidelines
Feb-26-2021 14:29:17 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	updated per query
Feb-26-2021 14:29:17 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	<b>Data Entry:</b> Pregnancy	updated per query
Feb-26-2021 14:27:49 (UTC-06:00)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Query 3: Answered	will update when patient calls back and I

090177e196ae3083\Final\Final On: 01-Apr-2021 04:08 (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

**Site No:** 1047

**Site Name:** (1047) Medical Affiliated Research Center

**Subject No:** 10471318

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 04:44

Central Time (US & Canada)				can interview her
Feb-26-2021 14:27:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Query 2: Answered	trying to contact subject to get clarification on these issues will update when I have the info
Feb-19-2021 00:18:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Query 3: Opened	Clinical Please submit a PG safety update to report father info (age, meds, conditions, social hx)
Feb-19-2021 00:15:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Query 2: Opened	CLINICAL Per PG report (#2021156268), subject stated she 'just had a positive urine pregnancy test' before 11Feb21. Please submit a safety update to report the positive urine pregnancy test date. Also submit contraception method in trial

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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:** 1047

**Site Name:** (1047) Medical Affiliated Research Center

**Subject No:** 10471318

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 04:44

				& if using now
Feb-19-2021 00:12:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Query 1: Opened	Clinical - Event term is Exposure during Pregnancy; however, PG Safety report has event term Pregnancy. Please review event term, harmonize reporting, and update where required.
Feb-18-2021 16:29:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	<b>Data Entry:</b> Exposure During Pregnancy	Initial Entry

**4. Start Date Time:**

Date	Location	User	Value	Reason
Mar-08-2021 11:34:37 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	<b>Data Entry:</b> Dec/UNK/2020 U NK:UNK	Transcription Error
Mar-02-2021 11:08:11 (UTC-06:00)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Query 1: Closed	Query closed; will follow for requested OB

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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:** 1047**Site Name:** (1047) Medical Affiliated Research Center**Subject No:** 10471318**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 04:44

Central Time (US & Canada)				ultrasound information.
Feb-26-2021 14:28:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED] (b) (4), (b) (6)	Query 1: Answered	will update when I obtain the information
Feb-19-2021 00:16:46 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED] (b) (4), (b) (6)	Query 1: Opened	Clinical As subject does not recall the 1st day of last menstrual period, please submit the estimated conception date based on OB ultrasound, when available
Feb-18-2021 16:29:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED] (b) (4), (b) (6)	<b>Data Entry:</b> Nov/UNK/2020 U NK:UNK	Initial Entry

**5. Is the adverse event still ongoing?**

Date	Location	User	Value	Reason
Feb-18-2021 16:29:26 (UTC-06:00) Central Time (US	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	<b>Data Entry:</b> YES	Initial Entry

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

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

**Form Status:** Data Complete

**Site No:** 1047

**Site Name:** (1047) Medical Affiliated Research Center

**Subject No:** 10471318

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 04:44

& Canada)

**6. Toxicity Grade:**

Date	Location	User	Value	Reason
Feb-18-2021 16:30:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**7. Is the adverse event serious?**

***If Yes, NOTIFY PFIZER IMMEDIATELY.***

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

Date	Location	User	Value	Reason
Feb-18-2021 16:29:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

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

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

Date	Location	User	Value	Reason
Feb-18-2021	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	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:** 1047

**Site Name:** (1047) Medical Affiliated Research Center

**Subject No:** 10471318

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 04:44

16:29:26 (UTC-06:00) Central Time (US & Canada)		(b) (4), (b) (6)	NO	
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**9. Is this event related to study treatment:**

Date	Location	User	Value	Reason
Feb-18-2021 16:29:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NOT RELATED If Not Related to stu dy treatment(s), this event is due to:  OTHER  <i>If Other, specify:</i>  pregnancy	Initial Entry

**10. Latest Action Taken with Study Treatment:**

Date	Location	User	Value	Reason
Feb-18-2021 16:29:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NOT APPLICABLE	Initial Entry

**11. Was a Concomitant Medication given?**

Date	Location	User	Value	Reason
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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:** 1047

**Site Name:** (1047) Medical Affiliated Research Center

**Subject No:** 10471318

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 04:44

Feb-18-2021 16:29:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry
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**12. Was a Non-Drug Treatment given?**

Date	Location	User	Value	Reason
Feb-18-2021 16:29:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

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

Date	Location	User	Value	Reason
Mar-09-2021 14:15:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query

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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:** 1047

**Site Name:** (1047) Medical Affiliated Research Center

**Subject No:** 10471318

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 04:44

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

Date	Location	User	Value	Reason
Mar-09-2021 13:40:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Closed	UNKNOWN is correctly reported per CRF completion GLs - no further queries should be issued. Thank you!
Mar-09-2021 08:16:02 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Answered	This was changed to unknown per query instructions the pregnancy is still ongoing.
Mar-09-2021 08:13:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Opened	For AE Exposure during pregnancy: Response to "What was the outcome of this adverse event?" is 'Unknown' but End Date/Time is provided or "Is the adverse event still ongoing?" is marked "Yes".
Mar-09-2021 08:13:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	updated per query

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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: 1047

Site Name: (1047) Medical Affiliated Research Center

Subject No: 10471318

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

Mar-09-2021 08:13:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> UNKNOWN	updated per query
Mar-08-2021 22:28:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	SAE RECON: AER#2021156268, the outcome in AE CRF was reported as NOT RECOVERED/NOT RESOLVED. Per 3 Nov EDP guidance , outcome should be recorded as UNKNOWN. Please confirm and update accordingly.
Feb-18-2021 16:29:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NOT RECOVERED/NOT RESOLVED	Initial Entry

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

Date	Location	User	Value	Reason
Feb-18-2021 16:29:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

090177e196ae3083\Final\Final On: 01-Apr-2021 04:08 (GMT)

**Header Text:** c4591001

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

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

**Site No:** 1047 **Site Name:** (1047) Medical Affiliated Research Center

**Subject No:** 10471318 **Subject Initials:** ---

**Generated By:** (b) (4) **Generated Time (GMT):** 29-Mar-2021 04:44

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

Date	Location	User	Value	Reason
Nov-30-2020 08:42:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Nov/30/2020	Initial Entry

**2. Phase of Disposition:**

Date	Location	User	Value	Reason
Nov-30-2020 08:42:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> VACCINATION	Initial Entry

**3. Status:**

Date	Location	User	Value	Reason
Nov-30-2020 08:42:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> COMPLETED	Initial Entry

090177e196ae3083\Final\Final On: 01-Apr-2021 04:08 (GMT)

**Header Text:** c4591001

**Visit:** Potential ReVax Initial Contact - **Form:** DATE OF VISIT - eCRF Audit Trail History  
Unscheduled

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

**Site No:** 1047      **Site Name:** (1047) Medical Affiliated Research Center

**Subject No:** 10471318      **Subject Initials:** ---

**Generated By:** (b) (4)      **Generated Time (GMT):** 29-Mar-2021 04:44

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*1. Date of Visit*

Date	Location	User	Value	Reason
Feb-11-2021 14:02:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Feb/5/2021	Initial Entry

090177e196ae3083\Final\Final On: 01-Apr-2021 04:08 (GMT)

**Header Text:** c4591001

**Visit:** Potential ReVax Initial Contact - **Form:** FURTHER VACCINATION CONFIRMATION -  
Unscheduled eCRF Audit Trail History

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

**Site No:** 1047 **Site Name:** (1047) Medical Affiliated Research Center

**Subject No:** 10471318 **Subject Initials:** ---

**Generated By:** (b) (4) **Generated Time (GMT):** 29-Mar-2021 04:44

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

Date	Location	User	Value	Reason
Feb-11-2021 14:03:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Feb-11-2021 14:02:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidat e	The response indicates participant was unblinded, however the TREATMENT UNBLINDED date is missing in the DISP visit. Please complete this date.
Feb-11-2021 14:02:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Participant is willi ng to return for Va ccination 3 Participant is:  eligible per oth er protocol allo wance(s) and c onfirmed to ha	Initial Entry

090177e196ae3083\Final\Final On: 01-Apr-2021 04:08 (GMT)

**Header Text:** c4591001

**Visit:** Potential ReVax Initial Contact - **Form:** FURTHER VACCINATION CONFIRMATION -  
Unscheduled eCRF Audit Trail History

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

**Site No:** 1047 **Site Name:** (1047) Medical Affiliated Research Center

**Subject No:** 10471318 **Subject Initials:** ---

**Generated By:** (b) (4) **Generated Time (GMT):** 29-Mar-2021 04:44

			ve received onl y placebo at Va ccination 1/2	
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**Header Text:** c4591001

**Visit:** Disposition - Unscheduled

**Form:** TREATMENT UNBLINDED - eCRF Audit Trail History

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

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

**Site No:** 1047

**Site Name:** (1047) Medical Affiliated Research Center

**Subject No:** 10471318

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 04:44

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**1. Date Treatment Unblinded :**

Date	Location	User	Value	Reason
Feb-11-2021 14:03:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Feb/5/2021	Initial Entry

**2. Primary Reason for Unblinding:**

Date	Location	User	Value	Reason
Feb-11-2021 14:03:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> ASSESS ELIGIBILI TY FOR ADDITIO NAL VACCINATIO N	Initial Entry



**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:** 1047

**Site Name:** (1047) Medical Affiliated Research Center

**Subject No:** 10471318

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 04:44

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**1. Subject Status**

Date	Location	User	Value	Reason
Nov-30-2020 08:42:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> FOLLOW-UP	Initial Entry
Oct-14-2020 12:08:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> ENROLLED/RANDOMIZED	Initial Entry
Oct-14-2020 10:42:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SCREENED	Initial Entry

**2. Subject Status Date**

Date	Location	User	Value	Reason
Nov-30-2020 08:42:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> Nov/30/2020	Initial Entry
Oct-14-2020 12:08:13	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> Oct/14/2020	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:** 1047

**Site Name:** (1047) Medical Affiliated Research Center

**Subject No:** 10471318

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 04:44

(UTC-06:00) Central Time (US & Canada)				
Oct-14-2020 10:42:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> Oct/14/2020	Initial Entry

**Header Text:** c4591001

**Visit:** Investigator Signature -  
Unscheduled

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

**Site No:** 1047

**Subject No:** 10471318

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

**Form:** CASEBOOK SIGNATURE FORM - eCRF Audit  
Trail History

**Form Status:** Data Complete, Verified

**Site Name:** (1047) Medical Affiliated Research Center

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:44

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*1. Casebook Signature*

Date	Location	User	Value	Reason
Jan-21-2021 09:28:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Click Here to Enabl e	Initial Entry

090177e196ae3083\Final\Final On: 01-Apr-2021 04:08 (GMT)