

**Header Text:** c4591001

**Visit:** COHORT\_SELECTION

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

**Site No:** 1141

**Subject No:** 11411221

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

**Form:** COHORT\_SELECTION

**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](#)

**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

090177e196ae4091\Final\Final On: 01-Apr-2021 05:42 (GMT)

**Header Text:** c4591001

**Visit:** COHORT\_SELECTION

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

**Site No:** 1141

**Subject No:** 11411221

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

**Form:** MAIN INFORMED CONSENT

**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](#)

**Informed Consent**

1.	Consent Was:	OBTAINED Date Written Consent Obtained Sep/16/2020
----	--------------	--

**Header Text:** c4591001

**Visit:** COHORT\_SELECTION

**Form:** DEMOGRAPHY

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

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

**Site No:** 1141

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

**Subject No:** 11411221

**Subject Initials:** ---

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

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

[eCRF Audit Trail History](#)

**Demography**

1.	Subject ID	[11411221]
2.	Birth Date:	(b) (6)/1974
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:	

**Header Text:** c4591001

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

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

**Site No:** 1141

**Subject No:** 11411221

**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	Sep/16/2020
2.	Erroneous Visit	

**Header Text:** c4591001

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

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

**Site No:** 1141

**Subject No:** 11411221

**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
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**Exclusion Criteria Met**

2.	Description of Exclusion Criterion Met	Not Applicable
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090177e196ae4091\Final\Final On: 01-Apr-2021 05:42 (GMT)

**Header Text:** c4591001

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

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

**Site No:** 1141

**Subject No:** 11411221

**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	Sep/16/2020
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:** 11411221

**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:	[Endometrial Ablation]
	Start Date:	UNK/UNK/2012
	Ongoing:	NO End Date: UNK/UNK/2012
1.b	Line/MH Number:	[2]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Post Menopausal]
	Start Date:	UNK/UNK/2012
	Ongoing:	YES
1.c	Line/MH Number:	[3]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Appendectomy]
	Start Date:	May/UNK/2012
	Ongoing:	NO End Date: May/UNK/2012

090177e196ae4091\Final\Final On: 01-Apr-2021 05:42 (GMT)

**Header Text:** c4591001

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

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

**Site No:** 1141

**Subject No:** 11411221

**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

1.d	Line/MH Number:	[4]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Appendicitis]
	Start Date:	May/UNK/2012
	Ongoing:	NO End Date: May/UNK/2012



**Header Text:** c4591001

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

**Form:** VITAL SIGNS - BASELINE

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

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

**Site No:** 1141

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

**Subject No:** 11411221

**Subject Initials:** ---

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

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

[eCRF Audit Trail History](#)

**Vital Signs**

1.	Date:	Sep/16/2020
2.	Weight:	[72.6]
3.	Unit:	kg
4.	Height:	[159.8]
5.	Unit:	cm
6.	Body Mass Index:	[28.4]

**Vital Signs Details**

7.a	Record Identifier:	1
	Temperature:	[98.7]
	Unit:	F
	Temperature Location:	ORAL CAVITY

090177e196ae4091\Final\Final On: 01-Apr-2021 05:42 (GMT)

**Header Text:** c4591001

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

**Form:** LAB URINALYSIS - PREGNANCY TEST

**Form Version:** 15-Sep-2020 21:51

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

**Site No:** 1141

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

**Subject No:** 11411221

**Subject Initials:** ---

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

**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/16/2020
4.	Laboratory Name and Address (Derived)	[STUDY SITE]
5.	Specimen Type:	URINE

**Lab Result**

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

090177e196ae4091\Final\Final On: 01-Apr-2021 05:42 (GMT)

**Header Text:** c4591001

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

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

**Site No:** 1141

**Subject No:** 11411221

**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 :	Sep/16/2020
2.	Randomization Number:	[91630]
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:** 11411221

**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: Sep/16/2020
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	[BM6HZW]
5.b	Sample ID	[BLC9J4]
5.c	Sample ID	[BLC9J5]

**Header Text:** c4591001

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

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

**Site No:** 1141

**Subject No:** 11411221

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

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

**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](#)

**Electronic Sample Tracking**

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Sep/16/2020
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	[BM6HZS]
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090177e196ae4091\Final\Final On: 01-Apr-2021 05:42 (GMT)

**Header Text:** c4591001

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

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

**Site No:** 1141

**Subject No:** 11411221

**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:	Sep/16/2020 15:19
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

090177e196ae4091\Final\Final On: 01-Apr-2021 05:42 (GMT)

**Header Text:** c4591001

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

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

**Site No:** 1141

**Subject No:** 11411221

**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
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090177e196ae4091\Final\Final On: 01-Apr-2021 05:42 (GMT)

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1141

**Subject No:** 11411221

**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	Oct/7/2020
2.	Erroneous Visit	



**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1141

**Subject No:** 11411221

**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:	Oct/7/2020
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**Vital Signs Details**

2.a	Record Identifier:	1
	Temperature:	[96.7]
	Unit:	F
	Temperature Location:	ORAL CAVITY

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

**Form Version:** 15-Sep-2020 21:51

**Site No:** 1141

**Subject No:** 11411221

**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:	Oct/7/2020
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:	

090177e196ae4091\Final\Final On: 01-Apr-2021 05:42 (GMT)

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1141

**Subject No:** 11411221

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

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

**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](#)

**Electronic Sample Tracking**

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Oct/7/2020
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[ ]

**Aliquot**

Please enter barcode for each aliquot.

5.a	Sample ID	[BP9M5N]
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090177e196ae4091\Final\Final On: 01-Apr-2021 05:42 (GMT)

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1141

**Subject No:** 11411221

**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:	Oct/7/2020 15:10
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

090177e196ae4091\Final\Final On: 01-Apr-2021 05:42 (GMT)

**Header Text:** c4591001

**Visit:** V3\_MONTH1\_POSTVAX2\_L

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

**Site No:** 1141

**Subject No:** 11411221

**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	Nov/11/2020
2.	Erroneous Visit	

**Header Text:** c4591001

**Visit:** V3\_MONTH1\_POSTVAX2\_L

**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

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

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

**Site No:** 1141

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

**Subject No:** 11411221

**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: Nov/11/2020
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[ ]

**Aliquot**

Please enter barcode for each aliquot.

5.a	Sample ID	[BP9MF2]
5.b	Sample ID	[BRX788]
5.c	Sample ID	[BRX789]

090177e196ae4091\Final\Final On: 01-Apr-2021 05:42 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled  
Visit on Dec/22/2020

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

**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:** 11411221

**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	Dec/22/2020
2.	Erroneous Visit	

**COVID-19 Illness Visit**

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

**Visit:** POT\_COVID\_ILL 1 - Unscheduled  
Visit on Dec/22/2020

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

**Form Version:** 10-Dec-2020 02:29

**Form Status:** Data Complete

**Site No:** 1141

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

**Subject No:** 11411221

**Subject Initials:** ---

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

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

[eCRF Audit Trail History](#)

**Signs and Symptoms**

1.	Date of Assessment:	Dec/22/2020
2.	Date of First Symptom Started:	Dec/21/2020
3.	Symptoms Ongoing?	NO
	Date of Last Symptom Resolved:	Jan/2/2021

**Symptoms**

4.a	Symptoms:	FEVER
	Was symptom present?	YES
4.b	Symptoms:	NEW OR INCREASED COUGH
	Was symptom present?	NO
4.c	Symptoms:	NEW OR INCREASED SHORTNESS OF BREATH
	Was symptom present?	NO
4.d	Symptoms:	CHILLS
	Was symptom present?	YES
4.e	Symptoms:	NEW OR INCREASED MUSCLE PAIN
	Was symptom present?	YES
4.f	Symptoms:	NEW LOSS OF TASTE OR SMELL
	Was symptom present?	NO
4.g	Symptoms:	NEW OR INCREASED SORE THROAT
	Was symptom present?	NO
4.h	Symptoms:	DIARRHEA
	Was symptom present?	NO

090177e196ae4091\Final\Final On: 01-Apr-2021 05:42 (GMT)



**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled  
Visit on Dec/22/2020

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

**Form Version:** 10-Dec-2020 02:29

**Form Status:** Data Complete

**Site No:** 1141

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

**Subject No:** 11411221

**Subject Initials:** ---

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

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

4.i	Symptoms:	VOMITING
	Was symptom present?	NO

**Symptoms - Other**

5.a	Symptoms - Other Text:	[rhinorrhea]
5.b	Symptoms - Other Text:	[foggy thinking]
5.c	Symptoms - Other Text:	[nausea]
5.d	Symptoms - Other Text:	[headache]

090177e196ae4091\Final\Final On: 01-Apr-2021 05:42 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1

**Form:** MICROBIOLOGY SPECIMEN

**Form Version:** 06-Jul-2020 21:54

**Site No:** 1141

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

**Subject No:** 11411221

**Subject Initials:** ---

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

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

#	Date of Collection	Specimen Type	Specimen Collection Location	Assay Code and Description	Device Type	Form Instance
1.	Dec/22/2020	SWABBED MATERIAL	NASOPHARYNX	SEVERE ACUTE RESP SYNDROME CORONAVIRUS 2	SARS-COV-2 DIAGNOSTIC TEST	<a href="#">Repeating Pages</a>

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled  
Visit on Dec/22/2020

**Form:** MICROBIOLOGY SPECIMEN

**Form Version:** 06-Jul-2020 21:54

**Form Status:** Data Complete

**Site No:** 1141

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

**Subject No:** 11411221

**Subject Initials:** ---

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

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

[Back to Form](#)

[eCRF Audit Trail History](#)

[Form Audit Trail](#)

**Microbiology Specimen**

1.	Actual Date of Collection:	Dec/22/2020
2.	Specimen Type:	SWABBED MATERIAL
3.	Specimen Collection Location:	NASOPHARYNX
4.	Assay Code and Description:	SEVERE ACUTE RESP SYNDROME CORONAVIRUS 2
5.	Device Type:	SARS-COV-2 DIAGNOSTIC TEST
6.	Trade Name:	OTHER
7.	Test Result:	POSITIVE
8.	Comments/Findings/Details:	[ ]
9.	Trade Name Other, Specify:	[NALT UNKNOWN]

090177e196ae4091\Final\Final On: 01-Apr-2021 05:42 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled  
Visit on Dec/22/2020

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

**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:** 11411221

**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_SELF
3.	Sample Collected?	YES Date of Collection: Dec/22/2020
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	[RW87825]
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090177e196ae4091\Final\Final On: 01-Apr-2021 05:42 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled  
Visit on Dec/22/2020

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

**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:** 11411221

**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?	NO
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[Swab not collected.]

**Aliquot**

Please enter barcode for each aliquot.

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

090177e196ae4091\Final\Final On: 01-Apr-2021 05:42 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled  
Visit on Dec/22/2020

**Form:** HEALTH CARE UTILIZATION

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

**Form Status:** Data Complete

**Site No:** 1141

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

**Subject No:** 11411221

**Subject Initials:** ---

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

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

[eCRF Audit Trail History](#)

**Health Care Utilization**

1.a	Physician or Healthcare Professional:	SPECIALIST
	Occurrence of Visits or Contacts:	NO
1.b	Physician or Healthcare Professional:	EMERGENCY ROOM
	Occurrence of Visits or Contacts:	NO
1.c	Physician or Healthcare Professional:	PRIMARY CARE PHYSICIAN
	Occurrence of Visits or Contacts:	NO
1.d	Physician or Healthcare Professional:	URGENT CARE
	Occurrence of Visits or Contacts:	NO
1.e	Physician or Healthcare Professional:	TELEPHONE CONSULTATION
	Occurrence of Visits or Contacts:	YES Number of Visits or Contacts: [1]
1.f	Physician or Healthcare Professional:	OTHER
	Occurrence of Visits or Contacts:	YES Number of Visits or Contacts: [1]

**Health Care Utilization Other**

090177e196ae4091\Final\Final On: 01-Apr-2021 05:42 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled  
Visit on Dec/22/2020

**Form:** HEALTH CARE UTILIZATION

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

**Form Status:** Data Complete

**Site No:** 1141

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

**Subject No:** 11411221

**Subject Initials:** ---

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

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

2.	Other Type of Practitioner Specify:	[Franklin General Hospital]
----	--	-----------------------------

**Health Care Utilization**

3.	Has the subject been hospitalized due to potential COVID-19 illness?	NO
----	--	----

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1

**Form:** RESPIRATORY TREATMENT

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

**Site No:** 1141

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

**Subject No:** 11411221

**Subject Initials:** ---

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

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

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



**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled  
Visit on Dec/22/2020

**Form:** RESPIRATORY TREATMENT

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

**Form Status:** Not Started

**Site No:** 1141

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

**Subject No:** 11411221

**Subject Initials:** ---

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

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

[Back to Form](#)

**Respiratory Treatment**

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

090177e196ae4091\Final\Final On: 01-Apr-2021 05:42 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled  
Visit on Dec/22/2020

**Form:** ILLNESS DETAILS

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

**Form Status:** Data Complete

**Site No:** 1141

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

**Subject No:** 11411221

**Subject Initials:** ---

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

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

[eCRF Audit Trail History](#)

**Illness Details**

1.	Category of Clinical Event:	POTENTIAL COVID-19 ILLNESS
2.	Was a diagnosis obtained for Potential COVID-19 Illness?	YES Respiratory Illness Diagnosis: [COVID-19]  Date of Diagnosis: Dec/22/2020
3.	Toxicity Grade:	2

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1

**Form:** ILLNESS DETAILS - SEVERE

**Form Version:** 17-Jul-2020 21:55

**Site No:** 1141

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

**Subject No:** 11411221

**Subject Initials:** ---

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

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

#	Category of Clinical Event:	Subcategory of Clinical Event	Diagnosis Obtained	Toxicity Grade	Form Instance
1.					<a href="#">Repeating Pages</a>

090177e196ae4091\Final\Final On: 01-Apr-2021 05:42 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled  
Visit on Dec/22/2020

**Form:** ILLNESS DETAILS - SEVERE

**Form Version:** 17-Jul-2020 21:55

**Form Status:** Not Started

**Site No:** 1141

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

**Subject No:** 11411221

**Subject Initials:** ---

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

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

[Back to Form](#)

**Illness Details**

1.	Category of Clinical Event:	
2.	Subcategory of Clinical Event:	
3.	Was a diagnosis obtained?	
4.	Toxicity Grade:	

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1

**Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY

**Form Version:** 15-Sep-2020 21:51

**Site No:** 1141

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

**Subject No:** 11411221

**Subject Initials:** ---

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

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

#	Category for Lab Test	Vendor Name	Collection Date:	Specimen Type	Lab Result			Form Instance
1.					Sponsor-Defined Identifier	Test:	Result:	<a href="#">Repeating Pages</a>

090177e196ae4091\Final\Final On: 01-Apr-2021 05:42 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled  
Visit on Dec/22/2020

**Form:** LOCAL LABORATORY DATA - REPEATING  
CHEMISTRY

**Form Version:** 15-Sep-2020 21:51

**Form Status:** Not Started

**Site No:** 1141

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

**Subject No:** 11411221

**Subject Initials:** ---

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

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

[Back to Form](#)

**Lab Chemistry Details**

1.	Lab Panel:	
2.	Laboratory Name and Address	[ ]
3.	Collection Date:	//
4.	Specimen Type:	

**Lab Result**

5.	Sponsor ID:	[ ]
	Test:	
	Result:	[ ]
	Not Done:	
	LNMT	Low [ ] High [ ] Unit

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1

**Form:** LOCAL LABORATORY DATA - REPEATING Hematology

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

**Site No:** 1141

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

**Subject No:** 11411221

**Subject Initials:** ---

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

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

#	Category for Lab Test	Vendor Name (DERIVED)	Collection Date:	Specimen Type	Lab Result			Form Instance
1.					Sponsor-Defined Identifier	Test:	Result:	<a href="#">Repeating Pages</a>

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled  
Visit on Dec/22/2020

**Form:** LOCAL LABORATORY DATA - REPEATING Hematology

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

**Form Status:** Not Started

**Site No:** 1141

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

**Subject No:** 11411221

**Subject Initials:** ---

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

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

[Back to Form](#)

**Laboratory Data Hematology**

1.	Lab Panel:	
2.	Laboratory Name and Address	[ ]
3.	Collection Date:	//
4.	Specimen Type:	

**Lab Result**

5.	Sponsor ID:	[ ]
	Test:	
	Result:	[ ]
	Not Done:	
	LNMT	Low [ ] High [ ] Unit

090177e196ae4091\Final\Final On: 01-Apr-2021 05:42 (GMT)



**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1

**Form:** VITAL SIGNS - COVID

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

**Site No:** 1141

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

**Subject No:** 11411221

**Subject Initials:** ---

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

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

#	Date:	Vital Signs Details			Form Instance
1.		<b>Record Identifier:</b>	<b>Systolic:</b>	<b>Diastolic:</b>	<a href="#">Repeating Pages</a>

090177e196ae4091\Final\Final On: 01-Apr-2021 05:42 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled  
Visit on Dec/22/2020

**Form:** VITAL SIGNS - COVID

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

**Form Status:** Not Started

**Site No:** 1141

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

**Subject No:** 11411221

**Subject Initials:** ---

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

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

[Back to Form](#)

**Vital Signs**

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

**Vital Signs Details**

2.	Record Identifier:	
	Systolic:	[ ]
	Diastolic:	[ ]
	Respiratory Rate in respirations/minute:	[ ]
	Heart Rate in beats/minute:	[ ]

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1

**Form:** VITAL SIGNS - PULSE OX ROOM AIR

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

**Site No:** 1141

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

**Subject No:** 11411221

**Subject Initials:** ---

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

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

#	Date:	Vital Signs Details		Form Instance
1.		<b>Record Identifier:</b>	<b>Oxygen Saturation</b>	<a href="#">Repeating Pages</a>

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled  
Visit on Dec/22/2020

**Form:** VITAL SIGNS - PULSE OX ROOM AIR

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

**Form Status:** Not Started

**Site No:** 1141

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

**Subject No:** 11411221

**Subject Initials:** ---

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

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

[Back to Form](#)

**Vital Signs**

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

**Vital Signs Details**

2.	Record Identifier:	
	SPO2 Pulse Oximetry %	[ ]

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1

**Form:** OXYGENATION PARAMETERS

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

**Site No:** 1141

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

**Subject No:** 11411221

**Subject Initials:** ---

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

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

#	Date Time of Assessment	Arterial Blood Gases PaO <sub>2</sub>	FiO <sub>2</sub> (Fraction of Inhaled Oxygen)	Form Instance
1.				<a href="#">Repeating Pages</a>

090177e196ae4091\Final\Final On: 01-Apr-2021 05:42 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled  
Visit on Dec/22/2020

**Form:** OXYGENATION PARAMETERS

**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:** 11411221

**Subject Initials:** ---

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

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

[Back to Form](#)

**Oxygenation Parameters**

1.	Date Time of Assessment:	//
2.	Arterial Blood Gases PaO2 (mmHg):	[ ]
3.	FiO2 (Fraction of Inhaled Oxygen):	[ ]

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1

**Form:** CONCOMITANT MEDICATIONS - VASOPRESSORS

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

**Site No:** 1141

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

**Subject No:** 11411221

**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>

090177e196ae4091\Final\Final On: 01-Apr-2021 05:42 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled  
Visit on Dec/22/2020

**Form:** CONCOMITANT MEDICATIONS - VASOPRESSORS

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

**Form Status:** Not Started

**Site No:** 1141

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

**Subject No:** 11411221

**Subject Initials:** ---

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

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

[Back to Form](#)

**Concomitant Medications**

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

090177e196ae4091\Final\Final On: 01-Apr-2021 05:42 (GMT)



**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1

**Form:** IMAGING

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

**Site No:** 1141

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

**Subject No:** 11411221

**Subject Initials:** ---

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

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

#	Date of Assessment	Location of Assessment	Imaging Method	Overall Assessment	Form Instance
1.					<a href="#">Repeating Pages</a>

090177e196ae4091\Final\Final On: 01-Apr-2021 05:42 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled

**Form:** IMAGING

Visit on Dec/22/2020

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

**Form Status:** Not Started

**Site No:** 1141

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

**Subject No:** 11411221

**Subject Initials:** ---

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

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

[Back to Form](#)

**Imaging**

1.	Date of Assessment:	//
2.	Location of Assessment:	
3.	Type of Imaging Exam:	
4.	Assessment:	

**Header Text:** c4591001

**Visit:** POT\_COVID\_CONVA 1 -  
Unscheduled Visit on Jan/20/2021

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

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

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

**Site No:** 1141

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

**Subject No:** 11411221

**Subject Initials:** ---

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

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

[eCRF Audit Trail History](#)

**Date of Visit**

1.	Date of Visit	Jan/20/2021
2.	Erroneous Visit	

**COVID-19 Illness Visit**

3.	COVID-19 Illness Visit:	COVID_A1
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**Header Text:** c4591001

**Visit:** POT\_COVID\_CONVA 1 -  
Unscheduled Visit on Jan/20/2021

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

**Site No:** 1141

**Subject No:** 11411221

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

**Form:** ELECTRONIC SAMPLE TRACKING -  
IMMUNOGENICITY

**Form Status:** Data Complete, 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](#)

**Electronic Sample Tracking**

1.	Data Origin	SITE
2.	Sample Type	SERUM
3.	Sample Collected?	YES Date of Collection: Jan/20/2021
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[ ]

**Aliquot**

Please enter barcode for each aliquot.

5.a	Sample ID	[BLFZ52]
5.b	Sample ID	[BLFZ51]
5.c	Sample ID	[BP9LZZ]

**Header Text:** c4591001

**Visit:** POT\_COVID\_REPEAT\_SWAB - New **Form:** DATE OF VISIT - REPEAT SWAB  
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:** 11411221

**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:	
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**Header Text:** c4591001

**Visit:** POT\_COVID\_REPEAT\_SWAB - New **Form:** ELECTRONIC SAMPLE TRACKING - REPEAT SWAB  
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:** 11411221

**Subject Initials:** ---

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

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

**Electronic Sample Tracking**

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

**Aliquot**

Please enter barcode for each aliquot.

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

**Visit:** Unplanned - New Unscheduled Visit

**Form:** DATE OF VISIT

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

**Form Status:** Not Started

**Site No:** 1141

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

**Subject No:** 11411221

**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:** 11411221

**Subject Initials:** ---

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

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

**Unplanned Assessments**

1.	Assessments	
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Header Text: c4591001

Visit: Logs

Form: ADVERSE EVENT REPORT

Form Version: 22-Apr-2020 21:02

Site No: 1141

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

Subject No: 11411221

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	Fever (100.9 F)	Jan/21/2021 12:00	NO End Date Time: Jan/22/2021 12:00	<a href="#">Repeating Pages</a>
2.	ADVERSE EVENT	2	chills	Jan/21/2021 12:00	NO End Date Time: Jan/22/2021 21:00	<a href="#">Repeating Pages</a>
3.	ADVERSE EVENT	3	Fatigue	Jan/21/2021 12:00	NO End Date Time: Jan/22/2021 21:00	<a href="#">Repeating Pages</a>
4.	ADVERSE EVENT	4	left axillary lymph node enlargement	Jan/23/2021 10:00	NO End Date Time: Jan/25/2021 05:00	<a href="#">Repeating Pages</a>
5.	ADVERSE EVENT	5	headache	Feb/11/2021 07:00	NO End Date Time: Feb/12/2021 12:00	<a href="#">Repeating Pages</a>

090177e196ae4091\Final\Final On: 01-Apr-2021 05:42 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1141

**Subject No:** 11411221

**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

[Back to Form](#)  
[eCRF Audit Trail History](#)  
[Form Audit Trail](#)

**Adverse Event Report**

1.	Category:	ADVERSE EVENT
2.	AE ID:	[1]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[Fever (100.9 F)]
4.	Start Date Time:	Jan/21/2021 12:00
5.	Is the adverse event still ongoing?	NO End Date Time: Jan/22/2021 12:00
6.	Toxicity Grade:	1
7.	Is the adverse event serious?  If Yes, NOTIFY PFIZER IMMEDIATELY.  Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).	NO
8.	Is this adverse event the result of a study Medication Error? If Yes, record the type of medication error on the Medication Error Log.	NO
9.	Is this event related to study treatment:	RELATED

090177e196ae4091\Final\Final On: 01-Apr-2021 05:42 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1141

**Subject No:** 11411221

**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

10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE
11.	Was a Concomitant Medication given?	YES
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	[ ]

090177e196ae4091\Final\Final On: 01-Apr-2021 05:42 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1141

**Subject No:** 11411221

**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

[Back to Form](#)

[eCRF Audit Trail History](#)

[Form Audit Trail](#)

**Adverse Event Report**

1.	Category:	ADVERSE EVENT
2.	AE ID:	[2]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[chills]
4.	Start Date Time:	Jan/21/2021 12:00
5.	Is the adverse event still ongoing?	NO End Date Time: Jan/22/2021 21:00
6.	Toxicity Grade:	1
7.	Is the adverse event serious?  If Yes, NOTIFY PFIZER IMMEDIATELY.  Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).	NO
8.	Is this adverse event the result of a study Medication Error? If Yes, record the type of medication error on the Medication Error Log.	NO
9.	Is this event related to study treatment:	RELATED

090177e196ae4091\Final\Final On: 01-Apr-2021 05:42 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1141

**Subject No:** 11411221

**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

10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE
11.	Was a Concomitant Medication given?	NO
12.	Was a Non-Drug Treatment given?	NO
13.	What was the outcome of this adverse event?:	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	[ ]

090177e196ae4091\Final\Final On: 01-Apr-2021 05:42 (GMT)

**Header Text:** c4591001**Visit:** Logs - Unscheduled**Form Version:** 22-Apr-2020 21:02**Site No:** 1141**Subject No:** 11411221**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[Back to Form](#)[eCRF Audit Trail History](#)[Form Audit Trail](#)**Adverse Event Report**

1.	Category:	ADVERSE EVENT
2.	AE ID:	[3]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[Fatigue]
4.	Start Date Time:	Jan/21/2021 12:00
5.	Is the adverse event still ongoing?	NO End Date Time: Jan/22/2021 21:00
6.	Toxicity Grade:	1
7.	Is the adverse event serious?  If Yes, NOTIFY PFIZER IMMEDIATELY.  Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).	NO
8.	Is this adverse event the result of a study Medication Error? If Yes, record the type of medication error on the Medication Error Log.	NO
9.	Is this event related to study treatment:	RELATED

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1141

**Subject No:** 11411221

**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

10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE
11.	Was a Concomitant Medication given?	NO
12.	Was a Non-Drug Treatment given?	NO
13.	What was the outcome of this adverse event?:	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	[ ]

090177e196ae4091\Final\Final On: 01-Apr-2021 05:42 (GMT)

**Header Text:** c4591001**Visit:** Logs - Unscheduled**Form Version:** 22-Apr-2020 21:02**Site No:** 1141**Subject No:** 11411221**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[Back to Form](#)[eCRF Audit Trail History](#)[Form Audit Trail](#)**Adverse Event Report**

1.	Category:	ADVERSE EVENT
2.	AE ID:	[4]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[left axillary lymph node enlargement]
4.	Start Date Time:	Jan/23/2021 10:00
5.	Is the adverse event still ongoing?	NO End Date Time: Jan/25/2021 05:00
6.	Toxicity Grade:	1
7.	Is the adverse event serious?  If Yes, NOTIFY PFIZER IMMEDIATELY.  Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).	NO
8.	Is this adverse event the result of a study Medication Error? If Yes, record the type of medication error on the Medication Error Log.	NO
9.	Is this event related to study treatment:	RELATED



**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1141

**Subject No:** 11411221

**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

10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE
11.	Was a Concomitant Medication given?	NO
12.	Was a Non-Drug Treatment given?	NO
13.	What was the outcome of this adverse event?:	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	[ ]

090177e196ae4091\Final\Final On: 01-Apr-2021 05:42 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1141

**Subject No:** 11411221

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

**Form:** ADVERSE EVENT REPORT

**Form Status:** Data Complete

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

**Subject Initials:** ---

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

[Back to Form](#)  
[eCRF Audit Trail History](#)  
[Form Audit Trail](#)

**Adverse Event Report**

1.	Category:	ADVERSE EVENT
2.	AE ID:	[5]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[headache]
4.	Start Date Time:	Feb/11/2021 07:00
5.	Is the adverse event still ongoing?	NO End Date Time: Feb/12/2021 12:00
6.	Toxicity Grade:	1
7.	Is the adverse event serious?  If Yes, NOTIFY PFIZER IMMEDIATELY.  Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).	NO
8.	Is this adverse event the result of a study Medication Error? If Yes, record the type of medication error on the Medication Error Log.	NO
9.	Is this event related to study treatment:	RELATED

090177e196ae4091\Final\Final On: 01-Apr-2021 05:42 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1141

**Subject No:** 11411221

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

**Form:** ADVERSE EVENT REPORT

**Form Status:** Data Complete

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

**Subject Initials:** ---

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

10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE
11.	Was a Concomitant Medication given?	NO
12.	Was a Non-Drug Treatment given?	NO
13.	What was the outcome of this adverse event?:	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	[ ]

090177e196ae4091\Final\Final On: 01-Apr-2021 05:42 (GMT)

**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:** 11411221

**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>

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1141

**Subject No:** 11411221

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

**Form:** MEDICATION ERROR

**Form Status:** Not Started

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

**Subject Initials:** ---

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

[Back to Form](#)

**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	[ ]

090177e196ae4091\Final\Final On: 01-Apr-2021 05:42 (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:** 11411221

**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.	1	VACCINATION S	NO	Influenza Vaccination	Oct/22/2020	<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:** Data Complete, Locked, Frozen, Verified

**Site No:** 1141

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

**Subject No:** 11411221

**Subject Initials:** ---

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

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

[Back to Form](#)

[eCRF Audit Trail History](#)

[Form Audit Trail](#)

**Concomitant Medications**

1.	What is the medication identifier?	[1]
2.	Category:	VACCINATIONS
3.	Concomitant Medications Pre-specified:	NO
4.	Medication:  Provide the complete generic drug name (including salt form, where applicable). Where generic name is unknown, enter the full trade or proprietary name. Include clarifying information in the Medication text (e.g., Ingredient(s), route, use, formulation).	[Influenza Vaccination]
5.	Date:	Oct/22/2020

090177e196ae4091\Final\Final On: 01-Apr-2021 05:42 (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:** 11411221

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

**Site No:** 1141

**Subject No:** 11411221

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

**Form:** CONCOMITANT MEDICATIONS - PROHIBITED

**Form Status:** Not Started

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

**Subject Initials:** ---

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

[Back to Form](#)

**Concomitant Medications**

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

090177e196ae4091\Final\Final On: 01-Apr-2021 05:42 (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:** 11411221

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

**Site No:** 1141

**Subject No:** 11411221

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

**Form:** RADIATION TREATMENT

**Form Status:** Not Started

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

**Subject Initials:** ---

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

[Back to Form](#)

**Radiation Treatment**

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

**Header Text:** c4591001

**Visit:** Logs

**Form:** TRANSFUSIONS

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

**Site No:** 1141

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

**Subject No:** 11411221

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

**Site No:** 1141

**Subject No:** 11411221

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

**Form:** TRANSFUSIONS

**Form Status:** Not Started

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

**Subject Initials:** ---

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

[Back to Form](#)

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

**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:** 11411221

**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 :	Nov/11/2020
2.	Phase of Disposition:	VACCINATION
3.	Status:	COMPLETED
4.	Specify Status:	[ ]

**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:** 11411221    **Subject Initials:** ---

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

**Date of Visit**

1.	Date of Visit	//
2.	Erroneous Visit	

090177e196ae4091\Final\Final On: 01-Apr-2021 05:42 (GMT)

**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:** 11411221

**Subject Initials:** ---

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

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

**Vital Signs**

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

**Vital Signs Details**

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



**Header Text:** c4591001

**Visit:** Unplanned Vaccination - Unscheduled

**Form:** 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:** 11411221

**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:	

090177e196ae4091\Final\Final On: 01-Apr-2021 05:42 (GMT)

**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:** 11411221

**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?	

090177e196ae4091\Final\Final On: 01-Apr-2021 05:42 (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:** 11411221

**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:** 11411221    **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:** Follow-Up - Unscheduled

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

**Site No:** 1141

**Subject No:** 11411221

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

**Form:** DISPOSITION - FOLLOW-UP

**Form Status:** Not Started

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

**Subject Initials:** ---

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

**Disposition - Follow-Up**

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

**Header Text:** c4591001

**Visit:** Potential ReVax Initial Contact -  
Unscheduled

**Form:** DATE OF VISIT

**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:** 11411221

**Subject Initials:** ---

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

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

[eCRF Audit Trail History](#)

**Date of Visit**

1.	Date of Visit	Jan/15/2021
2.	Erroneous Visit	

**Header Text:** c4591001

**Visit:** Potential ReVax Initial Contact -  
Unscheduled

**Form:** FURTHER VACCINATION CONFIRMATION

**Form Version:** 10-Dec-2020 02:25

**Form Status:** Data Complete, Frozen

**Site No:** 1141

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

**Subject No:** 11411221

**Subject Initials:** ---

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

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

[eCRF Audit Trail History](#)

**Further Vaccination Confirmation**

1.	Select appropriate response - Is participant willing to return for Vaccination 3?	Participant is willing to return for Vaccination 3 Participant is: eligible per local/national recommendations and confirmed to have received only placebo at Vaccination 1/2
----	---	---

**Header Text:** c4591001

**Visit:** Disposition - Unscheduled

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

**Site No:** 1141

**Subject No:** 11411221

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

**Form:** TREATMENT UNBLINDED

**Form Status:** Data Complete, 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](#)

**Treatment Unblinded**

1.	Date Treatment Unblinded :	Jan/15/2021
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:** 11411221

**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 :	//
----	------------------------------	----

090177e196ae4091\Final\Final On: 01-Apr-2021 05:42 (GMT)

**Header Text:** c4591001

**Visit:** Disposition - Unscheduled

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

**Site No:** 1141

**Subject No:** 11411221

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

**Form:** DEATH DETAILS CODED

**Form Status:** Not Started

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

**Subject Initials:** ---

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

**Death Details**

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

**Cause of Death**

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

**Header Text:** c4591001

**Visit:** V101\_VAX3

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

**Site No:** 1141

**Subject No:** 11411221

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

**Form:** DATE OF VISIT

**Form Status:** Data Complete, 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	Jan/20/2021
2.	Erroneous Visit	

**Header Text:** c4591001

**Visit:** V101\_VAX3

**Form Version:** 10-Dec-2020 02:31

**Site No:** 1141

**Subject No:** 11411221

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

**Form:** INFORMED CONSENT - FURTHER VACCINATION

**Form Status:** Data Complete, 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](#)

**Informed Consent - Further Vaccination**

1.	Consent Was:	OBTAINED Date Written Consent Obtained Jan/20/2021
----	--------------	--

**Header Text:** c4591001

**Visit:** V101\_VAX3

**Form:** INCLUSION/EXCLUSION CRITERIA - FURTHER VACCINATION

**Form Version:** 10-Dec-2020 02:30

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

**Site No:** 1141

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

**Subject No:** 11411221

**Subject Initials:** ---

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

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

[Form Comments](#)

**Inclusion Criteria Not Met**

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

**Exclusion Criteria Met**

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

**Header Text:** c4591001

**Visit:** V101\_VAX3

**Form:** DISPOSITION - SCREENING FOR FURTHER VACCINATION

**Form Version:** 10-Dec-2020 02:31

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

**Site No:** 1141

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

**Subject No:** 11411221

**Subject Initials:** ---

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

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

[eCRF Audit Trail History](#)

**Disposition - Screening for Further Vaccination**

1.	Date of Completion/Discontinuation /Death :	Jan/20/2021
2.	Phase of Disposition:	REPEAT SCREENING 1
3.	Status:	COMPLETED
4.	Specify Status:	[ ]

**Header Text:** c4591001

**Visit:** V101\_VAX3

**Form Version:** 14-Jan-2021 02:21

**Site No:** 1141

**Subject No:** 11411221

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

**Form:** LAB URINALYSIS - PREGNANCY TEST

**Form Status:** Data Complete, 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:	Jan/20/2021
4.	Laboratory Name and Address (Derived)	[STUDY SITE]
5.	Specimen Type:	URINE

**Lab Result**

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

090177e196ae4091\Final\Final On: 01-Apr-2021 05:42 (GMT)

**Header Text:** c4591001

**Visit:** V101\_VAX3

**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

**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:** 11411221

**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?	NO
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[drawn for convalescent visit]

**Aliquot**

Please enter barcode for each aliquot.

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

090177e196ae4091\Final\Final On: 01-Apr-2021 05:42 (GMT)



**Header Text:** c4591001

**Visit:** V101\_VAX3

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

**Site No:** 1141

**Subject No:** 11411221

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

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

**Form Status:** Data Complete, 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**

**Electronic Sample Tracking**

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Jan/20/2021
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[ ]

**Aliquot**

Please enter barcode for each aliquot.

5.a	Sample ID	[BP9LZY]
-----	-----------	----------

090177e196ae4091\Final\Final On: 01-Apr-2021 05:42 (GMT)

**Header Text:** c4591001

**Visit:** V101\_VAX3

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

**Site No:** 1141

**Subject No:** 11411221

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

**Form:** VACCINATION

**Form Status:** Data Complete, 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	[BNT162b2]
3.	Formulation:	INJECTION
4.	Dose Date Time:	Jan/20/2021 15:10
5.	Anatomical Location:	DELTOID MUSCLE
6.	Body Side:	LEFT
7.	Route:	INTRAMUSCULAR
8.	Actual Dose:	[30.0]
9.	Unit:	ug
10.	Timeframe Subject Was Observed	30 MINUTES
11.	Was the subject observed for at least the protocol specified observation period after investigational product administration?	YES

090177e196ae4091\Final\Final On: 01-Apr-2021 05:42 (GMT)

**Header Text:** c4591001

**Visit:** V102\_VAX4

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

**Site No:** 1141

**Subject No:** 11411221

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

**Form:** DATE OF VISIT

**Form Status:** Data Complete, 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	Feb/10/2021
2.	Erroneous Visit	

**Header Text:** c4591001

**Visit:** V102\_VAX4

**Form Version:** 14-Jan-2021 02:21

**Site No:** 1141

**Subject No:** 11411221

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

**Form:** LAB URINALYSIS - PREGNANCY TEST

**Form Status:** Data Complete, 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:		
2.	Lab Sub-Panel:		
3.	Collection Date:	Not Applicable //	<a href="#">Comments</a>
4.	Laboratory Name and Address (Derived)	[ ]	
5.	Specimen Type:		

**Lab Result**

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

090177e196ae4091\Final\Final On: 01-Apr-2021 05:42 (GMT)

**Header Text:** c4591001

**Visit:** V102\_VAX4

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

**Site No:** 1141

**Subject No:** 11411221

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

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

**Form Status:** Data Complete, 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](#)

**Electronic Sample Tracking**

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Feb/10/2021
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[ ]

**Aliquot**

Please enter barcode for each aliquot.

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

090177e196ae4091\Final\Final On: 01-Apr-2021 05:42 (GMT)

**Header Text:** c4591001

**Visit:** V102\_VAX4

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

**Site No:** 1141

**Subject No:** 11411221

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

**Form:** VACCINATION

**Form Status:** Data Complete, 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	[BNT162b2]
3.	Formulation:	INJECTION
4.	Dose Date Time:	Feb/10/2021 15:35
5.	Anatomical Location:	DELTOID MUSCLE
6.	Body Side:	RIGHT
7.	Route:	INTRAMUSCULAR
8.	Actual Dose:	[30.0]
9.	Unit:	ug
10.	Timeframe Subject Was Observed	30 MINUTES
11.	Was the subject observed for at least the protocol specified observation period after investigational product administration?	YES

090177e196ae4091\Final\Final On: 01-Apr-2021 05:42 (GMT)

**Header Text:** c4591001

**Visit:** V103\_MONTH1

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

**Site No:** 1141

**Subject No:** 11411221

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

**Form:** DATE OF VISIT

**Form Status:** Data Complete, 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	Mar/11/2021
2.	Erroneous Visit	

**Header Text:** c4591001

**Visit:** V103\_MONTH1

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

**Site No:** 1141

**Subject No:** 11411221

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

**Form:** CONTACT OUTCOME

**Form Status:** Data Complete, Verified

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

**Subject Initials:** ---

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

[eCRF Audit Trail History](#)

**Contact Outcome**

1.	Contact Type:	TELEPHONE VISIT
2.	Was contact made?	YES Date of Contact: Mar/11/2021
3.	Comments:	[ ]



**Header Text:** c4591001

**Visit:** V104\_MONTH6

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

**Site No:** 1141

**Subject No:** 11411221

**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:** V104\_MONTH6

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

**Site No:** 1141

**Subject No:** 11411221

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

**Form:** CONTACT OUTCOME

**Form Status:** Not Started

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

**Subject Initials:** ---

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

**Contact Outcome**

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

**Header Text:** c4591001

**Visit:** V105\_MONTH18

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

**Site No:** 1141

**Subject No:** 11411221

**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:** V105\_MONTH18

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

**Site No:** 1141

**Subject No:** 11411221

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

**Form:** CONTACT OUTCOME

**Form Status:** Not Started

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

**Subject Initials:** ---

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

**Contact Outcome**

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

**Header Text:** c4591001

**Visit:** FURTHER\_VACCINATION\_EOT -  
Unscheduled

**Form:** DISPOSITION - TREATMENT

**Form Version:** 20-Feb-2021 02:26

**Form Status:** Data Complete, Verified

**Site No:** 1141

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

**Subject No:** 11411221

**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 :	Mar/11/2021
2.	Phase of Disposition:	OPEN LABEL TREATMENT
3.	Status:	COMPLETED
4.	Specify Status:	[ ]

**Header Text:** c4591001

**Visit:** Subject Status - Unscheduled

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

**Site No:** 1141

**Subject No:** 11411221

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

**Form:** SUBJECT STATUS

**Form Status:** Data Complete, Verified

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

**Subject Initials:** ---

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

[eCRF Audit Trail History](#)

**Subject Status**

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

**Header Text:** c4591001

**Visit:** Investigator Signature - Unscheduled

**Form:** CASEBOOK SIGNATURE FORM

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

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

**Site No:** 1141

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

**Subject No:** 11411221

**Subject Initials:** ---

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

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

[eCRF Audit Trail History](#)

**Casebook Signature Form**

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

**Visit:** Investigator Signature - Unscheduled

**Form:** CASEBOOK SIGNATURE FORM

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

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

**Site No:** 1141

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

**Subject No:** 11411221

**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	Mar-12-2021 14:17:29 (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 Version:** 15-Sep-2020 21:53  
**Site No:** 1141  
**Subject No:** 11411221  
**Generated By:** (b) (4)

**Form:** INCLUSION/EXCLUSION CRITERIA - Comments  
**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](#)

Item	Date	User	Comment
Form	Sep-16-2020 16:33:26 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

**Header Text:** c4591001

**Visit:** V101\_VAX3

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

**Form Version:** 10-Dec-2020 02:30

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

**Site No:** 1141

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

**Subject No:** 11411221

**Subject Initials:** ---

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

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

[Back to Form](#)

Item	Date	User	Comment
Form	Jan-20-2021 16:28:13 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6) [REDACTED]	Not Applicable

**Header Text:** c4591001

**Visit:** V102\_VAX4

**Form Version:** 14-Jan-2021 02:21

**Site No:** 1141

**Subject No:** 11411221

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

**Form:** LAB URINALYSIS - PREGNANCY TEST - Comments

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

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

**Subject Initials:** ---

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

[Back to Form](#)

Item	Date	User	Comment
3	Feb-11-2021 15:03:27 (UTC-06:00) Central Time (US & Canada)	Hadley Mosby (b) (4)	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:** 11411221

**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	Mar-12-2021 14:17:29 (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.

(b) (6)	N/A	Mar-11-2021 12:35:16 (UTC-06:00) Central Time (US & Canada)		Edit - All signatures invalidated
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**Affidavit:**

N/A

Patricia Winokur	Approved	Mar-02-2021 15:35:48 (UTC-06:00) Central Time (US & Canada)	BOOK	Signed
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**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.

(b) (6)	N/A	Mar-02-2021 10:02:59 (UTC-06:00) Central Time (US & Canada)		Edit - All signatures invalidated
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090177e196ae4091\Final\Final On: 01-Apr-2021 05:42 (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:** 11411221**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 11:44**Affidavit:**

N/A

Patricia  
Winokur

Approved

Feb-12-2021 13:26:39 (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.

Hadley Mosby

N/A

Feb-11-2021 15:02:37 (UTC-06:00) Central  
Time (US & Canada)Edit - All  
signatures  
invalidated**Affidavit:**

N/A

Patricia  
Winokur

Approved

Jan-22-2021 17:42:02 (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.

(b) (6)

N/A

Jan-20-2021 16:27:09 (UTC-06:00) Central  
Time (US & Canada)Edit - All  
signatures  
invalidated**Affidavit:**

N/A

Patricia  
Winokur

Approved

Jan-04-2021 11:33:15 (UTC-06:00) Central  
Time (US & Canada)

BOOK

Signed

**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:** 11411221

**Subject Initials:** ---

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

**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.

(b) (6)	N/A	Dec-28-2020 12:03:43 (UTC-06:00) Central Time (US & Canada)		Edit - All signatures invalidated
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**Affidavit:**

N/A

Patricia Winokur	Approved	Dec-28-2020 08:36:25 (UTC-06:00) Central Time (US & Canada)	BOOK	Signed
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**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.

(b) (6)	N/A	Dec-22-2020 11:40:34 (UTC-06:00) Central Time (US & Canada)		Edit - All signatures invalidated
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**Affidavit:**

N/A

Patricia Winokur	Approved	Nov-11-2020 18:58:20 (UTC-06:00) Central Time (US & Canada)	BOOK	Signed
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090177e196ae4091\Final\Final On: 01-Apr-2021 05:42 (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:** 11411221

**Subject Initials:** ---

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

**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.

(b) (6)	N/A	Nov-11-2020 16:01:30 (UTC-06:00) Central Time (US & Canada)		Edit - All signatures invalidated
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**Affidavit:**

N/A

Patricia Winokur	Approved	Nov-06-2020 11:24:35 (UTC-06:00) Central Time (US & Canada)	BOOK	Signed
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**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.

090177e196ae4091\Final\Final On: 01-Apr-2021 05:42 (GMT)

**Header Text:** c4591001

**Visit:** COHORT\_SELECTION

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

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

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

**Site No:** 1141

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

**Subject No:** 11411221

**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
Sep-16-2020 16:32:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<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
Sep-16-2020 16:32:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> STAGE 3 COHORTS	Initial Entry

090177e196ae4091\Final\Final On: 01-Apr-2021 05:42 (GMT)



**Header Text:** c4591001

**Visit:** COHORT\_SELECTION

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

**Site No:** 1141

**Subject No:** 11411221

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

**Form:** MAIN INFORMED CONSENT - 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. Consent Was:*

Date	Location	User	Value	Reason
Sep-16-2020 16:32:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [Redacted] [Redacted]	<b>Data Entry:</b> OBTAINED Date Written Consent Obtain ed  Sep/16/2020	Initial Entry

Header Text: c4591001

Visit: COHORT\_SELECTION

Form Version: 15-Sep-2020 21:54

Site No: 1141

Subject No: 11411221

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
Sep-16-2020 16:32:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> 11411221	Item copied from previous form

**2. Birth Date:**

Date	Location	User	Value	Reason
Sep-16-2020 16:32:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> (b) (6)/1974	Enrollment Entry

**3. Sex:**

Date	Location	User	Value	Reason
Sep-16-2020 16:33:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [Redacted]	<u>Data Entry:</u> FEMALE	Initial Entry

**4. Ethnicity:**

Date	Location	User	Value	Reason
Sep-16-2020 16:33:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [Redacted]	<u>Data Entry:</u> NOT HISPANIC OR LATINO (A) OR OF SPANISH ORIGI N	Initial Entry

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

Date	Location	User	Value	Reason
Sep-16-2020 16:33:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [Redacted]	<u>Data Entry:</u> WHITE	Initial Entry

090177e196ae4091\Final\Final On: 01-Apr-2021 05:42 (GMT)

**Header Text:** c4591001

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

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

**Site No:** 1141

**Subject No:** 11411221

**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

[Back to Form](#)

*1. Date of Visit*

Date	Location	User	Value	Reason
Sep-16-2020 16:33:19 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sep/16/2020	Initial Entry

**Header Text:** c4591001

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

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

**Site No:** 1141

**Subject No:** 11411221

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

**Form:** DISPOSITION - SCREENING - 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. Date of Completion/Discontinuation/Death**

Date	Location	User	Value	Reason
Sep-16-2020 16:33:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sep/16/2020	Initial Entry

**2. Phase of Disposition:**

Date	Location	User	Value	Reason
Sep-16-2020 16:33:36 (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
Sep-16-2020 16:33:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> COMPLETED	Initial Entry

090177e196ae4091\Final\Final On: 01-Apr-2021 05:42 (GMT)

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 22-Apr-2020 21:03

Site No: 1141

Subject No: 11411221

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - 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.a*

Date	Location	User	Value	Reason
Sep-16-2020 16:34:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Line/MH Num 1</b> <b>ber:</b> <b>Medical Histor</b> Endometrial A <b>y Term:</b> blation <b>Start Date:</b> UNK/UNK/20 12 <b>Ongoing:</b> NO End Date:  UNK/UNK/ 2012	Initial Entry

*1.a Line/MH Number:*

Date	Location	User	Value	Reason
Sep-16-2020 16:34:07 (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
Sep-16-2020 16:34:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [Redacted]	<b>Data Entry:</b> Endometrial Ablation	Initial Entry

*1.a Start Date:*

Date	Location	User	Value	Reason
Sep-16-2020 16:34:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [Redacted]	<b>Data Entry:</b> UNK/UNK/2012	Initial Entry

090177e196ae4091\Final\Final On: 01-Apr-2021 05:42 (GMT)

**Header Text:** c4591001

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

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

**Site No:** 1141

**Subject No:** 11411221

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

**Form:** GENERAL MEDICAL HISTORY - 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

***1.a Ongoing:***

Date	Location	User	Value	Reason
Sep-16-2020 16:34:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO End Date:  UNK/UNK/2012	Initial Entry

***1.b***

Date	Location	User	Value	Reason
Sep-16-2020 16:34:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Line/MH Number:</b> r: <b>Medical History</b> Post Menop <b>Term:</b> ausal <b>Start Date:</b> UNK/UNK/ 2012 <b>Ongoing:</b> YES	Initial Entry

090177e196ae4091\Final\Final On: 01-Apr-2021 05:42 (GMT)

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 22-Apr-2020 21:03

Site No: 1141

Subject No: 11411221

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - 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

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

Date	Location	User	Value	Reason
Sep-16-2020 16:34:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 2	Initial Entry

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

Date	Location	User	Value	Reason
Sep-16-2020 16:34:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Post Menopausal	Initial Entry

***1.b Start Date:***

Date	Location	User	Value	Reason
Sep-16-2020 16:34:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> UNK/UNK/2012	Initial Entry

***1.b Ongoing:***

Date	Location	User	Value	Reason
Sep-16-2020 16:34:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

***1.c***

Date	Location	User	Value	Reason
Sep-16-2020 16:34:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Line/MH Number:</b> 3 <b>Medical History Term:</b> Appendectomy <b>Start Date:</b> May/UNK/2012	Initial Entry

090177e196ae4091\Final\Final On: 01-Apr-2021 05:42 (GMT)

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 22-Apr-2020 21:03

Site No: 1141

Subject No: 11411221

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - 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

			<b>Ongoing:</b> NO End Date:  May/UNK/ 2012	
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**I.c Line/MH Number:**

Date	Location	User	Value	Reason
Sep-16-2020 16:34:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 3	Initial Entry

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

Date	Location	User	Value	Reason
Sep-16-2020 16:34:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Appendectomy	Initial Entry

**I.c Start Date:**

Date	Location	User	Value	Reason
Sep-16-2020 16:34:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> May/UNK/2012	Initial Entry

**I.c Ongoing:**

Date	Location	User	Value	Reason
Sep-16-2020 16:34:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO End Date:  May/UNK/2012	Initial Entry

**I.d**

Date	Location	User	Value	Reason
Sep-16-2020 16:35:05	ACV0PFEINFP6000	auto calc	<b>Data Entry:</b>	Initial Entry

090177e196ae4091\Final\Final On: 01-Apr-2021 05:42 (GMT)



**Header Text:** c4591001

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

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

**Site No:** 1141

**Subject No:** 11411221

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

**Form:** GENERAL MEDICAL HISTORY - 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)		(autocalc)	<b>Line/MH Number:</b> 4 <b>Medical History Term:</b> Appendicitis <b>Start Date:</b> May/UNK/2012 <b>Ongoing:</b> NO <b>End Date:</b> May/UNK/2012	
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Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 22-Apr-2020 21:03

Site No: 1141

Subject No: 11411221

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - 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

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

Date	Location	User	Value	Reason
Sep-16-2020 16:35:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 4	Initial Entry

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

Date	Location	User	Value	Reason
Sep-16-2020 16:35:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Appendicitis	Initial Entry

***1.d Start Date:***

Date	Location	User	Value	Reason
Sep-16-2020 16:35:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> May/UNK/2012	Initial Entry

***1.d Ongoing:***

Date	Location	User	Value	Reason
Sep-16-2020 16:35:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO End Date:  May/UNK/2012	Initial Entry

090177e196ae4091\Final\Final On: 01-Apr-2021 05:42 (GMT)

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 15-Sep-2020 21:56

Site No: 1141

Subject No: 11411221

Generated By: (b) (4)

Form: VITAL SIGNS - BASELINE - 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. Date:**

Date	Location	User	Value	Reason
Sep-16-2020 16:35:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sep/16/2020	Initial Entry

**2. Weight:**

Date	Location	User	Value	Reason
Sep-16-2020 16:35:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 72.6	Initial Entry

**3. Unit:**

Date	Location	User	Value	Reason
Sep-16-2020 16:35:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> kg	Initial Entry

**4. Height:**

Date	Location	User	Value	Reason
Sep-16-2020 16:35:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 159.8	Initial Entry

**5. Unit:**

Date	Location	User	Value	Reason
Sep-16-2020 16:35:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> cm	Initial Entry

**6. Body Mass Index:**

Date	Location	User	Value	Reason
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090177e196ae4091\Final\Final On: 01-Apr-2021 05:42 (GMT)

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 15-Sep-2020 21:56

Site No: 1141

Subject No: 11411221

Generated By: (b) (4)

Form: VITAL SIGNS - BASELINE - 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

Sep-16-2020 16:35:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 28.4	Initial Entry
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7.a

Date	Location	User	Value	Reason
Sep-16-2020 16:35:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Record Identifier: Temperature: 98.7 Temperature Unit: Temperature Location: ORAL CAVITY	Initial Entry

7.a Record Identifier:

Date	Location	User	Value	Reason
Sep-16-2020 16:35:36 (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
Sep-16-2020 16:35:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 98.7	Initial Entry

7.a Unit:

Date	Location	User	Value	Reason
Sep-16-2020 16:35:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> F	Initial Entry

7.a Temperature Location:

Date	Location	User	Value	Reason
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090177e196ae4091\Final\Final On: 01-Apr-2021 05:42 (GMT)

**Header Text:** c4591001

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

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

**Site No:** 1141

**Subject No:** 11411221

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

**Form:** VITAL SIGNS - BASELINE - 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

Sep-16-2020 16:35:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [Redacted] [Redacted]	<b>Data Entry:</b> ORAL CAVITY	Initial Entry
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**Header Text:** c4591001

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

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

**Form Version:** 15-Sep-2020 21:51

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

**Site No:** 1141

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

**Subject No:** 11411221

**Subject Initials:** ---

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

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

[Back to Form](#)

**1. Lab Panel:**

Date	Location	User	Value	Reason
Sep-16-2020 16:35:42 (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-16-2020 16:35:42 (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-16-2020 16:35:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sep/16/2020	Initial Entry

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

Date	Location	User	Value	Reason
Sep-16-2020 16:35:42 (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-16-2020 16:35:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> URINE	Initial Entry

**6.a**

090177e196ae4091\Final\Final On: 01-Apr-2021 05:42 (GMT)

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

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

Form Version: 15-Sep-2020 21:51

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1141

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

Subject No: 11411221

Subject Initials: ---

Generated By: (b) (4)

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

Date	Location	User	Value	Reason
Sep-16-2020 16:36:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sponsor-Defined Identifier:</b> <b>Test::</b> Choriogonadotropin Beta_PX 113 <b>Result::</b> <b>Not Done::</b> NOT DONE	Transcription Error
Sep-16-2020 16:35:55 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sponsor-Defined Identifier:</b> <b>Test::</b> Choriogonadotropin Beta_PX 113 <b>Result::</b> NEGATIVE <b>Not Done::</b> NOT DONE	Initial Entry
Sep-16-2020 16:35:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Sponsor-Defined Identifier:</b> <b>Test::</b> Choriogonadotropin Beta_PX 113 <b>Result::</b> NEGATIVE <b>Not Done::</b>	Initial Entry

**6.a Sponsor ID:**

Date	Location	User	Value	Reason
Sep-16-2020 16:35:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 113	Initial Entry

**6.a Test:**

090177e196ae4091\Final\Final On: 01-Apr-2021 05:42 (GMT)

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

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

Form Version: 15-Sep-2020 21:51

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1141

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

Subject No: 11411221

Subject Initials: ---

Generated By: (b) (4)

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

Date	Location	User	Value	Reason
Sep-16-2020 16:35:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Choriogonadotropin Beta_PX1 13	Initial Entry

**6.a Result:**

Date	Location	User	Value	Reason
Sep-16-2020 16:36:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	Transcription Error
Sep-16-2020 16:35:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NEGATIVE	Initial Entry

**6.a Not Done:**

Date	Location	User	Value	Reason
Sep-16-2020 16:36:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Sep-16-2020 16:35:55 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	Not Done is indicated however result is provided. Please correct or clarify.
Sep-16-2020 16:35:55 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NOT DONE	Initial Entry

090177e196ae4091\Final\Final On: 01-Apr-2021 05:42 (GMT)



**Header Text:** c4591001

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

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

**Site No:** 1141

**Subject No:** 11411221

**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

[Back to Form](#)

**1. Randomization Date :**

Date	Location	User	Value	Reason
Sep-16-2020 16:36:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sep/16/2020	Initial Entry

**2. Randomization Number:**

Date	Location	User	Value	Reason
Sep-18-2020 08:14:23 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Closed as data updated.
Sep-17-2020 06:13:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Transcription Error
Sep-17-2020 06:13:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 91630	Transcription Error
Sep-17-2020 02:46:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	PFE SDQ PROD (b) (4)	Query 1: Opened	As per Impala, Randomization Number is 91630 . Please review and update as appropriate. "[ (b) (4) ]"

090177e196ae4091\Final\Final On: 01-Apr-2021 05:42 (GMT)

**Header Text:** c4591001

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

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

**Site No:** 1141

**Subject No:** 11411221

**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

Sep-16-2020 16:36:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	<b>Data Entry</b> : 9163	Initial Entry
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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:** 11411221

**Subject Initials:** ---

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

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

[Back to Form](#)

**1. Data Origin**

Date	Location	User	Value	Reason
Sep-16-2020 16:36:37 (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-16-2020 16:36:37 (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
Sep-17-2020 06:13:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Sep-17-2020 03:27:24 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Sep-16-2020 16:36:37 (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.
Sep-16-2020 16:36:37 (UTC-06:00) Central	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

090177e196ae4091\Final\Final On: 01-Apr-2021 05:42 (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: 11411221

Subject Initials: ---

Generated By: (b) (4)

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

Time (US & Canada)	(b) (4), (b) (6)	Date of Collection:	Sep/16/2020
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5.a

Date	Location	User	Value	Reason
Sep-17-2020 06:13:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample ID: BM6HZW</b>	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Sep-17-2020 06:13:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BM6HZW	Initial Entry

5.b

Date	Location	User	Value	Reason
Sep-17-2020 06:13:54 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample ID: BLC9J4</b>	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Sep-17-2020 06:13:54 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BLC9J4	Initial Entry

5.c

Date	Location	User	Value	Reason
Sep-17-2020 06:14:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample ID: BLC9J5</b>	Initial Entry

090177e196ae4091\Final\Final On: 01-Apr-2021 05:42 (GMT)

**Header Text:** c4591001

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

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

**Site No:** 1141

**Subject No:** 11411221

**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

**5.c Sample ID**

Date	Location	User	Value	Reason
Sep-17-2020 06:14:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BLC9J5	Initial Entry

**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:** 11411221

**Subject Initials:** ---

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

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

[Back to Form](#)

**1. Data Origin**

Date	Location	User	Value	Reason
Sep-16-2020 16:36:48 (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-16-2020 16:36:48 (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-17-2020 06:14:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Sep-17-2020 03:27:24 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Sep-16-2020 16:36:48 (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.
Sep-16-2020 16:36:48 (UTC-06:00) Central	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

090177e196ae4091\Final\Final On: 01-Apr-2021 05:42 (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:** 11411221

**Subject Initials:** ---

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

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

Time (US & Canada)	(b) (4), (b) (6)	Date of Collection:	Sep/16/2020
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**5.a**

Date	Location	User	Value	Reason
Sep-17-2020 06:14:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample ID:</b> BM6HZS	Initial Entry

**5.a Sample ID**

Date	Location	User	Value	Reason
Sep-17-2020 06:14:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BM6HZS	Initial Entry

090177e196ae4091\Final\Final On: 01-Apr-2021 05:42 (GMT)

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 22-Apr-2020 21:04

Site No: 1141

Subject No: 11411221

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

[Back to Form](#)

1. Was there a temporary delay of vaccination?

Date	Location	User	Value	Reason
Sep-16-2020 16:37:03 (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-16-2020 16:37:03 (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-16-2020 16:37:03 (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
Sep-16-2020 16:37:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sep/16/2020 15:19	Initial Entry

5. Anatomical Location:

Date	Location	User	Value	Reason
Sep-16-2020 16:37:03 (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
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090177e196ae4091\Final\Final On: 01-Apr-2021 05:42 (GMT)



**Header Text:** c4591001

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

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

**Site No:** 1141

**Subject No:** 11411221

**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

Sep-16-2020 16:37:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> LEFT	Initial Entry
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**7. Route:**

Date	Location	User	Value	Reason
Sep-16-2020 16:37:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> INTRAMUSCULAR	Initial Entry

**10. Timeframe Subject Was Observed**

Date	Location	User	Value	Reason
Sep-16-2020 16:37:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> THE PROTOCOL SPECIFIED OBSERVATION 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-16-2020 16:37:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

090177e196ae4091\Final\Final On: 01-Apr-2021 05:42 (GMT)

**Header Text:** c4591001

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

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

**Site No:** 1141

**Subject No:** 11411221

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

**Form:** REACTOGENICITY DIARY - 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. Select appropriate response - Reactogenicity diary collection*

Date	Location	User	Value	Reason
Sep-16-2020 16:37:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO - REACTOGENICITY E- DIARY NOT COLLECTED F OR THIS SUBJECT	Initial Entry

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1141

**Subject No:** 11411221

**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

[Back to Form](#)

*1. Date of Visit*

Date	Location	User	Value	Reason
Oct-07-2020 18:06:18 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Oct/7/2020	Initial Entry

Header Text: c4591001

Visit: V2\_VAX2\_L

Form Version: 15-Sep-2020 21:54

Site No: 1141

Subject No: 11411221

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

[Back to Form](#)

**1. Date:**

Date	Location	User	Value	Reason
Oct-07-2020 18:06:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Oct/7/2020	Initial Entry

**2.a**

Date	Location	User	Value	Reason
Oct-07-2020 18:06:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Record Identifier:</b> r: <b>Temperature:</b> 96.7 <b>Temperature Unit:</b> <b>Temperature Location:</b> ORAL CAVITY	Initial Entry

**2.a Record Identifier:**

Date	Location	User	Value	Reason
Oct-07-2020 18:06:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 1	Initial Entry

**2.a Temperature:**

Date	Location	User	Value	Reason
Oct-13-2020 13:21:17 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Oct-12-2020 15:12:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Not clinically significant
Oct-09-2020 01:44:26	ACV0PFEINFP6000	Sandip	Query 1: Reissued:Opened	Kindly verify and

090177e196ae4091\Final\Final On: 01-Apr-2021 05:42 (GMT)

**Header Text:** c4591001**Visit:** V2\_VAX2\_L**Form Version:** 15-Sep-2020 21:54**Site No:** 1141**Subject No:** 11411221**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

(UTC-06:00) Central Time (US & Canada)		Namdeorao Suryawanshi (b) (4)		confirm if subject is clinically significant or non-clinically significant. Thank you.
Oct-08-2020 14:31:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Original value is correct
Oct-07-2020 18:06:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	Temperature 96.7 F is outside of Normal Range 97 - 99.5 F.
Oct-07-2020 18:06:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 96.7	Initial Entry

**2.a Unit:**

Date	Location	User	Value	Reason
Oct-07-2020 18:06:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> F	Initial Entry

**2.a Temperature Location:**

Date	Location	User	Value	Reason
Oct-07-2020 18:06:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> ORAL CAVITY	Initial Entry

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

**Form Version:** 15-Sep-2020 21:51

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

**Site No:** 1141

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

**Subject No:** 11411221

**Subject Initials:** ---

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

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

[Back to Form](#)

**1. Lab Panel:**

Date	Location	User	Value	Reason
Oct-07-2020 18:06:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> URINALYSIS	Initial Entry

**2. Lab Sub-Panel:**

Date	Location	User	Value	Reason
Oct-07-2020 18:06:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> PREGNANCY	Initial Entry

**3. Collection Date:**

Date	Location	User	Value	Reason
Oct-07-2020 18:06:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Oct/7/2020	Initial Entry

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

Date	Location	User	Value	Reason
Oct-07-2020 18:06:35 (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
Oct-07-2020 18:06:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> URINE	Initial Entry

**6.a**

090177e196ae4091\Final\Final On: 01-Apr-2021 05:42 (GMT)

Header Text: c4591001

Visit: V2\_VAX2\_L

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

Form Version: 15-Sep-2020 21:51

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1141

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

Subject No: 11411221

Subject Initials: ---

Generated By: (b) (4)

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

Date	Location	User	Value	Reason
Oct-07-2020 18:06:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Sponsor-Defined Identifier</b> 113 : <b>Test::</b> Choriogonadotropin Beta_PX113 <b>Result::</b> NEGATIVE <b>Not Done::</b>	Initial Entry

6.a Sponsor ID:

Date	Location	User	Value	Reason
Oct-07-2020 18:06:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 113	Initial Entry

6.a Test:

Date	Location	User	Value	Reason
Oct-07-2020 18:06:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Choriogonadotropin Beta_PX113	Initial Entry

6.a Result:

Date	Location	User	Value	Reason
Oct-07-2020 18:06:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NEGATIVE	Initial Entry

090177e196ae4091\Final\Final On: 01-Apr-2021 05:42 (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:** 11411221

**Subject Initials:** ---

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

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

[Back to Form](#)

**1. Data Origin**

Date	Location	User	Value	Reason
Oct-07-2020 18:06:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SITE	Initial Entry

**2. Sample Type**

Date	Location	User	Value	Reason
Oct-07-2020 18:06:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> NASAL_SWAB	Initial Entry

**3. Sample Collected?**

Date	Location	User	Value	Reason
Oct-08-2020 06:14:23 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Oct-08-2020 02:21:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Oct-07-2020 18:06:39 (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.
Oct-07-2020 18:06:39 (UTC-06:00) Central	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

090177e196ae4091\Final\Final On: 01-Apr-2021 05:42 (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:** 11411221

**Subject Initials:** ---

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

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

Time (US & Canada)	(b) (4), (b) (6)	Date of Collection:	Oct/7/2020
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**5.a**

Date	Location	User	Value	Reason
Oct-08-2020 06:14:23 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample ID:</b> BP9M5N	Initial Entry

**5.a Sample ID**

Date	Location	User	Value	Reason
Oct-08-2020 06:14:23 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BP9M5N	Initial Entry

090177e196ae4091\Final\Final On: 01-Apr-2021 05:42 (GMT)

Header Text: c4591001

Visit: V2\_VAX2\_L

Form Version: 22-Apr-2020 21:04

Site No: 1141

Subject No: 11411221

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

[Back to Form](#)

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

Date	Location	User	Value	Reason
Oct-07-2020 18:06:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**2. Treatment Name**

Date	Location	User	Value	Reason
Oct-07-2020 18:06:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> BLINDED THERAPY	Initial Entry

**3. Formulation:**

Date	Location	User	Value	Reason
Oct-07-2020 18:06:53 (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
Oct-07-2020 18:06:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Oct/7/2020 15:10	Initial Entry

**5. Anatomical Location:**

Date	Location	User	Value	Reason
Oct-07-2020 18:06:53 (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
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090177e196ae4091\Final\Final On: 01-Apr-2021 05:42 (GMT)

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1141

**Subject No:** 11411221

**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

Oct-07-2020 18:06:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> LEFT	Initial Entry
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**7. Route:**

Date	Location	User	Value	Reason
Oct-07-2020 18:06:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> INTRAMUSCULAR	Initial Entry

**10. Timeframe Subject Was Observed**

Date	Location	User	Value	Reason
Oct-07-2020 18:06:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> THE PROTOCOL SPECIFIED OBSERVATION PERIOD	Initial Entry

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

Date	Location	User	Value	Reason
Oct-07-2020 18:06:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

090177e196ae4091\Final\Final On: 01-Apr-2021 05:42 (GMT)

**Header Text:** c4591001

**Visit:** V3\_MONTH1\_POSTVAX2\_L

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

**Site No:** 1141

**Subject No:** 11411221

**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

[Back to Form](#)

*1. Date of Visit*

Date	Location	User	Value	Reason
Nov-11-2020 16:11:19 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Nov/11/2020	Initial Entry

**Header Text:** c4591001

**Visit:** V3\_MONTH1\_POSTVAX2\_L

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

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

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

**Site No:** 1141

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

**Subject No:** 11411221

**Subject Initials:** ---

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

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

[Back to Form](#)

**1. Data Origin**

Date	Location	User	Value	Reason
Nov-11-2020 16:01:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SITE	Initial Entry

**2. Sample Type**

Date	Location	User	Value	Reason
Nov-11-2020 16:01:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SERUM	Initial Entry

**3. Sample Collected?**

Date	Location	User	Value	Reason
Nov-11-2020 16:01:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Nov-11-2020 16:01:30 (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.
Nov-11-2020 16:01:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES Date of Collection:  Nov/11/2020	Initial Entry

**5.a**

Date	Location	User	Value	Reason
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090177e196ae4091\Final\Final On: 01-Apr-2021 05:42 (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: 11411221

Subject Initials: ---

Generated By: (b) (4)

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

Nov-11-2020 16:01:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sample ID: BP9MF2	Initial Entry
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5.a Sample ID

Date	Location	User	Value	Reason
Nov-11-2020 16:01:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BP9MF2	Initial Entry

5.b

Date	Location	User	Value	Reason
Nov-11-2020 16:02:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sample ID: BRX788	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Nov-11-2020 16:02:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BRX788	Initial Entry

5.c

Date	Location	User	Value	Reason
Nov-11-2020 16:03:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sample ID: BRX789	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Nov-11-2020 16:03:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BRX789	Initial Entry

090177e196ae4091\Final\Final On: 01-Apr-2021 05:42 (GMT)

**Header Text:** c4591001**Visit:** POT\_COVID\_ILL 1 - Unscheduled  
Visit on Dec/22/2020**Form:** DATE OF VISIT - ILLNESS ONSET - 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:** 11411221**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 11:44[Back to Form](#)**1. Date of Visit**

Date	Location	User	Value	Reason
Dec-22-2020 12:02:54 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Dec-22-2020 11:42:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Deleted	Close Auto Query
Dec-22-2020 11:40:32 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Candidate	Date of Visit is completed but Date of Assessment in the Signs and Symptoms form is missing. Please review and update as appropriate.
Dec-22-2020 11:40:32 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	Date of Visit is completed but Date of Collection in both Nasal Swab Self and Nasal Swab are missing. Please review and update as appropriate.
Dec-22-2020 11:40:32 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Dec/22/2020	Initial Entry

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

Date	Location	User	Value	Reason
Dec-22-2020 11:40:32 (UTC-06:00) Central	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> COVID_A	Initial Entry

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled  
Visit on Dec/22/2020

**Form:** DATE OF VISIT - ILLNESS ONSET - 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:** 11411221

**Subject Initials:** ---

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

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

Time (US & Canada)				
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**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled  
Visit on Dec/22/2020

**Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 -  
eCRF Audit Trail History

**Form Version:** 10-Dec-2020 02:29

**Form Status:** Data Complete

**Site No:** 1141

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

**Subject No:** 11411221

**Subject Initials:** ---

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

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

[Back to Form](#)

**1. Date of Assessment:**

Date	Location	User	Value	Reason
Dec-22-2020 11:42:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Dec/22/2020	Initial Entry

**2. Date of First Symptom Started:**

Date	Location	User	Value	Reason
Dec-22-2020 11:42:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Dec/21/2020	Initial Entry

**3. Symptoms Ongoing?**

Date	Location	User	Value	Reason
Mar-02-2021 13:43:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Mar-02-2021 10:02:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	New Information
Mar-02-2021 10:02:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO Date of Last Symptom Reso lved:  Jan/2/2021	New Information
Mar-01-2021 15:34:04 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	Clin: As subject was recently vaccinated on 20Jan2021, please clarify whether the reported

090177e196ae4091\Final\Final On: 01-Apr-2021 05:42 (GMT)

Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled  
Visit on Dec/22/2020

Form: SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 -  
eCRF Audit Trail History

Form Version: 10-Dec-2020 02:29

Form Status: Data Complete

Site No: 1141

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

Subject No: 11411221

Subject Initials: ---

Generated By: (b) (4)

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

				symptoms are still ongoing. If symptoms have ended, please update 'Symptoms Ongoing' to 'NO' and add Date of Last Symptom Resolved on the CRF.
Dec-22-2020 11:42:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

4.a

Date	Location	User	Value	Reason
Dec-22-2020 11:42:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptoms:</b> FEVER <b>Symptom Present:</b> YES	Initial Entry

4.a Symptoms:

Date	Location	User	Value	Reason
Dec-22-2020 11:42:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> FEVER	Initial Entry

4.a Was symptom present?

Date	Location	User	Value	Reason
Dec-22-2020 11:42:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

4.b

Date	Location	User	Value	Reason
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090177e196ae4091\Final\Final On: 01-Apr-2021 05:42 (GMT)

Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled  
Visit on Dec/22/2020

Form: SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 -  
eCRF Audit Trail History

Form Version: 10-Dec-2020 02:29

Form Status: Data Complete

Site No: 1141

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

Subject No: 11411221

Subject Initials: ---

Generated By: (b) (4)

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

Dec-22-2020 11:42:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptom</b> NEW OR INCRE <b>s:</b> ASED COUGH <b>Symptom</b> NO <b>Present:</b>	Initial Entry
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**4.b Symptoms:**

Date	Location	User	Value	Reason
Dec-22-2020 11:42:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NEW OR INCREASED COU GH	Initial Entry

**4.b Was symptom present?**

Date	Location	User	Value	Reason
Dec-22-2020 11:42:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**4.c**

Date	Location	User	Value	Reason
Dec-22-2020 11:42:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sympto</b> NEW OR INCREA <b>ms:</b> SED SHORTNESS OF BREATH <b>Sympto</b> NO <b>m Pres</b> <b>ent:</b>	Initial Entry

090177e196ae4091\Final\Final On: 01-Apr-2021 05:42 (GMT)

Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled  
Visit on Dec/22/2020

Form: SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 -  
eCRF Audit Trail History

Form Version: 10-Dec-2020 02:29

Form Status: Data Complete

Site No: 1141

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

Subject No: 11411221

Subject Initials: ---

Generated By: (b) (4)

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

4.c Symptoms:

Date	Location	User	Value	Reason
Dec-22-2020 11:42:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NEW OR INCREASED SHO RTNESS OF BREATH	Initial Entry

4.c Was symptom present?

Date	Location	User	Value	Reason
Dec-22-2020 11:42:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

4.d

Date	Location	User	Value	Reason
Dec-22-2020 11:42:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptoms:</b> CHILLS <b>Symptom Present:</b> YES	Initial Entry

4.d Symptoms:

Date	Location	User	Value	Reason
Dec-22-2020 11:42:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> CHILLS	Initial Entry

4.d Was symptom present?

Date	Location	User	Value	Reason
Dec-22-2020 11:42:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

4.e

Date	Location	User	Value	Reason
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090177e196ae4091\Final\Final On: 01-Apr-2021 05:42 (GMT)

Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled  
Visit on Dec/22/2020

Form: SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 -  
eCRF Audit Trail History

Form Version: 10-Dec-2020 02:29

Form Status: Data Complete

Site No: 1141

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

Subject No: 11411221

Subject Initials: ---

Generated By: (b) (4)

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

Dec-22-2020 11:42:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptoms:</b> NEW OR INCREASED MUSCLE PAIN <b>Symptom Present:</b> YES	Initial Entry
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**4.e Symptoms:**

Date	Location	User	Value	Reason
Dec-22-2020 11:42:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NEW OR INCREASED MUSCLE PAIN	Initial Entry

**4.e Was symptom present?**

Date	Location	User	Value	Reason
Dec-22-2020 11:42:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

**4.f**

Date	Location	User	Value	Reason
Dec-22-2020 11:42:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptoms:</b> NEW LOSS OF TASTE OR SMELL <b>Symptom Present:</b> NO	Initial Entry

090177e196ae4091\Final\Final On: 01-Apr-2021 05:42 (GMT)

Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled  
Visit on Dec/22/2020

Form: SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 -  
eCRF Audit Trail History

Form Version: 10-Dec-2020 02:29

Form Status: Data Complete

Site No: 1141

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

Subject No: 11411221

Subject Initials: ---

Generated By: (b) (4)

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

4.f Symptoms:

Date	Location	User	Value	Reason
Dec-22-2020 11:42:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NEW LOSS OF TASTE OR S MELL	Initial Entry

4.f Was symptom present?

Date	Location	User	Value	Reason
Dec-22-2020 11:42:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

4.g

Date	Location	User	Value	Reason
Dec-22-2020 11:42:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sympto</b> NEW OR INCRE <b>ms:</b> ASSED SORE THR OAT <b>Sympto</b> NO <b>m Prese</b> <b>nt:</b>	Initial Entry

4.g Symptoms:

Date	Location	User	Value	Reason
Dec-22-2020 11:42:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NEW OR INCREASED SOR E THROAT	Initial Entry

4.g Was symptom present?

Date	Location	User	Value	Reason
Dec-22-2020 11:42:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

090177e196ae4091\Final\Final On: 01-Apr-2021 05:42 (GMT)

Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled  
Visit on Dec/22/2020

Form: SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 -  
eCRF Audit Trail History

Form Version: 10-Dec-2020 02:29

Form Status: Data Complete

Site No: 1141

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

Subject No: 11411221

Subject Initials: ---

Generated By: (b) (4)

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

4.h

Date	Location	User	Value	Reason
Dec-22-2020 11:42:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptoms:</b> DIARRHE A <b>Symptom Present:</b> NO	Initial Entry

4.h Symptoms:

Date	Location	User	Value	Reason
Dec-22-2020 11:42:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> DIARRHEA	Initial Entry

4.h Was symptom present?

Date	Location	User	Value	Reason
Dec-22-2020 11:42:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

4.i

Date	Location	User	Value	Reason
Dec-22-2020 11:42:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptoms:</b> VOMITIN G <b>Symptom Present:</b> NO	Initial Entry

090177e196ae4091\Final\Final On: 01-Apr-2021 05:42 (GMT)

Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled  
Visit on Dec/22/2020

Form: SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 -  
eCRF Audit Trail History

Form Version: 10-Dec-2020 02:29

Form Status: Data Complete

Site No: 1141

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

Subject No: 11411221

Subject Initials: ---

Generated By: (b) (4)

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

4.i Symptoms:

Date	Location	User	Value	Reason
Dec-22-2020 11:42:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> VOMITING	Initial Entry

4.i Was symptom present?

Date	Location	User	Value	Reason
Dec-22-2020 11:42:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

5.a

Date	Location	User	Value	Reason
Dec-22-2020 11:42:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Symptoms - Other: rhinorrhea	Initial Entry

5.a Symptoms - Other Text:

Date	Location	User	Value	Reason
Dec-22-2020 11:42:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> rhinorrhea	Initial Entry

5.b

Date	Location	User	Value	Reason
Dec-22-2020 11:42:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Symptoms - Other: foggy thinking	Initial Entry

090177e196ae4091\Final\Final On: 01-Apr-2021 05:42 (GMT)



Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled  
Visit on Dec/22/2020

Form: SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 -  
eCRF Audit Trail History

Form Version: 10-Dec-2020 02:29

Form Status: Data Complete

Site No: 1141

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

Subject No: 11411221

Subject Initials: ---

Generated By: (b) (4)

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

5.b Symptoms - Other Text:

Date	Location	User	Value	Reason
Dec-22-2020 11:42:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> foggy thinking	Initial Entry

5.c

Date	Location	User	Value	Reason
Dec-22-2020 11:43:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptoms - Other:</b> nausea	Initial Entry

5.c Symptoms - Other Text:

Date	Location	User	Value	Reason
Dec-22-2020 11:43:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> nausea	Initial Entry

5.d

Date	Location	User	Value	Reason
Dec-22-2020 11:43:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptoms - Other</b> headach : e	Initial Entry

5.d Symptoms - Other Text:

Date	Location	User	Value	Reason
Dec-22-2020 11:43:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> headache	Initial Entry

090177e196ae4091\Final\Final On: 01-Apr-2021 05:42 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled  
Visit on Dec/22/2020

**Form:** MICROBIOLOGY SPECIMEN - Audit Trail

**Form Version:** 06-Jul-2020 21:54

**Form Status:**

**Site No:** 1141

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

**Subject No:** 11411221

**Subject Initials:** ---

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

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

[Back to Form](#)

Date	Location	User	Value	Reason
Dec-22-2020 12:02:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled  
Visit on Dec/22/2020

Form: MICROBIOLOGY SPECIMEN - eCRF Audit Trail History

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete

Site No: 1141

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

Subject No: 11411221

Subject Initials: ---

Generated By: (b) (4)

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

[Back to Form](#)

**1. Actual Date of Collection:**

Date	Location	User	Value	Reason
Dec-22-2020 12:02:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Dec/22/2020	Initial Entry

**2. Specimen Type:**

Date	Location	User	Value	Reason
Dec-22-2020 12:02:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> SWABBED MATERIAL	Initial Entry

**3. Specimen Collection Location:**

Date	Location	User	Value	Reason
Dec-22-2020 12:02:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NASOPHARYNX	Initial Entry

**4. Assay Code and Description:**

Date	Location	User	Value	Reason
Dec-22-2020 12:02:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SEVERE ACUTE RESP SYND ROME CORONAVIRUS 2	Initial Entry

**5. Device Type:**

Date	Location	User	Value	Reason
Dec-22-2020 12:02:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SARS-COV-2 DIAGNOSTIC T EST	Initial Entry

**6. Trade Name:**

Date	Location	User	Value	Reason
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090177e196ae4091\Final\Final On: 01-Apr-2021 05:42 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled  
Visit on Dec/22/2020

**Form:** MICROBIOLOGY SPECIMEN - eCRF Audit Trail History

**Form Version:** 06-Jul-2020 21:54

**Form Status:** Data Complete

**Site No:** 1141

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

**Subject No:** 11411221

**Subject Initials:** ---

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

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

Dec-22-2020 12:02:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> OTHER	Initial Entry
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**7. Test Result:**

Date	Location	User	Value	Reason
Dec-22-2020 12:02:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> POSITIVE	Initial Entry

**9. Trade Name Other, Specify:**

Date	Location	User	Value	Reason
Dec-22-2020 12:02:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NALT UNKNOWN	Initial Entry

090177e196ae4091\Final\Final On: 01-Apr-2021 05:42 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled  
Visit on Dec/22/2020

**Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB  
SELF - 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:** 11411221

**Subject Initials:** ---

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

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

[Back to Form](#)

**1. Data Origin**

Date	Location	User	Value	Reason
Dec-22-2020 12:02:54 (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
Dec-22-2020 12:02:54 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> NASAL_SWAB_SELF	Initial Entry

**3. Sample Collected?**

Date	Location	User	Value	Reason
Dec-28-2020 12:03:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Dec-23-2020 06:05:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Dec-22-2020 12:02:54 (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.
Dec-22-2020 12:02:54 (UTC-06:00) Central	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

090177e196ae4091\Final\Final On: 01-Apr-2021 05:42 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled  
Visit on Dec/22/2020

**Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB  
SELF - 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:** 11411221

**Subject Initials:** ---

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

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

Time (US & Canada)	(b) (4), (b) (6)	Date of Collection:	Dec/22/2020
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**5.a**

Date	Location	User	Value	Reason
Dec-28-2020 12:03:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample ID:</b> RW87825	Initial Entry

**5.a Sample ID**

Date	Location	User	Value	Reason
Dec-28-2020 12:03:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> RW87825	Initial Entry

090177e196ae4091\Final\Final On: 01-Apr-2021 05:42 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled  
Visit on Dec/22/2020

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

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

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

**Site No:** 1141

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

**Subject No:** 11411221

**Subject Initials:** ---

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

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

[Back to Form](#)

**1. Data Origin**

Date	Location	User	Value	Reason
Dec-22-2020 11:43:49 (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
Dec-22-2020 11:43:49 (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
Dec-22-2020 11:43:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**4. If no sample was collected or sample was not collected according to protocol, please provide reason:**

Date	Location	User	Value	Reason
Dec-22-2020 11:43:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Swab not collected.	Initial Entry

090177e196ae4091\Final\Final On: 01-Apr-2021 05:42 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled  
Visit on Dec/22/2020

**Form:** HEALTH CARE UTILIZATION - eCRF Audit Trail History

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

**Form Status:** Data Complete

**Site No:** 1141

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

**Subject No:** 11411221

**Subject Initials:** ---

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

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

[Back to Form](#)

*I.a*

Date	Location	User	Value	Reason
Dec-22-2020 11:44:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Type of Practitioner:</b> SPECIALIST <b>Occurrence of Visits or Contacts:</b> NO	Initial Entry

*I.a Physician or Healthcare Professional:*

Date	Location	User	Value	Reason
Dec-22-2020 11:44:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> SPECIALIST	Initial Entry

*I.a Occurrence of Visits or Contacts:*

Date	Location	User	Value	Reason
Dec-22-2020 11:44:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

*I.b*

Date	Location	User	Value	Reason
Dec-22-2020 11:44:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Type of Practitioner:</b> EMERGENCY ROOM <b>Occurrence of Visits or Contacts:</b> NO	Initial Entry

090177e196ae4091\Final\Final On: 01-Apr-2021 05:42 (GMT)



Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled  
Visit on Dec/22/2020

Form: HEALTH CARE UTILIZATION - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:26

Form Status: Data Complete

Site No: 1141

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

Subject No: 11411221

Subject Initials: ---

Generated By: (b) (4)

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

***I.b Physician or Healthcare Professional:***

Date	Location	User	Value	Reason
Dec-22-2020 11:44:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> EMERGENCY ROOM	Initial Entry

***I.b Occurrence of Visits or Contacts:***

Date	Location	User	Value	Reason
Dec-22-2020 11:44:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

***I.c***

Date	Location	User	Value	Reason
Dec-22-2020 11:44:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Type of Practitioner: PRIMARY CARE PHYSICIAN Occurrence of Visits or Contacts: NO	Initial Entry

***I.c Physician or Healthcare Professional:***

Date	Location	User	Value	Reason
Dec-22-2020 11:44:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> PRIMARY CARE PHYSICIAN	Initial Entry

***I.c Occurrence of Visits or Contacts:***

Date	Location	User	Value	Reason
Dec-22-2020 11:44:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

090177e196ae4091\Final\Final On: 01-Apr-2021 05:42 (GMT)

Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled  
Visit on Dec/22/2020

Form: HEALTH CARE UTILIZATION - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:26

Form Status: Data Complete

Site No: 1141

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

Subject No: 11411221

Subject Initials: ---

Generated By: (b) (4)

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

*I.d*

Date	Location	User	Value	Reason
Dec-22-2020 11:44:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Type of Practitioner:</b> URGENT CARE <b>Occurrence of Visits or Contacts:</b> NO	Initial Entry

*I.d Physician or Healthcare Professional:*

Date	Location	User	Value	Reason
Dec-22-2020 11:44:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> URGENT CARE	Initial Entry

*I.d Occurrence of Visits or Contacts:*

Date	Location	User	Value	Reason
Dec-22-2020 11:44:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

*I.e*

Date	Location	User	Value	Reason
Dec-22-2020 11:44:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Type of Practitioner:</b> TELEPHONE CONSULTATION <b>Occurrence of Visits or Contacts:</b> YES <i>Number of Visits or Contacts:</i> 1	Initial Entry

090177e196ae4091\Final\Final On: 01-Apr-2021 05:42 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled  
Visit on Dec/22/2020

**Form:** HEALTH CARE UTILIZATION - eCRF Audit Trail History

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

**Form Status:** Data Complete

**Site No:** 1141

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

**Subject No:** 11411221

**Subject Initials:** ---

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

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

***I.e Physician or Healthcare Professional:***

Date	Location	User	Value	Reason
Dec-22-2020 11:44:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> TELEPHONE CONSULTATI ON	Initial Entry

***I.e Occurrence of Visits or Contacts:***

Date	Location	User	Value	Reason
Dec-22-2020 11:44:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES <i>Number of Visits or Contacts</i> :  1	Initial Entry

***I.f***

Date	Location	User	Value	Reason
Dec-22-2020 11:44:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Type of Practitioner:</b> OTHER <b>Occurrence of Visits or Contacts:</b> YES <i>Number of Visits or Contacts:</i>  1	Initial Entry

090177e196ae4091\Final\Final On: 01-Apr-2021 05:42 (GMT)

**Header Text:** c4591001**Visit:** POT\_COVID\_ILL 1 - Unscheduled  
Visit on Dec/22/2020**Form:** HEALTH CARE UTILIZATION - eCRF Audit Trail History**Form Version:** 10-Dec-2020 02:26**Form Status:** Data Complete**Site No:** 1141**Site Name:** (1141) University of Iowa Hospital and Clinics**Subject No:** 11411221**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 11:44**1.f Physician or Healthcare Professional:**

Date	Location	User	Value	Reason
Dec-22-2020 11:44:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> OTHER	Initial Entry

**1.f Occurrence of Visits or Contacts:**

Date	Location	User	Value	Reason
Dec-22-2020 12:06:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Dec-22-2020 11:44:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	“Other” is selected , however other specific item is blank. Please review and update as appropriate.
Dec-22-2020 11:44:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES <i>Number of Visits or Contact s:</i>  1	Initial Entry

**2. Other Type of Practitioner Specify:**

Date	Location	User	Value	Reason
Dec-22-2020 12:06:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Franklin General Hospital	Initial Entry

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

Date	Location	User	Value	Reason
Dec-22-2020 11:44:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled  
Visit on Dec/22/2020

**Form:** ILLNESS DETAILS - eCRF Audit Trail History

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

**Form Status:** Data Complete

**Site No:** 1141

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

**Subject No:** 11411221

**Subject Initials:** ---

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

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

[Back to Form](#)

**1. Category of Clinical Event:**

Date	Location	User	Value	Reason
Dec-22-2020 11:44:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> POTENTIAL COVID-19 ILLN ESS	Initial Entry

**2. Was a diagnosis obtained for Potential COVID-19 Illness?**

Date	Location	User	Value	Reason
Dec-31-2020 10:40:06 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Dec-30-2020 13:39:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Closed	Close Auto Query
Dec-30-2020 13:39:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES <i>Respiratory Illness Diagnos is:</i>  COVID-19  Date of Diagnosis:  Dec/22/2020	New Information
Dec-30-2020 13:38:27 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Opened	Yes is selected, however, either the diagnosis details or date of diagnosis is missing. Please correct.
Dec-30-2020 13:38:27 (UTC-06:00) Central	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	New Information

090177e196ae4091\Final\Final On: 01-Apr-2021 05:42 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled  
Visit on Dec/22/2020

**Form:** ILLNESS DETAILS - eCRF Audit Trail History

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

**Form Status:** Data Complete

**Site No:** 1141

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

**Subject No:** 11411221

**Subject Initials:** ---

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

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

Time (US & Canada)				
Dec-30-2020 13:38:27 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES Date of Diagnosis:  Dec/22/2020	New Information
Dec-30-2020 10:50:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	Clin: As subject is symptomatic and has a positive local swab collected on 22Dec2020, diagnosis of COVID-19 should be recorded.
Dec-22-2020 11:44:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**3. Toxicity Grade:**

Date	Location	User	Value	Reason
Dec-31-2020 00:49:55 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Dec-30-2020 13:39:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	New Information
Dec-30-2020 13:39:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 2	New Information
Dec-23-2020 00:59:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	DM: The response for "Toxicity Grade" is missing. Kindly review and update.

090177e196ae4091\Final\Final On: 01-Apr-2021 05:42 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_CONVA 1 -  
Unscheduled Visit on Jan/20/2021

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

**Site No:** 1141

**Subject No:** 11411221

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

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

**Form Status:** Data Complete, 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. Date of Visit**

Date	Location	User	Value	Reason
Jan-20-2021 16:30:19 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Jan/20/2021	Initial Entry

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

Date	Location	User	Value	Reason
Jan-20-2021 16:30:19 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> COVID_A1	Initial Entry

090177e196ae4091\Final\Final On: 01-Apr-2021 05:42 (GMT)

**Header Text:** c4591001**Visit:** POT\_COVID\_CONVA 1 -  
Unscheduled Visit on Jan/20/2021**Form Version:** 22-Apr-2020 21:03**Site No:** 1141**Subject No:** 11411221**Generated By:** (b) (4)**Form:** ELECTRONIC SAMPLE TRACKING -  
IMMUNOGENICITY - eCRF Audit Trail History**Form Status:** Data Complete, 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. Data Origin**

Date	Location	User	Value	Reason
Jan-20-2021 16:30:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SITE	Initial Entry

**2. Sample Type**

Date	Location	User	Value	Reason
Jan-20-2021 16:30:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SERUM	Initial Entry

**3. Sample Collected?**

Date	Location	User	Value	Reason
Jan-20-2021 16:30:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Jan-20-2021 16:30:34 (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.
Jan-20-2021 16:30:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES Date of Collection:  Jan/20/2021	Initial Entry

**5.a**

Date	Location	User	Value	Reason
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Header Text: c4591001

Visit: POT\_COVID\_CONVA 1 -  
Unscheduled Visit on Jan/20/2021

Form Version: 22-Apr-2020 21:03

Site No: 1141

Subject No: 11411221

Generated By: (b) (4)

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

Form Status: Data Complete, Frozen, Verified

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

Subject Initials: ---

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

Jan-20-2021 16:30:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sample ID: BLFZ52	Initial Entry
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5.a Sample ID

Date	Location	User	Value	Reason
Jan-20-2021 16:30:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BLFZ52	Initial Entry

5.b

Date	Location	User	Value	Reason
Jan-20-2021 16:31:06 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sample ID: BLFZ51	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Jan-20-2021 16:31:06 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BLFZ51	Initial Entry

5.c

Date	Location	User	Value	Reason
Jan-20-2021 16:31:18 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sample ID: BP9LZZ	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Jan-20-2021 16:31:18 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BP9LZZ	Initial Entry

090177e196ae4091\Final\Final On: 01-Apr-2021 05:42 (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:** 11411221

**Subject Initials:** ---

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

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

[Back to Form](#)

Date	Location	User	Value	Reason
Feb-11-2021 15:15:19 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Hadley Mosby (b) (4)	Form Created	

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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**Site No:** 1141

**Subject No:** 11411221

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

**Subject Initials:** ---

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

[Back to Form](#)

Date	Location	User	Value	Reason
Feb-11-2021 15:16:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Hadley Mosby (b) (4)	Form Created	

090177e196ae4091\Final\Final On: 01-Apr-2021 05:42 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Subject Initials:** ---

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

[Back to Form](#)

Date	Location	User	Value	Reason
Feb-11-2021 15:17:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Hadley Mosby (b) (4)	Form Created	

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1141

**Subject No:** 11411221

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

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

**Form Status:**

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

**Subject Initials:** ---

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

[Back to Form](#)

Date	Location	User	Value	Reason
Feb-11-2021 15:19:24 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Hadley Mosby (b) (4)	Form Created	

090177e196ae4091\Final\Final On: 01-Apr-2021 05:42 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1141

**Subject No:** 11411221

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

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

**Form Status:**

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

**Subject Initials:** ---

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

[Back to Form](#)

Date	Location	User	Value	Reason
Mar-11-2021 12:35:16 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1141

Subject No: 11411221

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Frozen

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

Subject Initials: ---

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

[Back to Form](#)

**1. Category:**

Date	Location	User	Value	Reason
Feb-11-2021 15:15:19 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> ADVERSE EVENT	Initial Entry

**2. AE ID:**

Date	Location	User	Value	Reason
Feb-11-2021 15:15:19 (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
Feb-11-2021 15:15:19 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Hadley Mosby (b) (4)	<b>Data Entry:</b> Fever (100.9 F)	Initial Entry

**4. Start Date Time:**

Date	Location	User	Value	Reason
Feb-11-2021 15:15:19 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Hadley Mosby (b) (4)	<b>Data Entry:</b> Jan/21/2021 12:00	Initial Entry

**5. Is the adverse event still ongoing?**

Date	Location	User	Value	Reason
Feb-11-2021 15:15:19 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Hadley Mosby (b) (4)	<b>Data Entry:</b> NO End Date Time:  Jan/22/2021 12:00	Initial Entry

**6. Toxicity Grade:**

090177e196ae4091\Final\Final On: 01-Apr-2021 05:42 (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: 11411221

Subject Initials: ---

Generated By: (b) (4)

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

Date	Location	User	Value	Reason
Feb-11-2021 15:15:19 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Hadley Mosby (b) (4)	<b>Data Entry:</b> 1	Initial Entry

**7. Is the adverse event serious?**

**If Yes, NOTIFY PFIZER IMMEDIATELY.**

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

Date	Location	User	Value	Reason
Feb-11-2021 15:15:19 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Hadley Mosby (b) (4)	<b>Data Entry:</b> NO	Initial Entry

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

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

Date	Location	User	Value	Reason
Feb-11-2021 15:15:19 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Hadley Mosby (b) (4)	<b>Data Entry:</b> NO	Initial Entry

**9. Is this event related to study treatment:**

Date	Location	User	Value	Reason
Feb-11-2021 15:15:19 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Hadley Mosby (b) (4)	<b>Data Entry:</b> RELATED	Initial Entry

**10. Latest Action Taken with Study Treatment:**

Date	Location	User	Value	Reason
Feb-11-2021 15:15:19 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Hadley Mosby (b) (4)	<b>Data Entry:</b> NOT APPLICABLE	Initial Entry

090177e196ae4091\Final\Final On: 01-Apr-2021 05:42 (GMT)



**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1141

**Subject No:** 11411221

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

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

**Form Status:** Data Complete, Frozen

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

**Subject Initials:** ---

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

**11. Was a Concomitant Medication given?**

Date	Location	User	Value	Reason
Feb-11-2021 15:15:19 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Hadley Mosby (b) (4)	<b>Data Entry:</b> YES	Initial Entry

**12. Was a Non-Drug Treatment given?**

Date	Location	User	Value	Reason
Feb-11-2021 15:15:19 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Hadley Mosby (b) (4)	<b>Data Entry:</b> NO	Initial Entry

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

Date	Location	User	Value	Reason
Feb-11-2021 15:15:19 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Hadley Mosby (b) (4)	<b>Data Entry:</b> RECOVERED/RESOLVED	Initial Entry

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

Date	Location	User	Value	Reason
Feb-11-2021 15:15:19 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Hadley Mosby (b) (4)	<b>Data Entry:</b> NO	Initial Entry

090177e196ae4091\Final\Final On: 01-Apr-2021 05:42 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1141

Subject No: 11411221

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Frozen

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

Subject Initials: ---

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

[Back to Form](#)

**1. Category:**

Date	Location	User	Value	Reason
Feb-11-2021 15:16:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> ADVERSE EVENT	Initial Entry

**2. AE ID:**

Date	Location	User	Value	Reason
Feb-11-2021 15:16:56 (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
Feb-11-2021 15:16:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Hadley Mosby (b) (4)	<b>Data Entry:</b> chills	Initial Entry

**4. Start Date Time:**

Date	Location	User	Value	Reason
Feb-11-2021 15:16:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Hadley Mosby (b) (4)	<b>Data Entry:</b> Jan/21/2021 12:00	Initial Entry

**5. Is the adverse event still ongoing?**

Date	Location	User	Value	Reason
Feb-11-2021 15:16:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Hadley Mosby (b) (4)	<b>Data Entry:</b> NO End Date Time: Jan/22/2021 21:00	Initial Entry

090177e196ae4091\Final\Final On: 01-Apr-2021 05:42 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1141

Subject No: 11411221

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Frozen

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

Subject Initials: ---

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

6. Toxicity Grade:

Date	Location	User	Value	Reason
Feb-11-2021 15:16:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Hadley Mosby (b) (4)	<b>Data Entry:</b> 1	Initial Entry

7. Is the adverse event serious?

If Yes, NOTIFY PFIZER IMMEDIATELY.

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

Date	Location	User	Value	Reason
Feb-11-2021 15:16:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Hadley Mosby (b) (4)	<b>Data Entry:</b> NO	Initial Entry

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

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

Date	Location	User	Value	Reason
Feb-11-2021 15:16:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Hadley Mosby (b) (4)	<b>Data Entry:</b> NO	Initial Entry

9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Feb-11-2021 15:16:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Hadley Mosby (b) (4)	<b>Data Entry:</b> RELATED	Initial Entry

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Feb-11-2021 15:16:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Hadley Mosby (b) (4)	<b>Data Entry:</b> NOT APPLICABLE	Initial Entry

090177e196ae4091\Final\Final On: 01-Apr-2021 05:42 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1141

**Subject No:** 11411221

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

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

**Form Status:** Data Complete, Frozen

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

**Subject Initials:** ---

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

**11. Was a Concomitant Medication given?**

Date	Location	User	Value	Reason
Feb-11-2021 15:16:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Hadley Mosby (b) (4)	<b>Data Entry:</b> NO	Initial Entry

**12. Was a Non-Drug Treatment given?**

Date	Location	User	Value	Reason
Feb-11-2021 15:16:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Hadley Mosby (b) (4)	<b>Data Entry:</b> NO	Initial Entry

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

Date	Location	User	Value	Reason
Feb-11-2021 15:16:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Hadley Mosby (b) (4)	<b>Data Entry:</b> RECOVERED/RESOLVED	Initial Entry

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

Date	Location	User	Value	Reason
Feb-11-2021 15:16:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Hadley Mosby (b) (4)	<b>Data Entry:</b> NO	Initial Entry

090177e196ae4091\Final\Final On: 01-Apr-2021 05:42 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1141

Subject No: 11411221

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Frozen

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

Subject Initials: ---

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

[Back to Form](#)

**1. Category:**

Date	Location	User	Value	Reason
Feb-11-2021 15:17:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> ADVERSE EVENT	Initial Entry

**2. AE ID:**

Date	Location	User	Value	Reason
Feb-11-2021 15:17:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 3	Initial Entry

**3. Adverse Event:**

*(If possible specify diagnosis, not individual symptoms)*

Date	Location	User	Value	Reason
Feb-11-2021 15:17:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Hadley Mosby (b) (4)	<b>Data Entry:</b> Fatigue	Initial Entry

**4. Start Date Time:**

Date	Location	User	Value	Reason
Feb-11-2021 15:17:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Hadley Mosby (b) (4)	<b>Data Entry:</b> Jan/21/2021 12:00	Initial Entry

**5. Is the adverse event still ongoing?**

Date	Location	User	Value	Reason
Feb-11-2021 15:17:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Hadley Mosby (b) (4)	<b>Data Entry:</b> NO End Date Time: Jan/22/2021 21:00	Initial Entry

090177e196ae4091\Final\Final On: 01-Apr-2021 05:42 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1141

Subject No: 11411221

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Frozen

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

Subject Initials: ---

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

6. Toxicity Grade:

Date	Location	User	Value	Reason
Feb-11-2021 15:17:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Hadley Mosby (b) (4)	<b>Data Entry:</b> 1	Initial Entry

7. Is the adverse event serious?

If Yes, NOTIFY PFIZER IMMEDIATELY.

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

Date	Location	User	Value	Reason
Feb-11-2021 15:17:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Hadley Mosby (b) (4)	<b>Data Entry:</b> NO	Initial Entry

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

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

Date	Location	User	Value	Reason
Feb-11-2021 15:17:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Hadley Mosby (b) (4)	<b>Data Entry:</b> NO	Initial Entry

9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Feb-11-2021 15:17:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Hadley Mosby (b) (4)	<b>Data Entry:</b> RELATED	Initial Entry

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Feb-11-2021 15:17:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Hadley Mosby (b) (4)	<b>Data Entry:</b> NOT APPLICABLE	Initial Entry

090177e196ae4091\Final\Final On: 01-Apr-2021 05:42 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

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**Form Status:** Data Complete, Frozen

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

**Subject Initials:** ---

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

**11. Was a Concomitant Medication given?**

Date	Location	User	Value	Reason
Feb-11-2021 15:17:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Hadley Mosby (b) (4)	<b>Data Entry:</b> NO	Initial Entry

**12. Was a Non-Drug Treatment given?**

Date	Location	User	Value	Reason
Feb-11-2021 15:17:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Hadley Mosby (b) (4)	<b>Data Entry:</b> NO	Initial Entry

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

Date	Location	User	Value	Reason
Feb-11-2021 15:17:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Hadley Mosby (b) (4)	<b>Data Entry:</b> RECOVERED/RESOLVED	Initial Entry

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

Date	Location	User	Value	Reason
Feb-11-2021 15:17:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Hadley Mosby (b) (4)	<b>Data Entry:</b> NO	Initial Entry

090177e196ae4091\Final\Final On: 01-Apr-2021 05:42 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1141

Subject No: 11411221

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Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Frozen

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

Subject Initials: ---

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

[Back to Form](#)

**1. Category:**

Date	Location	User	Value	Reason
Feb-11-2021 15:19:24 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> ADVERSE EVENT	Initial Entry

**2. AE ID:**

Date	Location	User	Value	Reason
Feb-11-2021 15:19:24 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 4	Initial Entry

**3. Adverse Event:**

*(If possible specify diagnosis, not individual symptoms)*

Date	Location	User	Value	Reason
Feb-11-2021 15:19:24 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Hadley Mosby (b) (4)	<b>Data Entry:</b> left axillary lymph node enlarg ement	Initial Entry

**4. Start Date Time:**

Date	Location	User	Value	Reason
Feb-11-2021 15:19:24 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Hadley Mosby (b) (4)	<b>Data Entry:</b> Jan/23/2021 10:00	Initial Entry

**5. Is the adverse event still ongoing?**

Date	Location	User	Value	Reason
Feb-11-2021 15:19:24 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Hadley Mosby (b) (4)	<b>Data Entry:</b> NO End Date Time: Jan/25/2021 05:00	Initial Entry

090177e196ae4091\Final\Final On: 01-Apr-2021 05:42 (GMT)



Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1141

Subject No: 11411221

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Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Frozen

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

Subject Initials: ---

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

6. Toxicity Grade:

Date	Location	User	Value	Reason
Feb-11-2021 15:19:24 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Hadley Mosby (b) (4)	<b>Data Entry:</b> 1	Initial Entry

7. Is the adverse event serious?

If Yes, NOTIFY PFIZER IMMEDIATELY.

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

Date	Location	User	Value	Reason
Feb-11-2021 15:19:24 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Hadley Mosby (b) (4)	<b>Data Entry:</b> NO	Initial Entry

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

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

Date	Location	User	Value	Reason
Feb-11-2021 15:19:24 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Hadley Mosby (b) (4)	<b>Data Entry:</b> NO	Initial Entry

9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Feb-11-2021 15:19:24 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Hadley Mosby (b) (4)	<b>Data Entry:</b> RELATED	Initial Entry

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Feb-11-2021 15:19:24 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Hadley Mosby (b) (4)	<b>Data Entry:</b> NOT APPLICABLE	Initial Entry

090177e196ae4091\Final\Final On: 01-Apr-2021 05:42 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1141

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

**Form Status:** Data Complete, Frozen

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

**Subject Initials:** ---

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

**11. Was a Concomitant Medication given?**

Date	Location	User	Value	Reason
Feb-11-2021 15:19:24 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Hadley Mosby (b) (4)	<b>Data Entry:</b> NO	Initial Entry

**12. Was a Non-Drug Treatment given?**

Date	Location	User	Value	Reason
Feb-11-2021 15:19:24 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Hadley Mosby (b) (4)	<b>Data Entry:</b> NO	Initial Entry

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

Date	Location	User	Value	Reason
Feb-11-2021 15:19:24 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Hadley Mosby (b) (4)	<b>Data Entry:</b> RECOVERED/RESOLVED	Initial Entry

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

Date	Location	User	Value	Reason
Feb-11-2021 15:19:24 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Hadley Mosby (b) (4)	<b>Data Entry:</b> NO	Initial Entry

090177e196ae4091\Final\Final On: 01-Apr-2021 05:42 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1141

Subject No: 11411221

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete

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

Subject Initials: ---

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

[Back to Form](#)

**1. Category:**

Date	Location	User	Value	Reason
Mar-11-2021 12:35:16 (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
Mar-11-2021 12:35:16 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 5	Initial Entry

**3. Adverse Event:**

*(If possible specify diagnosis, not individual symptoms)*

Date	Location	User	Value	Reason
Mar-11-2021 12:35:16 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> headache	Initial Entry

**4. Start Date Time:**

Date	Location	User	Value	Reason
Mar-11-2021 12:35:16 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Feb/11/2021 07:00	Initial Entry

**5. Is the adverse event still ongoing?**

Date	Location	User	Value	Reason
Mar-11-2021 12:35:16 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO End Date Time: Feb/12/2021 12:00	Initial Entry

090177e196ae4091\Final\Final On: 01-Apr-2021 05:42 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1141

Subject No: 11411221

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete

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

Subject Initials: ---

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

6. Toxicity Grade:

Date	Location	User	Value	Reason
Mar-11-2021 12:35:16 (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; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).

Date	Location	User	Value	Reason
Mar-11-2021 12:35:16 (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
Mar-11-2021 12:35:16 (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
Mar-11-2021 12:35:16 (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:

Date	Location	User	Value	Reason
Mar-11-2021 12:35:16 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NOT APPLICABLE	Initial Entry

090177e196ae4091\Final\Final On: 01-Apr-2021 05:42 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1141

**Subject No:** 11411221

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

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

**Form Status:** Data Complete

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

**Subject Initials:** ---

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

**11. Was a Concomitant Medication given?**

Date	Location	User	Value	Reason
Mar-11-2021 12:35:16 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**12. Was a Non-Drug Treatment given?**

Date	Location	User	Value	Reason
Mar-11-2021 12:35:16 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

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

Date	Location	User	Value	Reason
Mar-11-2021 12:35:16 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> RECOVERED/RESOLVED	Initial Entry

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

Date	Location	User	Value	Reason
Mar-11-2021 12:35:16 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

090177e196ae4091\Final\Final On: 01-Apr-2021 05:42 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

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

**Form Status:**

**Site No:** 1141

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

**Subject No:** 11411221

**Subject Initials:** ---

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

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

[Back to Form](#)

Date	Location	User	Value	Reason
Nov-11-2020 16:11:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

Header Text: c4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - NON STUDY VACCINATIONS - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1141

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

Subject No: 11411221

Subject Initials: ---

Generated By: (b) (4)

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

[Back to Form](#)

**1. What is the medication identifier?**

Date	Location	User	Value	Reason
Nov-11-2020 16:11:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 1	Initial Entry

**2. Category:**

Date	Location	User	Value	Reason
Nov-11-2020 16:11:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> VACCINATIONS	Initial Entry

**3. Concomitant Medications Pre-specified:**

Date	Location	User	Value	Reason
Nov-11-2020 16:11:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> NO	Initial Entry

**4. Medication:**

*Provide the complete generic drug name (including salt form, where applicable). Where generic name is unknown, enter the full trade or proprietary name. Include clarifying information in the Medication text (e.g., Ingredient(s), route, use, formulation).*

Date	Location	User	Value	Reason
Nov-11-2020 16:11:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Influenza Vaccination	Initial Entry

**5. Date:**

Date	Location	User	Value	Reason
Nov-11-2020 16:11:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Oct/22/2020	Initial Entry

090177e196ae4091\Final\Final On: 01-Apr-2021 05:42 (GMT)

**Header Text:** c4591001

**Visit:** End of Treatment - Unscheduled

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

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

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

**Site No:** 1141

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

**Subject No:** 11411221

**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
Nov-11-2020 16:11:27 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Nov/11/2020	Initial Entry

**2. Phase of Disposition:**

Date	Location	User	Value	Reason
Nov-11-2020 16:11:27 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> VACCINATION	Initial Entry

**3. Status:**

Date	Location	User	Value	Reason
Nov-11-2020 16:11:27 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> COMPLETED	Initial Entry

090177e196ae4091\Final\Final On: 01-Apr-2021 05:42 (GMT)



**Header Text:** c4591001

**Visit:** Potential ReVax Initial Contact -  
Unscheduled

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

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

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

**Site No:** 1141

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

**Subject No:** 11411221

**Subject Initials:** ---

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

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

[Back to Form](#)

*1. Date of Visit*

Date	Location	User	Value	Reason
Jan-20-2021 16:27:19 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Jan/15/2021	Initial Entry

**Header Text:** c4591001

**Visit:** Potential ReVax Initial Contact -  
Unscheduled

**Form Version:** 10-Dec-2020 02:25

**Site No:** 1141

**Subject No:** 11411221

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

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

**Form Status:** Data Complete, Frozen

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

**Subject Initials:** ---

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

[Back to Form](#)

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

Date	Location	User	Value	Reason
Jan-20-2021 16:27:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Participant is willing to return for Vaccination 3 Participant is:  eligible per local/national r ecommendations and confi rmed to have received only placebo at Vaccination 1/2	Initial Entry

**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:** 11411221

**Subject Initials:** ---

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

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

[Back to Form](#)

**1. Date Treatment Unblinded :**

Date	Location	User	Value	Reason
Jan-20-2021 16:27:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Jan/15/2021	Initial Entry

**2. Primary Reason for Unblinding:**

Date	Location	User	Value	Reason
Jan-20-2021 16:27:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> ASSESS ELIGIBILITY FOR ADDITIONAL VACCINATI ON	Initial Entry

090177e196ae4091\Final\Final On: 01-Apr-2021 05:42 (GMT)

**Header Text:** c4591001

**Visit:** V101\_VAX3

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

**Site No:** 1141

**Subject No:** 11411221

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

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

**Form Status:** Data Complete, 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. Date of Visit*

Date	Location	User	Value	Reason
Jan-20-2021 16:27:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Jan/20/2021	Initial Entry

**Header Text:** c4591001

**Visit:** V101\_VAX3

**Form:** INFORMED CONSENT - FURTHER VACCINATION -  
eCRF Audit Trail History

**Form Version:** 10-Dec-2020 02:31

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

**Site No:** 1141

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

**Subject No:** 11411221

**Subject Initials:** ---

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

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

[Back to Form](#)

**I. Consent Was:**

Date	Location	User	Value	Reason
Jan-20-2021 16:27:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> OBTAINED Date Written Consent Obtai ned  Jan/20/2021	Initial Entry

**Header Text:** c4591001

**Visit:** V101\_VAX3

**Form:** DISPOSITION - SCREENING FOR FURTHER  
VACCINATION - eCRF Audit Trail History

**Form Version:** 10-Dec-2020 02:31

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

**Site No:** 1141

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

**Subject No:** 11411221

**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
Jan-20-2021 16:28:23 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Jan/20/2021	Initial Entry

**2. Phase of Disposition:**

Date	Location	User	Value	Reason
Jan-20-2021 16:28:23 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> REPEAT SCREENING 1	Initial Entry

**3. Status:**

Date	Location	User	Value	Reason
Jan-20-2021 16:28:23 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> COMPLETED	Initial Entry

090177e196ae4091\Final\Final On: 01-Apr-2021 05:42 (GMT)

Header Text: c4591001

Visit: V101\_VAX3

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

Form Version: 14-Jan-2021 02:21

Form Status: Data Complete, Frozen, Verified

Site No: 1141

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

Subject No: 11411221

Subject Initials: ---

Generated By: (b) (4)

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

[Back to Form](#)

**1. Lab Panel:**

Date	Location	User	Value	Reason
Jan-20-2021 16:28:47 (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
Jan-20-2021 16:28:47 (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
Jan-20-2021 16:28:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Jan/20/2021	Initial Entry

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

Date	Location	User	Value	Reason
Jan-20-2021 16:28:47 (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
Jan-20-2021 16:28:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> URINE	Initial Entry

**6.a**

090177e196ae4091\Final\Final On: 01-Apr-2021 05:42 (GMT)

Header Text: c4591001

Visit: V101\_VAX3

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

Form Version: 14-Jan-2021 02:21

Form Status: Data Complete, Frozen, Verified

Site No: 1141

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

Subject No: 11411221

Subject Initials: ---

Generated By: (b) (4)

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

Date	Location	User	Value	Reason
Jan-20-2021 16:28:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Sponsor-Defined Identifier</b> 113 : <b>Test::</b> Choriogonadotropin Beta_PX113 <b>Result::</b> <b>Not Done::</b> NOT DONE	Initial Entry

6.a Sponsor ID:

Date	Location	User	Value	Reason
Jan-20-2021 16:28:47 (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
Jan-20-2021 16:28:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Choriogonadotropin Beta_PX113	Initial Entry

6.a Not Done:

Date	Location	User	Value	Reason
Jan-20-2021 16:28:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NOT DONE	Initial Entry

090177e196ae4091\Final\Final On: 01-Apr-2021 05:42 (GMT)



**Header Text:** c4591001

**Visit:** V101\_VAX3

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

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

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

**Site No:** 1141

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

**Subject No:** 11411221

**Subject Initials:** ---

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

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

[Back to Form](#)

**1. Data Origin**

Date	Location	User	Value	Reason
Jan-20-2021 16:29:20 (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
Jan-20-2021 16:29:20 (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
Jan-20-2021 16:29:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**4. If no sample was collected or sample was not collected according to protocol, please provide reason:**

Date	Location	User	Value	Reason
Jan-20-2021 16:29:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> drawn for convalescent visit	Initial Entry

090177e196ae4091\Final\Final On: 01-Apr-2021 05:42 (GMT)

**Header Text:** c4591001**Visit:** V101\_VAX3**Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB - eCRF Audit Trail History**Form Version:** 22-Apr-2020 21:03**Form Status:** Data Complete, Frozen, Verified**Site No:** 1141**Site Name:** (1141) University of Iowa Hospital and Clinics**Subject No:** 11411221**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 11:44[Back to Form](#)**1. Data Origin**

Date	Location	User	Value	Reason
Jan-20-2021 16:29:29 (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
Jan-20-2021 16:29:29 (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
Jan-20-2021 16:29:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Jan-20-2021 16:29:29 (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.
Jan-20-2021 16:29:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES Date of Collection:  Jan/20/2021	Initial Entry

**5.a**

Date	Location	User	Value	Reason
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**Header Text:** c4591001

**Visit:** V101\_VAX3

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

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

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

**Site No:** 1141

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

**Subject No:** 11411221

**Subject Initials:** ---

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

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

Jan-20-2021 16:29:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	<b>Data Entry:</b> <b>Sample ID:</b> BP9LZY	Initial Entry
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**5.a Sample ID**

Date	Location	User	Value	Reason
Jan-20-2021 16:29:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	<b>Data Entry:</b> BP9LZY	Initial Entry

Header Text: c4591001

Visit: V101\_VAX3

Form Version: 10-Dec-2020 02:26

Site No: 1141

Subject No: 11411221

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, 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. Was there a temporary delay of vaccination?**

Date	Location	User	Value	Reason
Jan-20-2021 16:30:02 (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
Jan-20-2021 16:30:02 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> BNT162b2	Initial Entry

**3. Formulation:**

Date	Location	User	Value	Reason
Jan-20-2021 16:30:02 (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
Jan-20-2021 16:30:02 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Jan/20/2021 15:10	Initial Entry

**5. Anatomical Location:**

Date	Location	User	Value	Reason
Jan-20-2021 16:30:02 (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
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090177e196ae4091\Final\Final On: 01-Apr-2021 05:42 (GMT)

Header Text: c4591001

Visit: V101\_VAX3

Form Version: 10-Dec-2020 02:26

Site No: 1141

Subject No: 11411221

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

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

Subject Initials: ---

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

Jan-20-2021 16:30:02 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> LEFT	Initial Entry
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7. Route:

Date	Location	User	Value	Reason
Jan-20-2021 16:30:02 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> INTRAMUSCULAR	Initial Entry

8. Actual Dose:

Date	Location	User	Value	Reason
Jan-20-2021 16:30:02 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 30.0	Initial Entry

9. Unit:

Date	Location	User	Value	Reason
Jan-20-2021 16:30:02 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> ug	Initial Entry

10. Timeframe Subject Was Observed

Date	Location	User	Value	Reason
Jan-20-2021 16:30:02 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 30 MINUTES	Initial Entry

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

Date	Location	User	Value	Reason
Jan-20-2021 16:30:02 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

090177e196ae4091\Final\Final On: 01-Apr-2021 05:42 (GMT)

**Header Text:** c4591001

**Visit:** V102\_VAX4

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

**Site No:** 1141

**Subject No:** 11411221

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

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

**Form Status:** Data Complete, 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. Date of Visit*

Date	Location	User	Value	Reason
Feb-11-2021 15:02:37 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Hadley Mosby (b) (4)	<b>Data Entry:</b> Feb/10/2021	Initial Entry

Header Text: c4591001

Visit: V102\_VAX4

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

Form Version: 14-Jan-2021 02:21

Form Status: Data Complete, Frozen, Verified

Site No: 1141

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

Subject No: 11411221

Subject Initials: ---

Generated By: (b) (4)

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

[Back to Form](#)

3. Collection Date:

Date	Location	User	Value	Reason
Feb-11-2021 15:03:27 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Hadley Mosby (b) (4)	<b>Data Entry:</b> Not Applicable	Initial Entry

6.a

Date	Location	User	Value	Reason
Feb-11-2021 15:03:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Sponsor-Def</b> 113 <b>ined Identifi</b> <b>er:</b> <b>Test::</b> Choriogonadot ropin Beta_PX 113 <b>Result::</b> <b>Not Done::</b> NOT DONE	Initial Entry
Feb-11-2021 15:03:27 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Hadley Mosby (b) (4)	<b>Data Entry:</b> <b>Sponsor-Def</b> <b>ined Identifi</b> <b>er:</b> <b>Test::</b> Choriogonadot ropin Beta_PX 113 <b>Result::</b> <b>Not Done::</b>	Initial Entry

6.a Sponsor ID:

Date	Location	User	Value	Reason
Feb-11-2021 15:03:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 113	Initial Entry

090177e196ae4091\Final\Final On: 01-Apr-2021 05:42 (GMT)

**Header Text:** c4591001

**Visit:** V102\_VAX4

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

**Form Version:** 14-Jan-2021 02:21

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

**Site No:** 1141

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

**Subject No:** 11411221

**Subject Initials:** ---

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

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

**6.a Test:**

Date	Location	User	Value	Reason
Feb-11-2021 15:03:27 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Hadley Mosby (b) (4)	<b>Data Entry:</b> Choriogonadotropin Beta_PX1 13	Initial Entry

**6.a Not Done:**

Date	Location	User	Value	Reason
Feb-11-2021 15:03:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Hadley Mosby (b) (4)	<b>Data Entry:</b> NOT DONE	Initial Entry



**Header Text:** c4591001

**Visit:** V102\_VAX4

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

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

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

**Site No:** 1141

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

**Subject No:** 11411221

**Subject Initials:** ---

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

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

[Back to Form](#)

**1. Data Origin**

Date	Location	User	Value	Reason
Feb-11-2021 15:04:18 (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
Feb-11-2021 15:04:18 (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
Feb-12-2021 06:14:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Feb-12-2021 05:54:55 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Feb-11-2021 15:04:18 (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.
Feb-11-2021 15:04:18 (UTC-06:00) Central	ACV0PFEINFP6000	Hadley Mosby	<b>Data Entry:</b> YES	Initial Entry

090177e196ae4091\Final\Final On: 01-Apr-2021 05:42 (GMT)

**Header Text:** c4591001

**Visit:** V102\_VAX4

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

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

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

**Site No:** 1141

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

**Subject No:** 11411221

**Subject Initials:** ---

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

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

Time (US & Canada)	(b) (4)	Date of Collection:	
		Feb/10/2021	

**5.a**

Date	Location	User	Value	Reason
Feb-12-2021 06:14:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample ID:</b> BRFDSE	Initial Entry

**5.a Sample ID**

Date	Location	User	Value	Reason
Feb-12-2021 06:14:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BRFDSE	Initial Entry

090177e196ae4091\Final\Final On: 01-Apr-2021 05:42 (GMT)

Header Text: c4591001

Visit: V102\_VAX4

Form Version: 10-Dec-2020 02:26

Site No: 1141

Subject No: 11411221

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, 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. Was there a temporary delay of vaccination?**

Date	Location	User	Value	Reason
Feb-11-2021 15:05:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Hadley Mosby (b) (4)	<b>Data Entry:</b> NO	Initial Entry

**2. Treatment Name**

Date	Location	User	Value	Reason
Feb-11-2021 15:05:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> BNT162b2	Initial Entry

**3. Formulation:**

Date	Location	User	Value	Reason
Feb-11-2021 15:05:44 (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
Feb-11-2021 15:05:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Hadley Mosby (b) (4)	<b>Data Entry:</b> Feb/10/2021 15:35	Initial Entry

**5. Anatomical Location:**

Date	Location	User	Value	Reason
Feb-11-2021 15:05:44 (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
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090177e196ae4091\Final\Final On: 01-Apr-2021 05:42 (GMT)

Header Text: c4591001

Visit: V102\_VAX4

Form Version: 10-Dec-2020 02:26

Site No: 1141

Subject No: 11411221

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

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

Subject Initials: ---

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

Feb-11-2021 15:05:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Hadley Mosby (b) (4)	<b>Data Entry:</b> RIGHT	Initial Entry
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**7. Route:**

Date	Location	User	Value	Reason
Feb-11-2021 15:05:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> INTRAMUSCULAR	Initial Entry

**8. Actual Dose:**

Date	Location	User	Value	Reason
Feb-11-2021 15:05:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 30.0	Initial Entry

**9. Unit:**

Date	Location	User	Value	Reason
Feb-11-2021 15:05:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> ug	Initial Entry

**10. Timeframe Subject Was Observed**

Date	Location	User	Value	Reason
Feb-11-2021 15:05:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 30 MINUTES	Initial Entry

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

Date	Location	User	Value	Reason
Feb-11-2021 15:05:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Hadley Mosby (b) (4)	<b>Data Entry:</b> YES	Initial Entry

090177e196ae4091\Final\Final On: 01-Apr-2021 05:42 (GMT)

**Header Text:** c4591001

**Visit:** V103\_MONTH1

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

**Site No:** 1141

**Subject No:** 11411221

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

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

**Form Status:** Data Complete, Verified

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

**Subject Initials:** ---

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

[Back to Form](#)

*1. Date of Visit*

Date	Location	User	Value	Reason
Mar-11-2021 12:41:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Mar/11/2021	Initial Entry

**Header Text:** c4591001

**Visit:** V103\_MONTH1

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

**Site No:** 1141

**Subject No:** 11411221

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

**Form:** CONTACT OUTCOME - eCRF Audit Trail History

**Form Status:** Data Complete, Verified

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

**Subject Initials:** ---

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

[Back to Form](#)

**1. Contact Type:**

Date	Location	User	Value	Reason
Mar-11-2021 12:42:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> TELEPHONE VISIT	Initial Entry

**2. Was contact made?**

Date	Location	User	Value	Reason
Mar-11-2021 12:42:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES Date of Contact:  Mar/11/2021	Initial Entry

090177e196ae4091\Final\Final On: 01-Apr-2021 05:42 (GMT)

**Header Text:** c4591001

**Visit:** FURTHER\_VACCINATION\_EOT -  
Unscheduled

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

**Form Version:** 20-Feb-2021 02:26

**Form Status:** Data Complete, Verified

**Site No:** 1141

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

**Subject No:** 11411221

**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
Mar-11-2021 12:43:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Mar/11/2021	Initial Entry

**2. Phase of Disposition:**

Date	Location	User	Value	Reason
Mar-11-2021 12:43:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> OPEN LABEL TREATMENT	Initial Entry

**3. Status:**

Date	Location	User	Value	Reason
Mar-11-2021 12:43:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> COMPLETED	Initial Entry

090177e196ae4091\Final\Final On: 01-Apr-2021 05:42 (GMT)

**Header Text:** c4591001

**Visit:** Subject Status - Unscheduled

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

**Site No:** 1141

**Subject No:** 11411221

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

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

**Form Status:** Data Complete, 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 Status**

Date	Location	User	Value	Reason
Nov-11-2020 16:11:27 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> FOLLOW-UP	Initial Entry
Sep-16-2020 16:36:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> ENROLLED/RANDOMIZED	Initial Entry
Sep-16-2020 16:33:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SCREENED	Initial Entry

**2. Subject Status Date**

Date	Location	User	Value	Reason
Nov-11-2020 16:11:27 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> Nov/11/2020	Initial Entry
Sep-16-2020 16:36:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> Sep/16/2020	Initial Entry
Sep-16-2020 16:33:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> Sep/16/2020	Initial Entry

090177e196ae4091\Final\Final On: 01-Apr-2021 05:42 (GMT)



**Header Text:** c4591001

**Visit:** Investigator Signature - Unscheduled

**Form:** CASEBOOK SIGNATURE FORM - eCRF Audit Trail History

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

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

**Site No:** 1141

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

**Subject No:** 11411221

**Subject Initials:** ---

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

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

[Back to Form](#)

*I. Casebook Signature*

Date	Location	User	Value	Reason
Nov-06-2020 11:17:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Patricia Winokur (b) (4)	<b>Data Entry:</b> Click Here to Enable	Initial Entry