

**Header Text:** c4591001

**Visit:** COHORT\_SELECTION

**Form:** COHORT\_SELECTION

**Form Version:** 30-Jul-2020 21:29

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

**Site No:** 1141

**Site Name:** (1141) University of Iowa Hospital and Clinics

**Subject No:** 11411113

**Subject Initials:** ---

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

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

[eCRF Audit Trail History](#)

**Cohort Selection**

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

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

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**Header Text:** c4591001

**Visit:** COHORT\_SELECTION

**Form:** MAIN INFORMED CONSENT

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

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

**Site No:** 1141

**Site Name:** (1141) University of Iowa Hospital and Clinics

**Subject No:** 11411113

**Subject Initials:** ---

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

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

[eCRF Audit Trail History](#)

**Informed Consent**

1.	Consent Was:	OBTAINED Date Written Consent Obtained Aug/20/2020
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**Header Text:** c4591001

**Visit:** COHORT\_SELECTION

**Form:** DEMOGRAPHY

**Form Version:** 06-Jul-2020 21:55

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

**Site No:** 1141

**Site Name:** (1141) University of Iowa Hospital and Clinics

**Subject No:** 11411113

**Subject Initials:** ---

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

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

[eCRF Audit Trail History](#)

**Demography**

1.	Subject ID	[11411113]
2.	Birth Date:	(b) (6)/1992
3.	Sex:	FEMALE
4.	Ethnicity:	NOT HISPANIC OR LATINO(A) OR OF SPANISH ORIGIN
5.	Race: (Check X all that apply):	WHITE
6.	Racial Designation:	

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**Header Text:** c4591001

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

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

**Site No:** 1141

**Subject No:** 11411113

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

**Form:** DATE OF VISIT

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

**Site Name:** (1141) University of Iowa Hospital and Clinics

**Subject Initials:** ---

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

[eCRF Audit Trail History](#)

**Date of Visit**

1.	Date of Visit	Aug/20/2020
2.	Erroneous Visit	

**Header Text:** c4591001

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

**Form Version:** 30-Jul-2020 21:29

**Site No:** 1141

**Subject No:** 11411113

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

**Form:** INCLUSION/EXCLUSION CRITERIA

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

**Site Name:** (1141) University of Iowa Hospital and Clinics

**Subject Initials:** ---

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

**Form Comments**

**Inclusion Criteria Not Met**

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

**Exclusion Criteria Met**

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

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

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

**Site No:** 1141

**Subject No:** 11411113

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

**Form:** DISPOSITION - SCREENING

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

**Site Name:** (1141) University of Iowa Hospital and Clinics

**Subject Initials:** ---

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

[eCRF Audit Trail History](#)

**Disposition - Screening**

1.	Date of Completion/Discontinuation/Death	Aug/20/2020
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:** 1141

**Subject No:** 11411113

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

**Form:** GENERAL MEDICAL HISTORY

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

**Site Name:** (1141) University of Iowa Hospital and Clinics

**Subject Initials:** ---

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

[eCRF Audit Trail History](#)

**Medical History Details**

1.a	Line/MH Number:	[1]
	Disease/Syndrome /Surgery/Non-Drug Allergies/Drug Allergies:	[Headaches]
	Start Date:	UNK/UNK/2010
	Ongoing:	YES

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**Header Text:** c4591001

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

**Form:** VITAL SIGNS - BASELINE

**Form Version:** 30-Jul-2020 21:28

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

**Site No:** 1141

**Site Name:** (1141) University of Iowa Hospital and Clinics

**Subject No:** 11411113

**Subject Initials:** ---

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

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

[eCRF Audit Trail History](#)

**Vital Signs**

1.	Date:	Aug/20/2020
2.	Weight:	[85.4]
3.	Unit:	kg
4.	Height:	[170.0]
5.	Unit:	cm
6.	Body Mass Index:	[29.6]

**Vital Signs Details**

7.a	Record Identifier:	1
	Temperature:	[98.4]
	Unit:	F
	Temperature Location:	ORAL CAVITY

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**Header Text:** c4591001

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

**Form Version:** 30-Jul-2020 21:27

**Site No:** 1141

**Subject No:** 11411113

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

**Form:** LAB URINALYSIS - PREGNANCY TEST

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

**Site Name:** (1141) University of Iowa Hospital and Clinics

**Subject Initials:** ---

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

[eCRF Audit Trail History](#)

**Lab Urinalysis**

1.	Lab Panel:	URINALYSIS
2.	Lab Sub-Panel:	PREGNANCY
3.	Collection Date:	Aug/20/2020
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:	

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**Header Text:** c4591001

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

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

**Site No:** 1141

**Subject No:** 11411113

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

**Form:** RANDOMIZATION

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

**Site Name:** (1141) University of Iowa Hospital and Clinics

**Subject Initials:** ---

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

[eCRF Audit Trail History](#)

**Disposition**

1.	Randomization Date :	Aug/20/2020
2.	Randomization Number:	[59610]
3.	Randomization Group:	[ ]

**Header Text:** c4591001

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

**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

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

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

**Site No:** 1141

**Site Name:** (1141) University of Iowa Hospital and Clinics

**Subject No:** 11411113

**Subject Initials:** ---

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

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

[eCRF Audit Trail History](#)

**Electronic Sample Tracking**

1.	Data Origin	SITE
2.	Sample Type	SERUM
3.	Sample Collected?	YES Date of Collection: Aug/20/2020
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	[BM88LS]
5.b	Sample ID	[BM88LT]
5.c	Sample ID	[BM88LV]
5.d	Sample ID	[BLC994]
5.e	Sample ID	[BLC995]

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**Header Text:** c4591001**Visit:** V1\_DAY1\_VAX1\_L**Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB**Form Version:** 22-Apr-2020 21:03**Form Status:** Data Complete, Locked, Frozen, Verified**Site No:** 1141**Site Name:** (1141) University of Iowa Hospital and Clinics**Subject No:** 11411113**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 11:44[eCRF Audit Trail History](#)**Electronic Sample Tracking**

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Aug/20/2020
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	[BM88LM]
-----	-----------	----------

**Header Text:** c4591001

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

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

**Site No:** 1141

**Subject No:** 11411113

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

**Form:** VACCINATION

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

**Site Name:** (1141) University of Iowa Hospital and Clinics

**Subject Initials:** ---

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

[eCRF Audit Trail History](#)

**Vaccination**

1.	Was there a temporary delay of vaccination?	NO
2.	Treatment Name	[BLINDED THERAPY]
3.	Formulation:	INJECTION
4.	Dose Date Time:	Aug/20/2020 16:43
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:** 1141

**Subject No:** 11411113

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

**Form:** REACTOGENICITY DIARY

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

**Site Name:** (1141) University of Iowa Hospital and Clinics

**Subject Initials:** ---

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

[eCRF Audit Trail History](#)

**Reactogenicity Diary**

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

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

**Form:** DATE OF VISIT

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

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

**Site No:** 1141

**Site Name:** (1141) University of Iowa Hospital and Clinics

**Subject No:** 11411113

**Subject Initials:** ---

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

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

[eCRF Audit Trail History](#)

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

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

**Form Version:** 21-Aug-2020 02:51

**Site No:** 1141

**Subject No:** 11411113

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

**Form:** VITAL SIGNS - TEMP

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

**Site Name:** (1141) University of Iowa Hospital and Clinics

**Subject Initials:** ---

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

[eCRF Audit Trail History](#)

**Vital Signs**

1.	Date:	Sep/11/2020
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**Vital Signs Details**

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

090177e196ae40c3\Final\Final On: 01-Apr-2021 05:43 (GMT)



**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

**Form Version:** 30-Jul-2020 21:27

**Site No:** 1141

**Subject No:** 11411113

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

**Form:** LAB URINALYSIS - PREGNANCY TEST

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

**Site Name:** (1141) University of Iowa Hospital and Clinics

**Subject Initials:** ---

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

[eCRF Audit Trail History](#)

**Lab Urinalysis**

1.	Lab Panel:	URINALYSIS
2.	Lab Sub-Panel:	PREGNANCY
3.	Collection Date:	Sep/11/2020
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:	

090177e196ae40c3\Final\Final On: 01-Apr-2021 05:43 (GMT)

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

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

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

**Site No:** 1141

**Site Name:** (1141) University of Iowa Hospital and Clinics

**Subject No:** 11411113

**Subject Initials:** ---

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

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

[eCRF Audit Trail History](#)

**Electronic Sample Tracking**

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Sep/11/2020
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[ ]

**Aliquot**

Please enter barcode for each aliquot.

5.a	Sample ID	[BM6HXT]
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**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

**Form:** VACCINATION

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

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

**Site No:** 1141

**Site Name:** (1141) University of Iowa Hospital and Clinics

**Subject No:** 11411113

**Subject Initials:** ---

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

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

[eCRF Audit Trail History](#)

**Vaccination**

1.	Was there a temporary delay of vaccination?	NO
2.	Treatment Name	[BLINDED THERAPY]
3.	Formulation:	INJECTION
4.	Dose Date Time:	Sep/11/2020 13:49
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

090177e196ae40c3\Final\Final On: 01-Apr-2021 05:43 (GMT)

**Header Text:** c4591001

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

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

**Site No:** 1141 **Site Name:** (1141) University of Iowa Hospital and Clinics

**Subject No:** 11411113 **Subject Initials:** ---

**Generated By:** (b) (4) **Generated Time (GMT):** 29-Mar-2021 11:44

[eCRF Audit Trail History](#)

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

**Header Text:** c4591001

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

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

**Site No:** 1141 **Site Name:** (1141) University of Iowa Hospital and Clinics

**Subject No:** 11411113 **Subject Initials:** ---

**Generated By:** (b) (4) **Generated Time (GMT):** 29-Mar-2021 11:44

[eCRF Audit Trail History](#)

**Electronic Sample Tracking**

1.	Data Origin	SITE
2.	Sample Type	SERUM
3.	Sample Collected?	YES Date of Collection: Oct/9/2020
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[ ]

**Aliquot**

Please enter barcode for each aliquot.

5.a	Sample ID	[BP9M6D]
5.b	Sample ID	[BRX6YL]
5.c	Sample ID	[BRX6YM]

090177e196ae40c3\Final\Final On: 01-Apr-2021 05:43 (GMT)

**Header Text:** c4591001

**Visit:** V4\_MONTH6\_L

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

**Site No:** 1141

**Subject No:** 11411113

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

**Form:** DATE OF VISIT

**Form Status:** Not Started

**Site Name:** (1141) University of Iowa Hospital and Clinics

**Subject Initials:** ---

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

**Date of Visit**

1.	Date of Visit	//
2.	Erroneous Visit	

**Header Text:** c4591001

**Visit:** V4\_MONTH6\_L

**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

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

**Form Status:** Not Started

**Site No:** 1141

**Site Name:** (1141) University of Iowa Hospital and Clinics

**Subject No:** 11411113

**Subject Initials:** ---

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

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

**Electronic Sample Tracking**

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

**Aliquot**

Please enter barcode for each aliquot.

5.	Sample ID	[ ]
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090177e196ae40c3\Final\Final On: 01-Apr-2021 05:43 (GMT)

**Header Text:** c4591001

**Visit:** V5\_MONTH12\_L

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

**Site No:** 1141

**Subject No:** 11411113

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

**Form:** DATE OF VISIT

**Form Status:** Not Started

**Site Name:** (1141) University of Iowa Hospital and Clinics

**Subject Initials:** ---

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

**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:** 1141

**Subject No:** 11411113

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

**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

**Form Status:** Not Started

**Site Name:** (1141) University of Iowa Hospital and Clinics

**Subject Initials:** ---

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

**Electronic Sample Tracking**

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

**Aliquot**

Please enter barcode for each aliquot.

5.	Sample ID	[ ]
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090177e196ae40c3\Final\Final On: 01-Apr-2021 05:43 (GMT)

**Header Text:** c4591001

**Visit:** V6\_MONTH24\_L

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

**Site No:** 1141

**Subject No:** 11411113

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

**Form:** DATE OF VISIT

**Form Status:** Not Started

**Site Name:** (1141) University of Iowa Hospital and Clinics

**Subject Initials:** ---

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

**Date of Visit**

1.	Date of Visit	//
2.	Erroneous Visit	

**Header Text:** c4591001

**Visit:** V6\_MONTH24\_L

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

**Site No:** 1141

**Subject No:** 11411113

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

**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

**Form Status:** Not Started

**Site Name:** (1141) University of Iowa Hospital and Clinics

**Subject Initials:** ---

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

**Electronic Sample Tracking**

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

**Aliquot**

Please enter barcode for each aliquot.

5.	Sample ID	[ ]
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090177e196ae40c3\Final\Final On: 01-Apr-2021 05:43 (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:** 1141

**Site Name:** (1141) University of Iowa Hospital and Clinics

**Subject No:** 11411113

**Subject Initials:** ---

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

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

Date of Visit		
1.	Date of Visit	//
2.	Erroneous Visit	
COVID-19 Illness Visit		
3.	COVID-19 Illness Visit:	

**Header Text:** c4591001

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

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

**Site No:** 1141

**Subject No:** 11411113

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

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

**Form Status:** Not Started

**Site Name:** (1141) University of Iowa Hospital and  
Clinics

**Subject Initials:** ---

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

**Signs and Symptoms**

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

**Symptoms**

4.	Symptoms:	
	Was symptom present?	

**Symptoms - Other**

5.	Symptoms - Other Text:	[ ]
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090177e196ae40c3\Final\Final On: 01-Apr-2021 05:43 (GMT)

**Header Text:** c4591001

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

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

**Site No:** 1141

**Subject No:** 11411113

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

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

**Form Status:** Not Started

**Site Name:** (1141) University of Iowa Hospital and  
Clinics

**Subject Initials:** ---

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

**Electronic Sample Tracking**

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

**Aliquot**

Please enter barcode for each aliquot.

5.	Sample ID	[ ]
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090177e196ae40c3\Final\Final On: 01-Apr-2021 05:43 (GMT)

**Header Text:** c4591001

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

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

**Site No:** 1141

**Subject No:** 11411113

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

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

**Form Status:** Not Started

**Site Name:** (1141) University of Iowa Hospital and  
Clinics

**Subject Initials:** ---

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

**Electronic Sample Tracking**

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

**Aliquot**

Please enter barcode for each aliquot.

5.	Sample ID	[ ]
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090177e196ae40c3\Final\Final On: 01-Apr-2021 05:43 (GMT)

**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:** 1141

**Site Name:** (1141) University of Iowa Hospital and  
Clinics

**Subject No:** 11411113

**Subject Initials:** ---

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

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

**Health Care Utilization**

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

**Health Care Utilization Other**

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

**Health Care Utilization**

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

090177e196ae40c3\Final\Final On: 01-Apr-2021 05:43 (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:** 1141

**Site Name:** (1141) University of Iowa Hospital and  
Clinics

**Subject No:** 11411113

**Subject Initials:** ---

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

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

**Illness Details**

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

090177e196ae40c3\Final\Final On: 01-Apr-2021 05:43 (GMT)

**Header Text:** c4591001

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

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

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

**Form Status:** Not Started

**Site No:** 1141

**Site Name:** (1141) University of Iowa Hospital and  
Clinics

**Subject No:** 11411113

**Subject Initials:** ---

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

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

**Date of Visit**

1.	Date of Visit	//
2.	Erroneous Visit	

**COVID-19 Illness Visit**

3.	COVID-19 Illness Visit:	
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**Header Text:** c4591001**Visit:** POT\_COVID\_CONVA - New  
Unscheduled Visit**Form:** ELECTRONIC SAMPLE TRACKING -  
IMMUNOGENICITY**Form Version:** 22-Apr-2020 21:03**Form Status:** Not Started**Site No:** 1141**Site Name:** (1141) University of Iowa Hospital and  
Clinics**Subject No:** 11411113**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 11:44**Electronic Sample Tracking**

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

**Aliquot**

Please enter barcode for each aliquot.

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

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

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

**Site No:** 1141 **Site Name:** (1141) University of Iowa Hospital and  
Clinics

**Subject No:** 11411113 **Subject Initials:** ---

**Generated By:** (b) (4) **Generated Time (GMT):** 29-Mar-2021 11:44

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

**Header Text:** c4591001

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

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

**Site No:** 1141    **Site Name:** (1141) University of Iowa Hospital and Clinics

**Subject No:** 11411113    **Subject Initials:** ---

**Generated By:** (b) (4)    **Generated Time (GMT):** 29-Mar-2021 11:44

**Unplanned Assessments**

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

090177e196ae40c3\Final\Final On: 01-Apr-2021 05:43 (GMT)

**Header Text:** c4591001

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

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

**Site No:** 1141

**Site Name:** (1141) University of Iowa Hospital and Clinics

**Subject No:** 11411113

**Subject Initials:** ---

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

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

[eCRF Audit Trail History](#)

**Disposition - Treatment**

1.	Date of Completion/Discontinuation /Death :	Oct/9/2020
2.	Phase of Disposition:	VACCINATION
3.	Status:	COMPLETED
4.	Specify Status:	[ ]

**Header Text:** c4591001

**Visit:** Follow-Up - Unscheduled

**Form:** DISPOSITION - FOLLOW-UP

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

**Form Status:** Not Started

**Site No:** 1141

**Site Name:** (1141) University of Iowa Hospital and Clinics

**Subject No:** 11411113

**Subject Initials:** ---

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

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

**Disposition - Follow-Up**

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

090177e196ae40c3\Final\Final On: 01-Apr-2021 05:43 (GMT)

**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:** 1141

**Site Name:** (1141) University of Iowa Hospital and Clinics

**Subject No:** 11411113

**Subject Initials:** ---

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

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

**Date of Visit**

1.	Date of Visit	//
2.	Erroneous Visit	

**COVID-19 Repeat Swab**

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



**Header Text:** c4591001**Visit:** POT\_COVID\_REPEAT\_SWAB - New Unscheduled Visit **Form:** ELECTRONIC SAMPLE TRACKING - REPEAT SWAB**Form Version:** 10-Oct-2020 15:57 **Form Status:** Not Started**Site No:** 1141**Site Name:** (1141) University of Iowa Hospital and Clinics**Subject No:** 11411113**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 11:44**Electronic Sample Tracking**

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

**Aliquot**

Please enter barcode for each aliquot.

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

**Header Text:** c4591001

**Visit:** Logs

**Form:** ADVERSE EVENT REPORT

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

**Site No:** 1141

**Site Name:** (1141) University of Iowa Hospital and Clinics

**Subject No:** 11411113

**Subject Initials:** ---

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

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

#	Category	AE Identifier	Adverse Event	Start Date	Is the Adverse Event Still Ongoing	Form Instance
1.	ADVERSE EVENT	1	injection site pain	Sep/11/2020 18:00	NO End Date Time:  Sep/14/2020 08:00	<a href="#">Repeating Pages</a>
2.	ADVERSE EVENT	2	swollen left axillary lymph node	Sep/12/2020 08:00	NO End Date Time:  Sep/14/2020 08:00	<a href="#">Repeating Pages</a>

090177e196ae40c3\Final\Final On: 01-Apr-2021 05:43 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

**Form:** ADVERSE EVENT REPORT

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

**Form Status:** Data Complete, Frozen

**Site No:** 1141

**Site Name:** (1141) University of Iowa Hospital and Clinics

**Subject No:** 11411113

**Subject Initials:** ---

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

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

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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)	[injection site pain]
4.	Start Date Time:	Sep/11/2020 18:00
5.	Is the adverse event still ongoing?	NO End Date Time: Sep/14/2020 08:00
6.	Toxicity Grade:	1

090177e196ae40c3\Final\Final On: 01-Apr-2021 05:43 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1141

**Subject No:** 11411113

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

**Form:** ADVERSE EVENT REPORT

**Form Status:** Data Complete, Frozen

**Site Name:** (1141) University of Iowa Hospital and Clinics

**Subject Initials:** ---

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

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

090177e196ae40c3\Final\Final On: 01-Apr-2021 05:43 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

**Form:** ADVERSE EVENT REPORT

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

**Form Status:** Data Complete, Frozen

**Site No:** 1141

**Site Name:** (1141) University of Iowa Hospital and Clinics

**Subject No:** 11411113

**Subject Initials:** ---

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

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

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

090177e196ae40c3\Final\Final On: 01-Apr-2021 05:43 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1141

**Subject No:** 11411113

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

**Form:** ADVERSE EVENT REPORT

**Form Status:** Data Complete, Frozen

**Site Name:** (1141) University of Iowa Hospital and Clinics

**Subject Initials:** ---

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

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[Form Audit Trail](#)

### Adverse Event Report

1.	Category:	ADVERSE EVENT
2.	AE ID:	[2]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[swollen left axillary lymph node]
4.	Start Date Time:	Sep/12/2020 08:00
5.	Is the adverse event still ongoing?	NO End Date Time: Sep/14/2020 08:00
6.	Toxicity Grade:	1

090177e196ae40c3\Final\Final On: 01-Apr-2021 05:43 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1141

**Subject No:** 11411113

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

**Form:** ADVERSE EVENT REPORT

**Form Status:** Data Complete, Frozen

**Site Name:** (1141) University of Iowa Hospital and Clinics

**Subject Initials:** ---

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

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

090177e196ae40c3\Final\Final On: 01-Apr-2021 05:43 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

**Form:** ADVERSE EVENT REPORT

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

**Form Status:** Data Complete, Frozen

**Site No:** 1141

**Site Name:** (1141) University of Iowa Hospital and Clinics

**Subject No:** 11411113

**Subject Initials:** ---

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

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

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

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**Header Text:** c4591001

**Visit:** Logs

**Form:** MEDICATION ERROR

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

**Site No:** 1141

**Site Name:** (1141) University of Iowa Hospital and Clinics

**Subject No:** 11411113

**Subject Initials:** ---

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

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

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

090177e196ae40c3\Final\Final On: 01-Apr-2021 05:43 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

**Form:** MEDICATION ERROR

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

**Form Status:** Not Started

**Site No:** 1141

**Site Name:** (1141) University of Iowa Hospital and Clinics

**Subject No:** 11411113

**Subject Initials:** ---

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

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

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**Medication Error**

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

090177e196ae40c3\Final\Final On: 01-Apr-2021 05:43 (GMT)

**Header Text:** c4591001

**Visit:** Logs

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

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

**Site No:** 1141

**Site Name:** (1141) University of Iowa Hospital and Clinics

**Subject No:** 11411113

**Subject Initials:** ---

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

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

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

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

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

**Form Status:** Not Started

**Site No:** 1141

**Site Name:** (1141) University of Iowa Hospital and Clinics

**Subject No:** 11411113

**Subject Initials:** ---

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

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

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**Concomitant Medications**

1.	What is the medication identifier?	[ ]
2.	Category:	
3.	Concomitant Medications Pre-specified:	
4.	<p>Medication:</p> <p>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).</p>	[ ]
5.	Date:	//

090177e196ae40c3\Final\Final On: 01-Apr-2021 05:43 (GMT)

**Header Text:** c4591001

**Visit:** Logs

**Form:** CONCOMITANT MEDICATIONS - PROHIBITED

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

**Site No:** 1141

**Site Name:** (1141) University of Iowa Hospital and Clinics

**Subject No:** 11411113

**Subject Initials:** ---

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

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

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

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

**Form:** CONCOMITANT MEDICATIONS - PROHIBITED

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

**Form Status:** Not Started

**Site No:** 1141

**Site Name:** (1141) University of Iowa Hospital and Clinics

**Subject No:** 11411113

**Subject Initials:** ---

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

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

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**Concomitant Medications**

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

090177e196ae40c3\Final\Final On: 01-Apr-2021 05:43 (GMT)

**Header Text:** c4591001

**Visit:** Logs

**Form:** RADIATION TREATMENT

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

**Site No:** 1141

**Site Name:** (1141) University of Iowa Hospital and Clinics

**Subject No:** 11411113

**Subject Initials:** ---

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

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

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

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

**Form:** RADIATION TREATMENT

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

**Form Status:** Not Started

**Site No:** 1141

**Site Name:** (1141) University of Iowa Hospital and Clinics

**Subject No:** 11411113

**Subject Initials:** ---

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

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

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**Radiation Treatment**

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

090177e196ae40c3\Final\Final On: 01-Apr-2021 05:43 (GMT)



**Header Text:** c4591001

**Visit:** Logs

**Form:** TRANSFUSIONS

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

**Site No:** 1141

**Site Name:** (1141) University of Iowa Hospital and Clinics

**Subject No:** 11411113

**Subject Initials:** ---

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

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

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

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

**Form:** TRANSFUSIONS

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

**Form Status:** Not Started

**Site No:** 1141

**Site Name:** (1141) University of Iowa Hospital and Clinics

**Subject No:** 11411113

**Subject Initials:** ---

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

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

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

**Header Text:** c4591001

**Visit:** Unplanned Vaccination -  
Unscheduled

**Form:** DATE OF VISIT

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

**Form Status:** Not Started

**Site No:** 1141

**Site Name:** (1141) University of Iowa Hospital and  
Clinics

**Subject No:** 11411113

**Subject Initials:** ---

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

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

**Date of Visit**

1.	Date of Visit	//
2.	Erroneous Visit	

**Header Text:** c4591001

**Visit:** Unplanned Vaccination -  
Unscheduled

**Form:** VITAL SIGNS - TEMP

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

**Form Status:** Not Started

**Site No:** 1141

**Site Name:** (1141) University of Iowa Hospital and  
Clinics

**Subject No:** 11411113

**Subject Initials:** ---

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

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

**Vital Signs**

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

**Vital Signs Details**

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

090177e196ae40c3\Final\Final On: 01-Apr-2021 05:43 (GMT)

**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:** 1141**Site Name:** (1141) University of Iowa Hospital and  
Clinics**Subject No:** 11411113**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 11:44**Lab Urinalysis**

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

**Lab Result**

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

**Header Text:** c4591001

**Visit:** Unplanned Vaccination -  
Unscheduled

**Form:** VACCINATION

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

**Form Status:** Not Started

**Site No:** 1141

**Site Name:** (1141) University of Iowa Hospital and  
Clinics

**Subject No:** 11411113

**Subject Initials:** ---

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

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

**Vaccination**

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

090177e196ae40c3\Final\Final On: 01-Apr-2021 05:43 (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:** 1141

**Site Name:** (1141) University of Iowa Hospital and  
Clinics

**Subject No:** 11411113

**Subject Initials:** ---

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

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

**Contact Outcome**

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

**Header Text:** c4591001

**Visit:** Unplanned Vaccination -  
Unscheduled

**Form:** CONTACT OUTCOME - MONTH 6

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

**Form Status:** Not Started

**Site No:** 1141

**Site Name:** (1141) University of Iowa Hospital and  
Clinics

**Subject No:** 11411113

**Subject Initials:** ---

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

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

**Contact Outcome**

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



**Header Text:** c4591001

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

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

**Site No:** 1141 **Site Name:** (1141) University of Iowa Hospital and Clinics

**Subject No:** 11411113 **Subject Initials:** ---

**Generated By:** (b) (4) **Generated Time (GMT):** 29-Mar-2021 11:44

**Date of Visit**

1.	Date of Visit	//
2.	Erroneous Visit	

**Header Text:** c4591001

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

**Form:** INFORMED CONSENT - ASYMPTOMATIC  
SURVEILLANCE

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

**Form Status:** Not Started

**Site No:** 1141

**Site Name:** (1141) University of Iowa Hospital and  
Clinics

**Subject No:** 11411113

**Subject Initials:** ---

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

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

**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:** 1141**Site Name:** (1141) University of Iowa Hospital and  
Clinics**Subject No:** 11411113**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 11:44**Electronic Sample Tracking**

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

**Aliquot**

Please enter barcode for each aliquot.

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

**Header Text:** c4591001**Visit:** V201\_SURVEIL\_CONSENT -  
Unscheduled**Form:** ELECTRONIC SAMPLE TRACKING - NASAL  
SWAB**Form Version:** 22-Apr-2020 21:03**Form Status:** Not Started**Site No:** 1141**Site Name:** (1141) University of Iowa Hospital and  
Clinics**Subject No:** 11411113**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 11:44**Electronic Sample Tracking**

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

**Aliquot**

Please enter barcode for each aliquot.

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

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

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

**Site No:** 1141      **Site Name:** (1141) University of Iowa Hospital and Clinics

**Subject No:** 11411113      **Subject Initials:** ---

**Generated By:** (b) (4)      **Generated Time (GMT):** 29-Mar-2021 11:44

[eCRF Audit Trail History](#)

**Date of Visit**

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

**Header Text:** c4591001

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

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

**Site No:** 1141      **Site Name:** (1141) University of Iowa Hospital and  
Clinics

**Subject No:** 11411113      **Subject Initials:** ---

**Generated By:** (b) (4)      **Generated Time (GMT):** 29-Mar-2021 11:44

[eCRF Audit Trail History](#)

**Further Vaccination Confirmation**

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

**Header Text:** c4591001

**Visit:** Disposition - Unscheduled

**Form:** TREATMENT UNBLINDED

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

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

**Site No:** 1141

**Site Name:** (1141) University of Iowa Hospital and Clinics

**Subject No:** 11411113

**Subject Initials:** ---

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

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

[eCRF Audit Trail History](#)

**Treatment Unblinded**

1.	Date Treatment Unblinded :	Feb/8/2021
2.	Primary Reason for Unblinding:	ASSESS ELIGIBILITY FOR ADDITIONAL VACCINATION

**Header Text:** c4591001

**Visit:** Disposition - Unscheduled

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

**Site No:** 1141

**Subject No:** 11411113

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

**Form:** WITHDRAWAL OF CONSENT

**Form Status:** Not Started

**Site Name:** (1141) University of Iowa Hospital and Clinics

**Subject Initials:** ---

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

**Withdrawal Of Consent**

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



**Header Text:** c4591001

**Visit:** Disposition - Unscheduled

**Form:** DEATH DETAILS CODED

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

**Form Status:** Not Started

**Site No:** 1141

**Site Name:** (1141) University of Iowa Hospital and Clinics

**Subject No:** 11411113

**Subject Initials:** ---

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

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

**Death Details**

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

**Cause of Death**

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

090177e196ae40c3\Final\Final On: 01-Apr-2021 05:43 (GMT)

**Header Text:** c4591001

**Visit:** Subject Status - Unscheduled

**Form:** SUBJECT STATUS

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

**Form Status:** Data Complete, Verified

**Site No:** 1141

**Site Name:** (1141) University of Iowa Hospital and Clinics

**Subject No:** 11411113

**Subject Initials:** ---

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

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

[eCRF Audit Trail History](#)

**Subject Status**

1.	Subject Status	FOLLOW-UP
2.	Subject Status Date	Oct/9/2020

**Header Text:** c4591001

**Visit:** Investigator Signature -  
Unscheduled

**Form:** CASEBOOK SIGNATURE FORM

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

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

**Site No:** 1141

**Site Name:** (1141) University of Iowa Hospital and  
Clinics

**Subject No:** 11411113

**Subject Initials:** ---

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

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

[eCRF Audit Trail History](#)

**Casebook Signature Form**

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

**Header Text:** c4591001

**Visit:** Investigator Signature -  
Unscheduled

**Form:** CASEBOOK SIGNATURE FORM

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

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

**Site No:** 1141

**Site Name:** (1141) University of Iowa Hospital and  
Clinics

**Subject No:** 11411113

**Subject Initials:** ---

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

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

[Audit Trail](#)

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

- CRF\_Sign

Name	Signature Meaning	Date	Type	Action
Patricia Winokur	Approved	Feb-24-2021 08:00:59 (UTC-06:00) Central Time (US & Canada)	BOOK	Signed

**Affidavit:**

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

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

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

**Header Text:** c4591001

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

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

**Form Version:** 30-Jul-2020 21:29

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

**Site No:** 1141

**Site Name:** (1141) University of Iowa Hospital and  
Clinics

**Subject No:** 11411113

**Subject Initials:** ---

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

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

[Back to Form](#)

Item	Date	User	Comment
Form	Aug-21-2020 06:06:26 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6) [REDACTED]	Not Applicable

**Header Text:** c4591001

**Visit:** Investigator Signature -  
Unscheduled

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

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

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

**Site No:** 1141

**Site Name:** (1141) University of Iowa Hospital and  
Clinics

**Subject No:** 11411113

**Subject Initials:** ---

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

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

[Back to Form](#)

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

- CRF\_Sign

Name	Signature Meaning	Date	Type	Action
Patricia Winokur	Approved	Feb-24-2021 08:00:59 (UTC-06:00) Central Time (US & Canada)	BOOK	Signed

**Affidavit:**

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

(b) (6)	N/A	Feb-19-2021 09:24:41 (UTC-06:00) Central Time (US & Canada)		Edit - All signatures invalidated
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**Affidavit:**

N/A

Patricia Winokur	Approved	Feb-18-2021 12:51:50 (UTC-06:00) Central Time (US & Canada)	BOOK	Signed
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090177e196ae40c3\Final\Final On: 01-Apr-2021 05:43 (GMT)

**Header Text:** c4591001

**Visit:** Investigator Signature -  
Unscheduled

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

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

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

**Site No:** 1141

**Site Name:** (1141) University of Iowa Hospital and  
Clinics

**Subject No:** 11411113

**Subject Initials:** ---

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

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

**Affidavit:**

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

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

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

(b) (6)	N/A	Feb-18-2021 10:14:11 (UTC-06:00) Central Time (US & Canada)		Edit - All signatures invalidated
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**Affidavit:**

N/A

Patricia Winokur	Approved	Dec-01-2020 11:44:42 (UTC-06:00) Central Time (US & Canada)	BOOK	Signed
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090177e196ae40c3\Final\Final On: 01-Apr-2021 05:43 (GMT)

**Header Text:** c4591001

**Visit:** Investigator Signature -  
Unscheduled

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

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

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

**Site No:** 1141

**Site Name:** (1141) University of Iowa Hospital and  
Clinics

**Subject No:** 11411113

**Subject Initials:** ---

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

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

**Affidavit:**

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

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

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

(b) (6)	N/A	Nov-23-2020 11:00:18 (UTC-06:00) Central Time (US & Canada)		Edit - All signatures invalidated
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**Affidavit:**

N/A

Patricia Winokur	Approved	Nov-16-2020 15:17:42 (UTC-06:00) Central Time (US & Canada)	BOOK	Signed
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090177e196ae40c3\Final\Final On: 01-Apr-2021 05:43 (GMT)



**Header Text:** c4591001

**Visit:** Investigator Signature -  
Unscheduled

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

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

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

**Site No:** 1141

**Site Name:** (1141) University of Iowa Hospital and  
Clinics

**Subject No:** 11411113

**Subject Initials:** ---

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

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

**Affidavit:**

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

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

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

(b) (6)	N/A	Nov-16-2020 15:03:48 (UTC-06:00) Central Time (US & Canada)		Edit - All signatures invalidated
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**Affidavit:**

N/A

Patricia Winokur	Approved	Oct-22-2020 16:03:18 (UTC-06:00) Central Time (US & Canada)	BOOK	Signed
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090177e196ae40c3\Final\Final On: 01-Apr-2021 05:43 (GMT)

**Header Text:** c4591001

**Visit:** Investigator Signature -  
Unscheduled

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

**Site No:** 1141

**Subject No:** 11411113

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

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

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

**Site Name:** (1141) University of Iowa Hospital and  
Clinics

**Subject Initials:** ---

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

**Affidavit:**

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

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

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

**Header Text:** c4591001

**Visit:** COHORT\_SELECTION

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

**Form Version:** 30-Jul-2020 21:29

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

**Site No:** 1141

**Site Name:** (1141) University of Iowa Hospital and Clinics

**Subject No:** 11411113

**Subject Initials:** ---

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

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

[Back to Form](#)

*1. Select appropriate response - Protocol version*

Date	Location	User	Value	Reason
Aug-20-2020 17:52:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [Redacted] [Redacted]	<b>Data Entry:</b> 24 JUL 2020	Initial Entry

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

Date	Location	User	Value	Reason
Aug-20-2020 17:52:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [Redacted] [Redacted]	<b>Data Entry:</b> STAGE 3 COHORT S	Initial Entry

090177e196ae40c3\Final\Final On: 01-Apr-2021 05:43 (GMT)

**Header Text:** c4591001

**Visit:** COHORT\_SELECTION

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

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

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

**Site No:** 1141

**Site Name:** (1141) University of Iowa Hospital and Clinics

**Subject No:** 11411113

**Subject Initials:** ---

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

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

[Back to Form](#)

*1. Consent Was:*

Date	Location	User	Value	Reason
Aug-20-2020 17:52:37 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> OBTAINED Date Written Consent Obtained  Aug/20/2020	Initial Entry

090177e196ae40c3\Final\Final On: 01-Apr-2021 05:43 (GMT)

**Header Text:** c4591001

**Visit:** COHORT\_SELECTION

**Form Version:** 06-Jul-2020 21:55

**Site No:** 1141

**Subject No:** 11411113

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

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

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

**Site Name:** (1141) University of Iowa Hospital and Clinics

**Subject Initials:** ---

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

[Back to Form](#)

**1. Subject ID**

Date	Location	User	Value	Reason
Aug-20-2020 17:52:19 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 11411113	Item copied from previous form

**2. Birth Date:**

Date	Location	User	Value	Reason
Aug-20-2020 17:52:16 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> (b) (6)/1992	Enrollment Entry

**3. Sex:**

Date	Location	User	Value	Reason
Aug-20-2020 17:52:46 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [Redacted]	<b>Data Entry:</b> FEMALE	Initial Entry

**4. Ethnicity:**

Date	Location	User	Value	Reason
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090177e196ae40c3\Final\Final On: 01-Apr-2021 05:43 (GMT)

**Header Text:** c4591001

**Visit:** COHORT\_SELECTION

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

**Form Version:** 06-Jul-2020 21:55

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

**Site No:** 1141

**Site Name:** (1141) University of Iowa Hospital and Clinics

**Subject No:** 11411113

**Subject Initials:** ---

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

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

Aug-20-2020 17:52:46 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NOT HISPANIC OR LATINO(A) OR OF SPANISH ORIGIN	Initial Entry
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**5. Race: (Check X all that apply):**

Date	Location	User	Value	Reason
Aug-20-2020 17:52:46 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> WHITE	Initial Entry

090177e196ae40c3\Final\Final On: 01-Apr-2021 05:43 (GMT)

**Header Text:** c4591001

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

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

**Site No:** 1141

**Subject No:** 11411113

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

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

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

**Site Name:** (1141) University of Iowa Hospital and Clinics

**Subject Initials:** ---

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

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*1. Date of Visit*

Date	Location	User	Value	Reason
Aug-20-2020 17:52:55 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [Redacted] [Redacted]	<b>Data Entry:</b> Aug/20/2020	Initial Entry

090177e196ae40c3\Final\Final On: 01-Apr-2021 05:43 (GMT)

**Header Text:** c4591001

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

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

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

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

**Site No:** 1141

**Site Name:** (1141) University of Iowa Hospital and Clinics

**Subject No:** 11411113

**Subject Initials:** ---

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

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

[Back to Form](#)

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

Date	Location	User	Value	Reason
Aug-20-2020 17:53:02 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Aug/20/2020	Initial Entry

**2. Phase of Disposition:**

Date	Location	User	Value	Reason
Aug-20-2020 17:53:02 (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
Aug-20-2020 17:53:02 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> COMPLETED	Initial Entry

090177e196ae40c3\Final\Final On: 01-Apr-2021 05:43 (GMT)



**Header Text:** c4591001**Visit:** V1\_DAY1\_VAX1\_L**Form:** GENERAL MEDICAL HISTORY - eCRF Audit Trail History**Form Version:** 22-Apr-2020 21:03**Form Status:** Data Complete, Locked, Frozen, Verified**Site No:** 1141**Site Name:** (1141) University of Iowa Hospital and Clinics**Subject No:** 11411113**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 11:44[Back to Form](#)*1.a*

Date	Location	User	Value	Reason
Aug-20-2020 18:09:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> Line/MH N 1 umber: Medical His Headach tory Term: es Start Date: UNK/U NK/201 0 Ongoing: YES	Initial Entry

*1.a Line/MH Number:*

Date	Location	User	Value	Reason
Aug-20-2020 18:09:49 (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:*

Date	Location	User	Value	Reason
Aug-20-2020 18:09:49 (UTC-06:00)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED] [REDACTED]	<b>Data Entry:</b> Headaches	Initial Entry

**Header Text:** c4591001

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

**Form:** GENERAL MEDICAL HISTORY - eCRF Audit Trail History

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

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

**Site No:** 1141

**Site Name:** (1141) University of Iowa Hospital and Clinics

**Subject No:** 11411113

**Subject Initials:** ---

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

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

Central Time (US & Canada)

***1.a Start Date:***

Date	Location	User	Value	Reason
Aug-20-2020 18:09:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> UNK/UNK/2010	Initial Entry

***1.a Ongoing:***

Date	Location	User	Value	Reason
Aug-20-2020 18:09:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

090177e196ae40c3\Final\Final On: 01-Apr-2021 05:43 (GMT)

**Header Text:** c4591001

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

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

**Form Version:** 30-Jul-2020 21:28

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

**Site No:** 1141

**Site Name:** (1141) University of Iowa Hospital and Clinics

**Subject No:** 11411113

**Subject Initials:** ---

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

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

[Back to Form](#)

**1. Date:**

Date	Location	User	Value	Reason
Aug-20-2020 21:09:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Aug/20/2020	Initial Entry

**2. Weight:**

Date	Location	User	Value	Reason
Aug-20-2020 21:09:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 85.4	Initial Entry

**3. Unit:**

Date	Location	User	Value	Reason
Aug-20-2020 21:09:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> kg	Initial Entry

**4. Height:**

090177e196ae40c3\Final\Final On: 01-Apr-2021 05:43 (GMT)

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form: VITAL SIGNS - BASELINE - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:28

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1141

Site Name: (1141) University of Iowa Hospital and Clinics

Subject No: 11411113

Subject Initials: ---

Generated By: (b) (4)

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

Date	Location	User	Value	Reason
Aug-20-2020 21:09:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [Redacted] [Redacted]	<b>Data Entry:</b> 170.0	Initial Entry

5. Unit:

Date	Location	User	Value	Reason
Aug-20-2020 21:09:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [Redacted] [Redacted]	<b>Data Entry:</b> cm	Initial Entry

6. Body Mass Index:

Date	Location	User	Value	Reason
Aug-20-2020 21:09:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 29.6	Initial Entry

7.a

Date	Location	User	Value	Reason
Aug-20-2020 21:09:45 (UTC-06:00)	ACV0PFEINFP6000	(b) (4), (b) (6) [Redacted] [Redacted]	<b>Data Entry:</b> Record Ide 1	Initial Entry

090177e196ae40c3\Final\Final On: 01-Apr-2021 05:43 (GMT)

**Header Text:** c4591001

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

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

**Form Version:** 30-Jul-2020 21:28

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

**Site No:** 1141

**Site Name:** (1141) University of Iowa Hospital and Clinics

**Subject No:** 11411113

**Subject Initials:** ---

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

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

Central Time (US & Canada)			<b>ntifier::</b> <b>Temperatu</b> 98.4 <b>re:</b> <b>Temperatu</b> F <b>re Unit:</b> <b>Temperatu</b> ORAL <b>re Locatio</b> CAVIT <b>n::</b> Y	
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**7.a Record Identifier:**

Date	Location	User	Value	Reason
Aug-20-2020 21:09:45 (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
Aug-20-2020 21:09:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 98.4	Initial Entry

**7.a Unit:**

Date	Location	User	Value	Reason
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090177e196ae40c3\Final\Final On: 01-Apr-2021 05:43 (GMT)

**Header Text:** c4591001

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

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

**Form Version:** 30-Jul-2020 21:28

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

**Site No:** 1141

**Site Name:** (1141) University of Iowa Hospital and Clinics

**Subject No:** 11411113

**Subject Initials:** ---

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

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

Aug-20-2020 21:09:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [Redacted] [Redacted]	<b>Data Entry:</b> F	Initial Entry
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**7.a Temperature Location:**

Date	Location	User	Value	Reason
Aug-20-2020 21:09:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [Redacted] [Redacted]	<b>Data Entry:</b> ORAL CAVITY	Initial Entry

090177e196ae40c3\Final\Final On: 01-Apr-2021 05:43 (GMT)

**Header Text:** c4591001

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

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

**Form Version:** 30-Jul-2020 21:27

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

**Site No:** 1141

**Site Name:** (1141) University of Iowa Hospital and Clinics

**Subject No:** 11411113

**Subject Initials:** ---

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

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

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**1. Lab Panel:**

Date	Location	User	Value	Reason
Aug-20-2020 21:09:56 (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
Aug-20-2020 21:09:56 (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
Aug-20-2020 21:09:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [Redacted] [Redacted]	<b>Data Entry:</b> Aug/20/2020	Initial Entry

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

090177e196ae40c3\Final\Final On: 01-Apr-2021 05:43 (GMT)

**Header Text:** c4591001

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

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

**Form Version:** 30-Jul-2020 21:27

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

**Site No:** 1141

**Site Name:** (1141) University of Iowa Hospital and Clinics

**Subject No:** 11411113

**Subject Initials:** ---

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

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

Date	Location	User	Value	Reason
Aug-20-2020 21:09:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> STUDY SITE	Initial Entry

**5. Specimen Type:**

Date	Location	User	Value	Reason
Aug-20-2020 21:09:56 (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
Aug-20-2020 21:09:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Sponsor-</b> 113 <b>Defined Identifier:</b> <b>Test::</b> Choriogon adotropin Beta_PX11 3 <b>Result::</b> NEGATIVE	Initial Entry

090177e196ae40c3\Final\Final On: 01-Apr-2021 05:43 (GMT)



**Header Text:** c4591001

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

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

**Form Version:** 30-Jul-2020 21:27

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

**Site No:** 1141

**Site Name:** (1141) University of Iowa Hospital and Clinics

**Subject No:** 11411113

**Subject Initials:** ---

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

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

			<b>Not Done</b> ::	
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**6.a Sponsor ID:**

Date	Location	User	Value	Reason
Aug-20-2020 21:09:56 (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
Aug-20-2020 21:09:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [Redacted]	<b>Data Entry:</b> Choriogonadotropin Beta_PX113	Initial Entry

**6.a Result:**

Date	Location	User	Value	Reason
Aug-20-2020 21:09:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [Redacted]	<b>Data Entry:</b> NEGATIVE	Initial Entry

090177e196ae40c3\Final\Final On: 01-Apr-2021 05:43 (GMT)

**Header Text:** c4591001

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

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

**Site No:** 1141

**Subject No:** 11411113

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

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

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

**Site Name:** (1141) University of Iowa Hospital and Clinics

**Subject Initials:** ---

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

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**1. Randomization Date :**

Date	Location	User	Value	Reason
Aug-20-2020 21:10:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [Redacted] [Redacted]	<b>Data Entry:</b> Aug/20/2020	Initial Entry

**2. Randomization Number:**

Date	Location	User	Value	Reason
Aug-20-2020 21:10:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [Redacted] [Redacted]	<b>Data Entry:</b> 59610	Initial Entry

090177e196ae40c3\Final\Final On: 01-Apr-2021 05:43 (GMT)

**Header Text:** c4591001

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

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

**Site No:** 1141

**Subject No:** 11411113

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

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

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

**Site Name:** (1141) University of Iowa Hospital and Clinics

**Subject Initials:** ---

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

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**1. Data Origin**

Date	Location	User	Value	Reason
Aug-20-2020 21:10:18 (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
Aug-20-2020 21:10:18 (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
Aug-21-2020 06:06:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Aug-21-2020 02:58:26	ACV0PFEINFP6000	(b) (4), (b) (6) [Redacted]	Query 1: Opened	'Sample Collected?' is

090177e196ae40c3\Final\Final On: 01-Apr-2021 05:43 (GMT)

**Header Text:** c4591001**Visit:** V1\_DAY1\_VAX1\_L**Form Version:** 22-Apr-2020 21:03**Site No:** 1141**Subject No:** 11411113**Generated By:** (b) (4)**Form:** ELECTRONIC SAMPLE TRACKING -  
IMMUNOGENICITY - eCRF Audit Trail History**Form Status:** Data Complete, Locked, Frozen, Verified**Site Name:** (1141) University of Iowa Hospital and  
Clinics**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 11:44

(UTC-06:00) Central Time (US & Canada)		(b) (4), (b) (6)		Yes, however no barcodes are entered. Please review and correct as appropriate.
Aug-20-2020 21:10:18 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Aug-20-2020 21:10:18 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	<b>Data Entry:</b> YES Date of Collection :  Aug/20/2020	Initial Entry

**5.a**

Date	Location	User	Value	Reason
Aug-21-2020 06:06:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	<b>Data Entry:</b> <b>Sample ID: BM88LS</b>	Initial Entry

**5.a Sample ID**

**Header Text:** c4591001

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

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

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

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

**Site No:** 1141

**Site Name:** (1141) University of Iowa Hospital and Clinics

**Subject No:** 11411113

**Subject Initials:** ---

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

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

Date	Location	User	Value	Reason
Aug-21-2020 06:06:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BM88LS	Initial Entry

**5.b**

Date	Location	User	Value	Reason
Aug-21-2020 06:06:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample ID:</b> BM88LT	Initial Entry

**5.b Sample ID**

Date	Location	User	Value	Reason
Aug-21-2020 06:06:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BM88LT	Initial Entry

**5.c**

Date	Location	User	Value	Reason
Aug-21-2020 06:06:52 (UTC-06:00)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample ID:</b> BM88LV	Initial Entry

090177e196ae40c3\Final\Final On: 01-Apr-2021 05:43 (GMT)

**Header Text:** c4591001

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

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

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

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

**Site No:** 1141

**Site Name:** (1141) University of Iowa Hospital and Clinics

**Subject No:** 11411113

**Subject Initials:** ---

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

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

Central Time (US & Canada)

**5.c Sample ID**

Date	Location	User	Value	Reason
Aug-21-2020 06:06:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BM88LV	Initial Entry

**5.d**

Date	Location	User	Value	Reason
Aug-21-2020 06:06:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample ID:</b> BLC994	Initial Entry

**5.d Sample ID**

Date	Location	User	Value	Reason
Aug-21-2020 06:06:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BLC994	Initial Entry

**5.e**

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**Header Text:** c4591001

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

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

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

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

**Site No:** 1141

**Site Name:** (1141) University of Iowa Hospital and Clinics

**Subject No:** 11411113

**Subject Initials:** ---

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

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

Date	Location	User	Value	Reason
Aug-21-2020 06:07:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample ID:</b> BLC995	Initial Entry

**5.e Sample ID**

Date	Location	User	Value	Reason
Aug-21-2020 06:07:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BLC995	Initial Entry

090177e196ae40c3\Final\Final On: 01-Apr-2021 05:43 (GMT)

**Header Text:** c4591001

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

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

**Site No:** 1141

**Subject No:** 11411113

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

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

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

**Site Name:** (1141) University of Iowa Hospital and Clinics

**Subject Initials:** ---

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

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**1. Data Origin**

Date	Location	User	Value	Reason
Aug-20-2020 21:10:24 (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
Aug-20-2020 21:10:24 (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
Aug-21-2020 06:07:17 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Aug-21-2020 02:58:26	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	'Sample Collected?' is

090177e196ae40c3\Final\Final On: 01-Apr-2021 05:43 (GMT)



**Header Text:** c4591001  
**Visit:** V1\_DAY1\_VAX1\_L **Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB - eCRF Audit Trail History  
**Form Version:** 22-Apr-2020 21:03 **Form Status:** Data Complete, Locked, Frozen, Verified  
**Site No:** 1141 **Site Name:** (1141) University of Iowa Hospital and Clinics  
**Subject No:** 11411113 **Subject Initials:** ---  
**Generated By:** (b) (4) **Generated Time (GMT):** 29-Mar-2021 11:44

(UTC-06:00) Central Time (US & Canada)		(b) (4), (b) (6)		Yes, however no barcodes are entered. Please review and correct as appropriate.
Aug-20-2020 21:10:24 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Aug-20-2020 21:10:24 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES Date of Collection : Aug/20/2020	Initial Entry

**5.a**

Date	Location	User	Value	Reason
Aug-21-2020 06:07:17 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sample ID BM88L : M	Initial Entry

**5.a Sample ID**

**Header Text:** c4591001

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

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

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

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

**Site No:** 1141

**Site Name:** (1141) University of Iowa Hospital and Clinics

**Subject No:** 11411113

**Subject Initials:** ---

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

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

Date	Location	User	Value	Reason
Aug-21-2020 06:07:17 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BM88LM	Initial Entry

**Header Text:** c4591001

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

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

**Site No:** 1141

**Subject No:** 11411113

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

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

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

**Site Name:** (1141) University of Iowa Hospital and Clinics

**Subject Initials:** ---

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

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

Date	Location	User	Value	Reason
Aug-20-2020 21:10:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [Redacted] [Redacted]	<b>Data Entry:</b> NO	Initial Entry

**2. Treatment Name**

Date	Location	User	Value	Reason
Aug-20-2020 21:10:42 (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
Aug-20-2020 21:10:42 (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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090177e196ae40c3\Final\Final On: 01-Apr-2021 05:43 (GMT)

**Header Text:** c4591001

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

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

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

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

**Site No:** 1141

**Site Name:** (1141) University of Iowa Hospital and Clinics

**Subject No:** 11411113

**Subject Initials:** ---

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

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

Aug-20-2020 21:10:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Aug/20/2020 16:43	Initial Entry
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**5. Anatomical Location:**

Date	Location	User	Value	Reason
Aug-20-2020 21:10:42 (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
Aug-20-2020 21:10:42 (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
Aug-20-2020 21:10:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> INTRAMUSCULAR	Initial Entry

090177e196ae40c3\Final\Final On: 01-Apr-2021 05:43 (GMT)

**Header Text:** c4591001

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

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

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

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

**Site No:** 1141

**Site Name:** (1141) University of Iowa Hospital and Clinics

**Subject No:** 11411113

**Subject Initials:** ---

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

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

**10. Timeframe Subject Was Observed**

Date	Location	User	Value	Reason
Aug-20-2020 21:10:42 (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
Aug-20-2020 21:10:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [Redacted] [Redacted]	<b>Data Entry:</b> YES	Initial Entry

090177e196ae40c3\Final\Final On: 01-Apr-2021 05:43 (GMT)

**Header Text:** c4591001

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

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

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

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

**Site No:** 1141

**Site Name:** (1141) University of Iowa Hospital and Clinics

**Subject No:** 11411113

**Subject Initials:** ---

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

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

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*1. Select appropriate response - Reactogenicity diary collection*

Date	Location	User	Value	Reason
Aug-20-2020 21:10:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO - REACTOGENI CITY E-DIARY NO T COLLECTED FO R THIS SUBJECT	Initial Entry

090177e196ae40c3\Final\Final On: 01-Apr-2021 05:43 (GMT)

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1141

**Subject No:** 11411113

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

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

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

**Site Name:** (1141) University of Iowa Hospital and Clinics

**Subject Initials:** ---

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

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*1. Date of Visit*

Date	Location	User	Value	Reason
Sep-11-2020 16:12:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [Redacted] [Redacted]	<b>Data Entry:</b> Sep/11/2020	Initial Entry

090177e196ae40c3\Final\Final On: 01-Apr-2021 05:43 (GMT)

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

**Form Version:** 21-Aug-2020 02:51

**Site No:** 1141

**Subject No:** 11411113

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

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

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

**Site Name:** (1141) University of Iowa Hospital and Clinics

**Subject Initials:** ---

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

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**1. Date:**

Date	Location	User	Value	Reason
Sep-11-2020 16:13:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [Redacted] [Redacted]	<b>Data Entry:</b> Sep/11/2020	Initial Entry

**2.a**

Date	Location	User	Value	Reason
Sep-11-2020 16:13:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [Redacted] [Redacted]	<b>Data Entry:</b> <b>Record Identifier:</b> <b>Temperature:</b> 98.1 <b>Temperature Unit:</b> <b>Temperature Location:</b> ORAL <b>Temperature Unit:</b> CAVIT <b>Temperature Unit:</b> Y	Initial Entry

**2.a Record Identifier:**

Date	Location	User	Value	Reason
Sep-11-2020 16:13:40 (UTC-06:00)	ACV0PFEINFP6000	(b) (4), (b) (6) [Redacted] [Redacted]	<b>Data Entry:</b> 1	Initial Entry

090177e196ae40c3\Final\Final On: 01-Apr-2021 05:43 (GMT)



**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

**Form Version:** 21-Aug-2020 02:51

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

**Site No:** 1141

**Site Name:** (1141) University of Iowa Hospital and Clinics

**Subject No:** 11411113

**Subject Initials:** ---

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

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

Central Time (US & Canada)				
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**2.a Temperature:**

Date	Location	User	Value	Reason
Sep-11-2020 16:13:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [Redacted] [Redacted]	<b>Data Entry:</b> 98.1	Initial Entry

**2.a Unit:**

Date	Location	User	Value	Reason
Sep-11-2020 16:13:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [Redacted] [Redacted]	<b>Data Entry:</b> F	Initial Entry

**2.a Temperature Location:**

Date	Location	User	Value	Reason
Sep-11-2020 16:13:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [Redacted] [Redacted]	<b>Data Entry:</b> ORAL CAVITY	Initial Entry

090177e196ae40c3\Final\Final On: 01-Apr-2021 05:43 (GMT)

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

**Form Version:** 30-Jul-2020 21:27

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

**Site No:** 1141

**Site Name:** (1141) University of Iowa Hospital and Clinics

**Subject No:** 11411113

**Subject Initials:** ---

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

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

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**1. Lab Panel:**

Date	Location	User	Value	Reason
Sep-11-2020 16:13:51 (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
Sep-11-2020 16:13:51 (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
Sep-11-2020 16:13:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [Redacted] [Redacted]	<b>Data Entry:</b> Sep/11/2020	Initial Entry

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

090177e196ae40c3\Final\Final On: 01-Apr-2021 05:43 (GMT)

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

**Form Version:** 30-Jul-2020 21:27

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

**Site No:** 1141

**Site Name:** (1141) University of Iowa Hospital and Clinics

**Subject No:** 11411113

**Subject Initials:** ---

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

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

Date	Location	User	Value	Reason
Sep-11-2020 16:13:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> STUDY SITE	Initial Entry

**5. Specimen Type:**

Date	Location	User	Value	Reason
Sep-11-2020 16:13:51 (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
Sep-11-2020 16:13:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Sponsor-</b> 113 <b>Defined Identifier:</b> <b>Test::</b> Choriogon adotropin Beta_PX11 3 <b>Result::</b> NEGATIVE	Initial Entry

090177e196ae40c3\Final\Final On: 01-Apr-2021 05:43 (GMT)

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

**Form Version:** 30-Jul-2020 21:27

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

**Site No:** 1141

**Site Name:** (1141) University of Iowa Hospital and Clinics

**Subject No:** 11411113

**Subject Initials:** ---

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

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

			<b>Not Done</b> ::	
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**6.a Sponsor ID:**

Date	Location	User	Value	Reason
Sep-11-2020 16:13:51 (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
Sep-11-2020 16:13:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [Redacted]	<b>Data Entry:</b> Choriogonadotropin Beta_PX113	Initial Entry

**6.a Result:**

Date	Location	User	Value	Reason
Sep-11-2020 16:13:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [Redacted]	<b>Data Entry:</b> NEGATIVE	Initial Entry

090177e196ae40c3\Final\Final On: 01-Apr-2021 05:43 (GMT)

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1141

**Subject No:** 11411113

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

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

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

**Site Name:** (1141) University of Iowa Hospital and Clinics

**Subject Initials:** ---

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

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**1. Data Origin**

Date	Location	User	Value	Reason
Sep-11-2020 13:26:39 (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
Sep-11-2020 13:26:39 (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
Sep-11-2020 13:26:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Sep-11-2020 13:26:39	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is

090177e196ae40c3\Final\Final On: 01-Apr-2021 05:43 (GMT)

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

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

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

**Site No:** 1141

**Site Name:** (1141) University of Iowa Hospital and Clinics

**Subject No:** 11411113

**Subject Initials:** ---

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

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

(UTC-06:00) Central Time (US & Canada)				Yes, however no barcodes are entered. Please review and correct as appropriate.
Sep-11-2020 13:26:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	<b>Data Entry:</b> YES Date of Collection:  Sep/11/2020	Initial Entry

**5.a**

Date	Location	User	Value	Reason
Sep-11-2020 13:26:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	<b>Data Entry:</b> <b>Sample ID</b> BM6HX : T	Initial Entry

**5.a Sample ID**

Date	Location	User	Value	Reason
Sep-11-2020 13:26:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	<b>Data Entry:</b> BM6HXT	Initial Entry

090177e196ae40c3\Final\Final On: 01-Apr-2021 05:43 (GMT)

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1141

**Subject No:** 11411113

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

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

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

**Site Name:** (1141) University of Iowa Hospital and Clinics

**Subject Initials:** ---

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

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

Date	Location	User	Value	Reason
Sep-11-2020 16:14:25 (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
Sep-11-2020 16:14:25 (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
Sep-11-2020 16:14:25 (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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090177e196ae40c3\Final\Final On: 01-Apr-2021 05:43 (GMT)

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

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

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

**Site No:** 1141

**Site Name:** (1141) University of Iowa Hospital and Clinics

**Subject No:** 11411113

**Subject Initials:** ---

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

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

Sep-11-2020 16:14:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sep/11/2020 13:49	Initial Entry
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**5. Anatomical Location:**

Date	Location	User	Value	Reason
Sep-11-2020 16:14:25 (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
Sep-11-2020 16:14:25 (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
Sep-11-2020 16:14:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> INTRAMUSCULAR	Initial Entry

090177e196ae40c3\Final\Final On: 01-Apr-2021 05:43 (GMT)



**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1141

**Subject No:** 11411113

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

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

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

**Site Name:** (1141) University of Iowa Hospital and Clinics

**Subject Initials:** ---

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

**10. Timeframe Subject Was Observed**

Date	Location	User	Value	Reason
Sep-11-2020 16:14:25 (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
Sep-11-2020 16:14:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [Redacted] [Redacted]	<b>Data Entry:</b> YES	Initial Entry

090177e196ae40c3\Final\Final On: 01-Apr-2021 05:43 (GMT)

**Header Text:** c4591001

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

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

**Site No:** 1141 **Site Name:** (1141) University of Iowa Hospital and Clinics

**Subject No:** 11411113 **Subject Initials:** ---

**Generated By:** (b) (4) **Generated Time (GMT):** 29-Mar-2021 11:44

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*1. Date of Visit*

Date	Location	User	Value	Reason
Oct-09-2020 10:23:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Oct/9/2020	Initial Entry

090177e196ae40c3\Final\Final On: 01-Apr-2021 05:43 (GMT)

**Header Text:** c4591001

**Visit:** V3\_MONTH1\_POSTVAX2\_L **Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF Audit Trail History

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

**Site No:** 1141 **Site Name:** (1141) University of Iowa Hospital and Clinics

**Subject No:** 11411113 **Subject Initials:** ---

**Generated By:** (b) (4) **Generated Time (GMT):** 29-Mar-2021 11:44

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**1. Data Origin**

Date	Location	User	Value	Reason
Oct-09-2020 10:23:35 (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
Oct-09-2020 10:23:35 (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-09-2020 15:08:46 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Oct-09-2020 10:23:35	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is

090177e196ae40c3\Final\Final On: 01-Apr-2021 05:43 (GMT)

**Header Text:** c4591001

**Visit:** V3\_MONTH1\_POSTVAX2\_L **Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF Audit Trail History

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

**Site No:** 1141 **Site Name:** (1141) University of Iowa Hospital and Clinics

**Subject No:** 11411113 **Subject Initials:** ---

**Generated By:** (b) (4) **Generated Time (GMT):** 29-Mar-2021 11:44

(UTC-06:00) Central Time (US & Canada)				Yes, however no barcodes are entered. Please review and correct as appropriate.
Oct-09-2020 10:23:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	<b>Data Entry:</b> YES Date of Collection:  Oct/9/2020	Initial Entry

**5.a**

Date	Location	User	Value	Reason
Oct-09-2020 15:08:46 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	<b>Data Entry:</b> Sample I BP9M6 D: D	Initial Entry

**5.a Sample ID**

Date	Location	User	Value	Reason
Oct-09-2020 15:08:46 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	<b>Data Entry:</b> BP9M6D	Initial Entry

**5.b**

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**Header Text:** c4591001

**Visit:** V3\_MONTH1\_POSTVAX2\_L **Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF Audit Trail History

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

**Site No:** 1141 **Site Name:** (1141) University of Iowa Hospital and Clinics

**Subject No:** 11411113 **Subject Initials:** ---

**Generated By:** (b) (4) **Generated Time (GMT):** 29-Mar-2021 11:44

Date	Location	User	Value	Reason
Oct-09-2020 15:08:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	<b>Data Entry:</b> Sample I BRX6Y D: L	Initial Entry

**5.b Sample ID**

Date	Location	User	Value	Reason
Oct-09-2020 15:08:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	<b>Data Entry:</b> BRX6YL	Initial Entry

**5.c**

Date	Location	User	Value	Reason
Oct-09-2020 15:09:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	<b>Data Entry:</b> Sample I BRX6Y D: M	Initial Entry

090177e196ae40c3\Final\Final On: 01-Apr-2021 05:43 (GMT)

**Header Text:** c4591001

**Visit:** V3\_MONTH1\_POSTVAX2\_L **Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF Audit Trail History

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

**Site No:** 1141 **Site Name:** (1141) University of Iowa Hospital and Clinics

**Subject No:** 11411113 **Subject Initials:** ---

**Generated By:** (b) (4) **Generated Time (GMT):** 29-Mar-2021 11:44

*5.c Sample ID*

Date	Location	User	Value	Reason
Oct-09-2020 15:09:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	<b>Data Entry:</b> BRX6YM	Initial Entry

**Header Text:** c4591001

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

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

**Site No:** 1141 **Site Name:** (1141) University of Iowa Hospital and Clinics

**Subject No:** 11411113 **Subject Initials:** ---

**Generated By:** (b) (4) **Generated Time (GMT):** 29-Mar-2021 11:44

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

Date	Location	User	Value	Reason
Oct-09-2020 10:23:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Oct/9/2020	Initial Entry

**2. Phase of Disposition:**

Date	Location	User	Value	Reason
Oct-09-2020 10:23:45 (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
Oct-09-2020 10:23:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> COMPLETED	Initial Entry

090177e196ae40c3\Final\Final On: 01-Apr-2021 05:43 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

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

**Form Status:**

**Site No:** 1141

**Site Name:** (1141) University of Iowa Hospital and Clinics

**Subject No:** 11411113

**Subject Initials:** ---

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

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

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Date	Location	User	Value	Reason
Nov-16-2020 15:03:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	



**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

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

**Form Status:**

**Site No:** 1141

**Site Name:** (1141) University of Iowa Hospital and Clinics

**Subject No:** 11411113

**Subject Initials:** ---

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

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

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Date	Location	User	Value	Reason
Nov-16-2020 15:05:33 (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, Frozen

**Site No:** 1141

**Site Name:** (1141) University of Iowa Hospital and Clinics

**Subject No:** 11411113

**Subject Initials:** ---

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

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

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**1. Category:**

Date	Location	User	Value	Reason
Nov-16-2020 15:03:48 (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
Nov-16-2020 15:03:48 (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
Nov-16-2020 15:03:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> injection site pain	Initial Entry

**4. Start Date Time:**

090177e196ae40c3\Final\Final On: 01-Apr-2021 05:43 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

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

**Form Status:** Data Complete, Frozen

**Site No:** 1141

**Site Name:** (1141) University of Iowa Hospital and Clinics

**Subject No:** 11411113

**Subject Initials:** ---

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

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

Date	Location	User	Value	Reason
Nov-16-2020 15:03:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sep/11/2020 18:00	Initial Entry

**5. Is the adverse event still ongoing?**

Date	Location	User	Value	Reason
Nov-16-2020 15:03:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO End Date Time:  Sep/14/2020 08:00	Initial Entry

**6. Toxicity Grade:**

Date	Location	User	Value	Reason
Nov-16-2020 15:03:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 1	Initial Entry

**7. Is the adverse event serious?**

**If Yes, NOTIFY PFIZER IMMEDIATELY.**

**Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization;**

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**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

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

**Form Status:** Data Complete, Frozen

**Site No:** 1141

**Site Name:** (1141) University of Iowa Hospital and Clinics

**Subject No:** 11411113

**Subject Initials:** ---

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

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

*Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).*

Date	Location	User	Value	Reason
Nov-16-2020 15:03:48 (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
Nov-16-2020 15:03:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**9. Is this event related to study treatment:**

Date	Location	User	Value	Reason
Nov-16-2020 15:03:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> RELATED	Initial Entry

**10. Latest Action Taken with Study Treatment:**

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**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

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

**Form Status:** Data Complete, Frozen

**Site No:** 1141

**Site Name:** (1141) University of Iowa Hospital and Clinics

**Subject No:** 11411113

**Subject Initials:** ---

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

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

Date	Location	User	Value	Reason
Nov-16-2020 15:03:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	<b>Data Entry:</b> NOT APPLICABLE	Initial Entry

**11. Was a Concomitant Medication given?**

Date	Location	User	Value	Reason
Nov-16-2020 15:03:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	<b>Data Entry:</b> NO	Initial Entry

**12. Was a Non-Drug Treatment given?**

Date	Location	User	Value	Reason
Nov-16-2020 15:03:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	<b>Data Entry:</b> NO	Initial Entry

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

Date	Location	User	Value	Reason
Nov-16-2020 15:03:48 (UTC-06:00)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	<b>Data Entry:</b> RECOVERED/RES OLVED	Initial Entry

090177e196ae40c3\Final\Final On: 01-Apr-2021 05:43 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

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

**Form Status:** Data Complete, Frozen

**Site No:** 1141

**Site Name:** (1141) University of Iowa Hospital and Clinics

**Subject No:** 11411113

**Subject Initials:** ---

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

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

Central Time (US & Canada)

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

Date	Location	User	Value	Reason
Nov-16-2020 15:03:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

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

**Form Status:** Data Complete, Frozen

**Site No:** 1141

**Site Name:** (1141) University of Iowa Hospital and Clinics

**Subject No:** 11411113

**Subject Initials:** ---

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

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

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**1. Category:**

Date	Location	User	Value	Reason
Nov-16-2020 15:05:33 (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
Nov-16-2020 15:05:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 2	Initial Entry

**3. Adverse Event:**

*(If possible specify diagnosis, not individual symptoms)*

Date	Location	User	Value	Reason
Nov-23-2020 11:52:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Svitlana Tonkovyd (b) (4)	Query 1: Closed	Response satisfies query
Nov-23-2020	ACV0PFEINFP6000	auto query	Query 1: Answered	New

090177e196ae40c3\Final\Final On: 01-Apr-2021 05:43 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

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

**Form Status:** Data Complete, Frozen

**Site No:** 1141

**Site Name:** (1141) University of Iowa Hospital and Clinics

**Subject No:** 11411113

**Subject Initials:** ---

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

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

11:00:18 (UTC-06:00) Central Time (US & Canada)		(autoquery)		Information
Nov-23-2020 11:00:18 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [redacted] [redacted]	<b>Data Entry:</b> swollen left axillary lymph node	New Information
Nov-23-2020 02:58:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [redacted] [redacted]	Query 1: Opened	GPDCLIN: Please update the verbatim term to include if swollen axillary lymph node is left, right or bilateral. Thank you.
Nov-19-2020 20:34:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Patricia Banhero [redacted] (b) (4)	Query 1: Candidate	GPDCLIN: Please update the verbatim term to include if swollen axillary lymph node is left, right or bilateral. Thank you.

090177e196ae40c3\Final\Final On: 01-Apr-2021 05:43 (GMT)



**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

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

**Form Status:** Data Complete, Frozen

**Site No:** 1141

**Site Name:** (1141) University of Iowa Hospital and Clinics

**Subject No:** 11411113

**Subject Initials:** ---

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

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

Nov-16-2020 15:05:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> swollen axillary lymph node	Initial Entry
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**4. Start Date Time:**

Date	Location	User	Value	Reason
Nov-16-2020 15:05:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sep/12/2020 08:00	Initial Entry

**5. Is the adverse event still ongoing?**

Date	Location	User	Value	Reason
Nov-16-2020 15:05:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO End Date Time:  Sep/14/2020 08:00	Initial Entry

**6. Toxicity Grade:**

Date	Location	User	Value	Reason
Nov-16-2020 15:05:33 (UTC-06:00)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 1	Initial Entry

090177e196ae40c3\Final\Final On: 01-Apr-2021 05:43 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

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

**Form Status:** Data Complete, Frozen

**Site No:** 1141

**Site Name:** (1141) University of Iowa Hospital and Clinics

**Subject No:** 11411113

**Subject Initials:** ---

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

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

Central Time (US & Canada)

**7. Is the adverse event serious?**

**If Yes, NOTIFY PFIZER IMMEDIATELY.**

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

Date	Location	User	Value	Reason
Nov-16-2020 15:05:33 (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
Nov-16-2020 15:05:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**9. Is this event related to study treatment:**

Date	Location	User	Value	Reason
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090177e196ae40c3\Final\Final On: 01-Apr-2021 05:43 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

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

**Form Status:** Data Complete, Frozen

**Site No:** 1141

**Site Name:** (1141) University of Iowa Hospital and Clinics

**Subject No:** 11411113

**Subject Initials:** ---

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

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

Nov-16-2020 15:05:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	<b>Data Entry:</b> RELATED	Initial Entry
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**10. Latest Action Taken with Study Treatment:**

Date	Location	User	Value	Reason
Nov-16-2020 15:05:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	<b>Data Entry:</b> NOT APPLICABLE	Initial Entry

**11. Was a Concomitant Medication given?**

Date	Location	User	Value	Reason
Nov-16-2020 15:05:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	<b>Data Entry:</b> NO	Initial Entry

**12. Was a Non-Drug Treatment given?**

Date	Location	User	Value	Reason
Nov-16-2020 15:05:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	<b>Data Entry:</b> NO	Initial Entry

090177e196ae40c3\Final\Final On: 01-Apr-2021 05:43 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

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

**Form Status:** Data Complete, Frozen

**Site No:** 1141

**Site Name:** (1141) University of Iowa Hospital and Clinics

**Subject No:** 11411113

**Subject Initials:** ---

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

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

& Canada)

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

Date	Location	User	Value	Reason
Nov-16-2020 15:05:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> RECOVERED/RES OLVED	Initial Entry

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

Date	Location	User	Value	Reason
Nov-16-2020 15:05:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

090177e196ae40c3\Final\Final On: 01-Apr-2021 05:43 (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:** 1141      **Site Name:** (1141) University of Iowa Hospital and  
Clinics

**Subject No:** 11411113      **Subject Initials:** ---

**Generated By:** (b) (4)      **Generated Time (GMT):** 29-Mar-2021 11:44

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*1. Date of Visit*

Date	Location	User	Value	Reason
Feb-18-2021 10:14:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Feb/8/2021	Initial Entry

090177e196ae40c3\Final\Final On: 01-Apr-2021 05:43 (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:** 1141 **Site Name:** (1141) University of Iowa Hospital and  
Clinics

**Subject No:** 11411113 **Subject Initials:** ---

**Generated By:** (b) (4) **Generated Time (GMT):** 29-Mar-2021 11:44

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

Date	Location	User	Value	Reason
Feb-19-2021 09:24:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Feb-18-2021 21:23:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	The response indicates participant was unblinded, however the TREATMENT UNBLINDED date is missing in the DISP visit. Please complete this date.
Feb-18-2021 10:14:20 (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

090177e196ae40c3\Final\Final On: 01-Apr-2021 05:43 (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:** 1141 **Site Name:** (1141) University of Iowa Hospital and  
Clinics

**Subject No:** 11411113 **Subject Initials:** ---

**Generated By:** (b) (4) **Generated Time (GMT):** 29-Mar-2021 11:44

				visit. Please complete this date.
Feb-18-2021 10:14:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	<b>Data Entry:</b> Participant is willing to return for Vaccination 3 Participant is:  eligible and NOT confirmed to have received only placebo at Vaccination 1/2	Initial Entry

090177e196ae40c3\Final\Final On: 01-Apr-2021 05:43 (GMT)

**Header Text:** c4591001

**Visit:** Disposition - Unscheduled

**Form:** TREATMENT UNBLINDED - eCRF Audit Trail History

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

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

**Site No:** 1141

**Site Name:** (1141) University of Iowa Hospital and Clinics

**Subject No:** 11411113

**Subject Initials:** ---

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

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

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**1. Date Treatment Unblinded :**

Date	Location	User	Value	Reason
Feb-19-2021 09:24:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Feb/8/2021	Initial Entry

**2. Primary Reason for Unblinding:**

Date	Location	User	Value	Reason
Feb-19-2021 09:24:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> ASSESS ELIGIBILIT Y FOR ADDITIONAL VACCINATION	Initial Entry

090177e196ae40c3\Final\Final On: 01-Apr-2021 05:43 (GMT)



**Header Text:** c4591001

**Visit:** Subject Status - Unscheduled

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

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

**Form Status:** Data Complete, Verified

**Site No:** 1141

**Site Name:** (1141) University of Iowa Hospital and Clinics

**Subject No:** 11411113

**Subject Initials:** ---

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

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

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**1. Subject Status**

Date	Location	User	Value	Reason
Oct-09-2020 10:23:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> FOLLOW-UP	Initial Entry
Aug-20-2020 21:10:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> ENROLLED/RANDOMIZED	Initial Entry
Aug-20-2020 17:53:02 (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
Oct-09-2020 10:23:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> Oct/9/2020	Initial Entry
Aug-20-2020	ACV0PFEINFP6000	auto calc	<b>Data Entry:</b>	Initial Entry

090177e196ae40c3\Final\Final On: 01-Apr-2021 05:43 (GMT)

**Header Text:** c4591001

**Visit:** Subject Status - Unscheduled

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

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

**Form Status:** Data Complete, Verified

**Site No:** 1141

**Site Name:** (1141) University of Iowa Hospital and Clinics

**Subject No:** 11411113

**Subject Initials:** ---

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

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

21:10:08 (UTC-06:00) Central Time (US & Canada)		(autocalc)	Aug/20/2020	
Aug-20-2020 17:53:02 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> Aug/20/2020	Initial Entry

**Header Text:** c4591001

**Visit:** Investigator Signature -  
Unscheduled

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

**Site No:** 1141

**Subject No:** 11411113

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

**Form:** CASEBOOK SIGNATURE FORM - eCRF Audit  
Trail History

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

**Site Name:** (1141) University of Iowa Hospital and  
Clinics

**Subject Initials:** ---

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

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*1. Casebook Signature*

Date	Location	User	Value	Reason
Oct-22-2020 09:02:32 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Click Here to Enable	Initial Entry

090177e196ae40c3\Final\Final On: 01-Apr-2021 05:43 (GMT)