

**Header Text:** c4591001

**Visit:** COHORT\_SELECTION

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

**Site No:** 1141

**Subject No:** 11411143

**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

**Header Text:** c4591001  
**Visit:** COHORT\_SELECTION  
**Form Version:** 22-Apr-2020 21:02  
**Site No:** 1141  
**Subject No:** 11411143  
**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 Aug/27/2020

**Header Text:** c4591001

**Visit:** COHORT\_SELECTION

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

**Site No:** 1141

**Subject No:** 11411143

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

**Form:** DEMOGRAPHY

**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](#)

**Demography**

1.	Subject ID	[11411143]
2.	Birth Date:	(b) (6)/1964
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:** 11411143

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

**Form:** DATE OF VISIT

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

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

**Subject Initials:** ---

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

[eCRF Audit Trail History](#)

**Date of Visit**

1.	Date of Visit	Aug/27/2020
2.	Erroneous Visit	

<b>Header Text:</b> c4591001	<b>Form:</b> INCLUSION/EXCLUSION CRITERIA
<b>Visit:</b> V1_DAY1_VAX1_L	<b>Form Status:</b> Data Complete, Locked, Frozen, Verified
<b>Form Version:</b> 30-Jul-2020 21:29	<b>Site Name:</b> (1141) University of Iowa Hospital and Clinics
<b>Site No:</b> 1141	<b>Subject Initials:</b> ---
<b>Subject No:</b> 11411143	<b>Generated Time (GMT):</b> 29-Mar-2021 11:44
<b>Generated By:</b> (b) (4)	

**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:** V1\_DAY1\_VAX1\_L  
**Form Version:** 22-Apr-2020 21:03  
**Site No:** 1141  
**Subject No:** 11411143  
**Generated By:** (b) (4)

**Form:** DISPOSITION - SCREENING  
**Form Status:** Data Complete, Locked, Frozen, Verified  
**Site Name:** (1141) University of Iowa Hospital and Clinics  
**Subject Initials:** ---  
**Generated Time (GMT):** 29-Mar-2021 11:44

[eCRF Audit Trail History](#)

Disposition - Screening		
1.	Date of Completion/Discontinuation /Death	Aug/27/2020
2.	Phase of Disposition:	SCREENING
3.	Status:	COMPLETED
4.	Specify Status:	[ ]

090177e196ae408e\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: 11411143

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:	[hypertension]
	Start Date:	UNK/UNK/2010
	Ongoing:	YES
1.b	Line/MH Number:	[2]
	Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:	[seasonal affective disorder]
	Start Date:	UNK/UNK/1999
	Ongoing:	YES
1.c	Line/MH Number:	[3]
	Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:	[insomnia]
	Start Date:	UNK/UNK/2000
	Ongoing:	YES
1.d	Line/MH Number:	[4]
	Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:	[generalized pain]
	Start Date:	UNK/UNK/1980
	Ongoing:	YES
1.e	Line/MH Number:	[5]
	Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:	[nearsighted]
	Start Date:	UNK/UNK/1975
	Ongoing:	YES
1.f	Line/MH Number:	[6]
	Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:	[right hip osteoarthritis]
	Start Date:	Apr/UNK/2018
	Ongoing:	NO End Date: May/29/2018

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Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 22-Apr-2020 21:03

Site No: 1141

Subject No: 11411143

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.g	Line/MH Number:	[7]
	Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:	[right hip replacement]
	Start Date:	May/29/2018
	Ongoing:	NO End Date: May/29/2018
1.h	Line/MH Number:	[8]
	Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:	[degenerative disk disease- back]
	Start Date:	Jan/UNK/2007
	Ongoing:	NO End Date: Mar/29/2007
1.i	Line/MH Number:	[9]
	Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:	[Rods placed in back]
	Start Date:	Mar/29/2007
	Ongoing:	NO End Date: Mar/29/2007
1.j	Line/MH Number:	[10]
	Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:	[tummy tuck]
	Start Date:	Apr/UNK/2017
	Ongoing:	NO End Date: Apr/UNK/2017
1.k	Line/MH Number:	[11]
	Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:	[abdominal apron]
	Start Date:	UNK/UNK/1999
	Ongoing:	NO End Date: Apr/UNK/2017
1.l	Line/MH Number:	[12]
	Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:	[lower back pain (L5 Region)]
	Start Date:	UNK/UNK/2007
	Ongoing:	YES

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**Header Text:** c4591001

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

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

**Site No:** 1141

**Subject No:** 11411143

**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.m	Line/MH Number:	[13]
	Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:	[post menopausal]
	Start Date:	UNK/UNK/2018
	Ongoing:	YES

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**Header Text:** c4591001  
**Visit:** V1\_DAY1\_VAX1\_L  
**Form Version:** 21-Aug-2020 02:51  
**Site No:** 1141  
**Subject No:** 11411143  
**Generated By:** (b) (4)

**Form:** VITAL SIGNS - BASELINE  
**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:	Aug/27/2020
2.	Weight:	[86.0]
3.	Unit:	kg
4.	Height:	[157.0]
5.	Unit:	cm
6.	Body Mass Index:	[34.9]
Vital Signs Details		
7.a	Record Identifier:	1
	Temperature:	[96.1]
	Unit:	F
	Temperature Location:	ORAL CAVITY

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**Header Text:** c4591001  
**Visit:** V1\_DAY1\_VAX1\_L  
**Form Version:** 21-Aug-2020 02:49  
**Site No:** 1141  
**Subject No:** 11411143  
**Generated By:** (b) (4)

**Form:** LAB URINALYSIS - PREGNANCY TEST  
**Form Status:** Data Complete, Locked, Frozen, Verified  
**Site Name:** (1141) University of Iowa Hospital and Clinics  
**Subject Initials:** ---  
**Generated Time (GMT):** 29-Mar-2021 11:44

[eCRF Audit Trail History](#)

**Lab Urinalysis**

1.	Lab Panel:	URINALYSIS
2.	Lab Sub-Panel:	PREGNANCY
3.	Collection Date:	Aug/27/2020
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

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<b>Header Text:</b> c4591001	<b>Form:</b> RANDOMIZATION
<b>Visit:</b> V1_DAY1_VAX1_L	<b>Form Status:</b> Data Complete, Locked, Frozen, Verified
<b>Form Version:</b> 22-Apr-2020 21:03	<b>Site Name:</b> (1141) University of Iowa Hospital and Clinics
<b>Site No:</b> 1141	<b>Subject Initials:</b> ---
<b>Subject No:</b> 11411143	<b>Generated Time (GMT):</b> 29-Mar-2021 11:44
<b>Generated By:</b> (b) (4)	

[eCRF Audit Trail History](#)

Disposition		
1.	Randomization Date :	Aug/27/2020
2.	Randomization Number:	[241295]
3.	Randomization Group:	[ ]

**Header Text:** c4591001  
**Visit:** V1\_DAY1\_VAX1\_L  
**Form Version:** 22-Apr-2020 21:03  
**Site No:** 1141  
**Subject No:** 11411143  
**Generated By:** (b) (4)

**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY  
**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	SERUM
3.	Sample Collected?	YES Date of Collection: Aug/27/2020
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	[BM88SV]
5.b	Sample ID	[BM88SW]
5.c	Sample ID	[BM88SX]
5.d	Sample ID	[BLC9C3]
5.e	Sample ID	[BLC9C2]

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**Header Text:** c4591001  
**Visit:** V1\_DAY1\_VAX1\_L  
**Form Version:** 22-Apr-2020 21:03  
**Site No:** 1141  
**Subject No:** 11411143  
**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: Aug/27/2020
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	[BM88SP]
-----	-----------	----------

090177e196ae408e\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:** 11411143  
**Generated By:** (b) (4)

**Form:** VACCINATION  
**Form Status:** Data Complete, Locked, Frozen, Verified  
**Site Name:** (1141) University of Iowa Hospital and Clinics  
**Subject Initials:** ---  
**Generated Time (GMT):** 29-Mar-2021 11:44

[eCRF Audit Trail History](#)

Vaccination		
1.	Was there a temporary delay of vaccination?	NO
2.	Treatment Name	[BLINDED THERAPY]
3.	Formulation:	INJECTION
4.	Dose Date Time:	Aug/27/2020 15:09
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

090177e196ae408e\Final\Final On: 01-Apr-2021 05:42 (GMT)

<b>Header Text:</b> c4591001	<b>Form:</b> REACTOGENICITY DIARY
<b>Visit:</b> V1_DAY1_VAX1_L	<b>Form Status:</b> Data Complete, Locked, Frozen, Verified
<b>Form Version:</b> 06-Jul-2020 21:53	<b>Site Name:</b> (1141) University of Iowa Hospital and Clinics
<b>Site No:</b> 1141	<b>Subject Initials:</b> ---
<b>Subject No:</b> 11411143	<b>Generated Time (GMT):</b> 29-Mar-2021 11:44
<b>Generated By:</b> (b) (4)	

[eCRF Audit Trail History](#)

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

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**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1141

**Subject No:** 11411143

**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/18/2020
2.	Erroneous Visit	

<b>Header Text:</b> c4591001	<b>Form:</b> VITAL SIGNS - TEMP
<b>Visit:</b> V2_VAX2_L	<b>Form Status:</b> Data Complete, Locked, Frozen, Verified
<b>Form Version:</b> 15-Sep-2020 21:54	<b>Site Name:</b> (1141) University of Iowa Hospital and Clinics
<b>Site No:</b> 1141	<b>Subject Initials:</b> ---
<b>Subject No:</b> 11411143	<b>Generated Time (GMT):</b> 29-Mar-2021 11:44
<b>Generated By:</b> (b) (4)	

[eCRF Audit Trail History](#)

**Vital Signs**

1.	Date:	Sep/18/2020
----	-------	-------------

**Vital Signs Details**

2.a	Record Identifier:	1
	Temperature:	[99.0]
	Unit:	F
	Temperature Location:	ORAL CAVITY

090177e196ae408e\Final\Final On: 01-Apr-2021 05:42 (GMT)

**Header Text:** c4591001  
**Visit:** V2\_VAX2\_L  
**Form Version:** 21-Aug-2020 02:49  
**Site No:** 1141  
**Subject No:** 11411143  
**Generated By:** (b) (4)

**Form:** LAB URINALYSIS - PREGNANCY TEST  
**Form Status:** Data Complete, Locked, Frozen, Verified  
**Site Name:** (1141) University of Iowa Hospital and Clinics  
**Subject Initials:** ---  
**Generated Time (GMT):** 29-Mar-2021 11:44

[eCRF Audit Trail History](#)

**Lab Urinalysis**

1.	Lab Panel:	URINALYSIS
2.	Lab Sub-Panel:	PREGNANCY
3.	Collection Date:	Sep/18/2020
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

090177e196ae408e\Final\Final On: 01-Apr-2021 05:42 (GMT)

<b>Header Text:</b> c4591001	<b>Form:</b> ELECTRONIC SAMPLE TRACKING - NASAL SWAB
<b>Visit:</b> V2_VAX2_L	<b>Form Status:</b> Data Complete, Locked, Frozen, Verified
<b>Form Version:</b> 22-Apr-2020 21:03	<b>Site Name:</b> (1141) University of Iowa Hospital and Clinics
<b>Site No:</b> 1141	<b>Subject Initials:</b> ---
<b>Subject No:</b> 11411143	<b>Generated Time (GMT):</b> 29-Mar-2021 11:44
<b>Generated By:</b> (b) (4)	

[eCRF Audit Trail History](#)

**Electronic Sample Tracking**

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Sep/18/2020
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	[BM6J0X]
-----	-----------	----------

**Header Text:** c4591001  
**Visit:** V2\_VAX2\_L **Form:** VACCINATION  
**Form Version:** 22-Apr-2020 21:04 **Form Status:** Data Complete, Locked, Frozen, Verified  
**Site No:** 1141 **Site Name:** (1141) University of Iowa Hospital and Clinics  
**Subject No:** 11411143 **Subject Initials:** ---  
**Generated By:** (b) (4) **Generated Time (GMT):** 29-Mar-2021 11:44

[eCRF Audit Trail History](#)

Vaccination		
1.	Was there a temporary delay of vaccination?	NO
2.	Treatment Name	[BLINDED THERAPY]
3.	Formulation:	INJECTION
4.	Dose Date Time:	Sep/18/2020 10:50
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

090177e196ae408e\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:** 11411143

**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/19/2020
2.	Erroneous Visit	

**Header Text:** c4591001  
**Visit:** V3\_MONTH1\_POSTVAX2\_L  
**Form Version:** 22-Apr-2020 21:03  
**Site No:** 1141  
**Subject No:** 11411143  
**Generated By:** (b) (4)

**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY  
**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	SERUM
3.	Sample Collected?	YES Date of Collection: Oct/19/2020
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	[BP9M91]
5.b	Sample ID	[BRX71W]
5.c	Sample ID	[BRX71W]
5.d	Sample ID	[BRX71X]

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<b>Header Text:</b> c4591001		<b>Form:</b> DATE OF VISIT
<b>Visit:</b> V4_MONTH6_L		<b>Form Status:</b> Not Started
<b>Form Version:</b> 22-Apr-2020 21:02		<b>Site Name:</b> (1141) University of Iowa Hospital and Clinics
<b>Site No:</b> 1141		<b>Subject Initials:</b> ---
<b>Subject No:</b> 11411143		<b>Generated Time (GMT):</b> 29-Mar-2021 11:44
<b>Generated By:</b> (b) (4)		
<b>Date of Visit</b>		
1.	Date of Visit	//
2.	Erroneous Visit	



<b>Header Text:</b> c4591001	<b>Form:</b> ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY
<b>Visit:</b> V4_MONTH6_L	<b>Form Status:</b> Not Started
<b>Form Version:</b> 22-Apr-2020 21:03	<b>Site Name:</b> (1141) University of Iowa Hospital and Clinics
<b>Site No:</b> 1141	<b>Subject Initials:</b> ---
<b>Subject No:</b> 11411143	<b>Generated Time (GMT):</b> 29-Mar-2021 11:44
<b>Generated By:</b> (b) (4)	

**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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<b>Header Text:</b> c4591001		<b>Form:</b> DATE OF VISIT
<b>Visit:</b> V5_MONTH12_L		<b>Form Status:</b> Not Started
<b>Form Version:</b> 22-Apr-2020 21:02		<b>Site Name:</b> (1141) University of Iowa Hospital and Clinics
<b>Site No:</b> 1141		<b>Subject Initials:</b> ---
<b>Subject No:</b> 11411143		<b>Generated Time (GMT):</b> 29-Mar-2021 11:44
<b>Generated By:</b> (b) (4)		
<b>Date of Visit</b>		
1.	Date of Visit	//
2.	Erroneous Visit	

<b>Header Text:</b> c4591001	<b>Form:</b> ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY
<b>Visit:</b> V5_MONTH12_L	<b>Form Status:</b> Not Started
<b>Form Version:</b> 22-Apr-2020 21:03	<b>Site Name:</b> (1141) University of Iowa Hospital and Clinics
<b>Site No:</b> 1141	<b>Subject Initials:</b> ---
<b>Subject No:</b> 11411143	<b>Generated Time (GMT):</b> 29-Mar-2021 11:44
<b>Generated By:</b> (b) (4)	

**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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<b>Header Text:</b> c4591001	<b>Form:</b> DATE OF VISIT
<b>Visit:</b> V6_MONTH24_L	<b>Form Status:</b> Not Started
<b>Form Version:</b> 22-Apr-2020 21:02	<b>Site Name:</b> (1141) University of Iowa Hospital and Clinics
<b>Site No:</b> 1141	<b>Subject Initials:</b> ---
<b>Subject No:</b> 11411143	<b>Generated Time (GMT):</b> 29-Mar-2021 11:44
<b>Generated By:</b> (b) (4)	

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

<b>Header Text:</b> c4591001	<b>Form:</b> ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY
<b>Visit:</b> V6_MONTH24_L	<b>Form Status:</b> Not Started
<b>Form Version:</b> 22-Apr-2020 21:03	<b>Site Name:</b> (1141) University of Iowa Hospital and Clinics
<b>Site No:</b> 1141	<b>Subject Initials:</b> ---
<b>Subject No:</b> 11411143	<b>Generated Time (GMT):</b> 29-Mar-2021 11:44
<b>Generated By:</b> (b) (4)	

**Electronic Sample Tracking**

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

**Aliquot**

Please enter barcode for each aliquot.

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

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on  
Sep/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:** 11411143

**Subject Initials:** ---

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

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

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**Date of Visit**

1.	Date of Visit	Sep/22/2020
2.	Erroneous Visit	ERRONEOUS VISIT

**COVID-19 Illness Visit**

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

**Header Text:** c4591001  
**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Sep/22/2020  
**Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19  
**Form Version:** 20-Feb-2021 02:17  
**Form Status:** Not Started  
**Site No:** 1141  
**Site Name:** (1141) University of Iowa Hospital and Clinics  
**Subject No:** 11411143  
**Subject Initials:** ---  
**Generated By:** (b) (4)  
**Generated Time (GMT):** 29-Mar-2021 11:44

**Signs and Symptoms**

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

**Symptoms**

4.	Symptoms:	
	Was symptom present?	

**Symptoms - Other**

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

090177e196ae408e\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:** 11411143

**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.						<a href="#">Repeating Pages</a>



**Header Text:** c4591001

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

**Form:** MICROBIOLOGY SPECIMEN

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

**Form Status:** Not Started

**Site No:** 1141

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

**Subject No:** 11411143

**Subject Initials:** ---

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

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

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**Microbiology Specimen**

1.	Actual Date of Collection:	//
2.	Specimen Type:	
3.	Specimen Collection Location:	
4.	Assay Code and Description:	
5.	Device Type:	
6.	Trade Name:	
7.	Test Result:	
8.	Comments/Findings/Details:	[ ]
9.	Trade Name Other, Specify:	[ ]

**Header Text:** c4591001  
**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Sep/22/2020  
**Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB SELF  
**Form Version:** 22-Apr-2020 21:03  
**Form Status:** Not Started  
**Site No:** 1141  
**Site Name:** (1141) University of Iowa Hospital and Clinics  
**Subject No:** 11411143  
**Subject Initials:** ---  
**Generated By:** (b) (4)  
**Generated Time (GMT):** 29-Mar-2021 11:44

**Electronic Sample Tracking**

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

**Aliquot**

Please enter barcode for each aliquot.

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

**Header Text:** c4591001  
**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Sep/22/2020  
**Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB  
**Form Version:** 22-Apr-2020 21:03  
**Form Status:** Not Started  
**Site No:** 1141  
**Site Name:** (1141) University of Iowa Hospital and Clinics  
**Subject No:** 11411143  
**Subject Initials:** ---  
**Generated By:** (b) (4)  
**Generated Time (GMT):** 29-Mar-2021 11:44

**Electronic Sample Tracking**

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

**Aliquot**

Please enter barcode for each aliquot.

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

**Header Text:** c4591001  
**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Sep/22/2020  
**Form:** HEALTH CARE UTILIZATION  
**Form Version:** 20-Feb-2021 02:19  
**Form Status:** Not Started  
**Site No:** 1141  
**Site Name:** (1141) University of Iowa Hospital and Clinics  
**Subject No:** 11411143  
**Subject Initials:** ---  
**Generated By:** (b) (4)  
**Generated Time (GMT):** 29-Mar-2021 11:44

**Health Care Utilization**

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

**Health Care Utilization Other**

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

**Health Care Utilization**

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

**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:** 11411143

**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>

090177e196ae408e\Final\Final On: 01-Apr-2021 05:42 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on  
Sep/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:** 11411143

**Subject Initials:** ---

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

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

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**Respiratory Treatment**

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

**Header Text:** c4591001  
**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Sep/22/2020  
**Form:** ILLNESS DETAILS  
**Form Version:** 06-Jul-2020 21:52  
**Form Status:** Not Started  
**Site No:** 1141  
**Site Name:** (1141) University of Iowa Hospital and Clinics  
**Subject No:** 11411143  
**Subject Initials:** ---  
**Generated By:** (b) (4)  
**Generated Time (GMT):** 29-Mar-2021 11:44

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

090177e196ae408e\Final\Final On: 01-Apr-2021 05:42 (GMT)

**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:** 11411143

**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>

090177e196ae408e\Final\Final On: 01-Apr-2021 05:42 (GMT)



**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on  
Sep/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:** 11411143

**Subject Initials:** ---

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

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

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**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 - Unscheduled Visit on Sep/22/2020

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

**Form Version:** 21-Aug-2020 02:49

**Form Status:** Not Started

**Site No:** 1141

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

**Subject No:** 11411143

**Subject Initials:** ---

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

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

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**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

090177e196ae408e\Final\Final On: 01-Apr-2021 05:42 (GMT)



**Header Text:** c4591001

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

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

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

**Form Status:** Not Started

**Site No:** 1141

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

**Subject No:** 11411143

**Subject Initials:** ---

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

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

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**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

090177e196ae408e\Final\Final On: 01-Apr-2021 05:42 (GMT)



**Header Text:** c4591001

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

**Form:** VITAL SIGNS - COVID

**Form Version:** 21-Aug-2020 02:50

**Form Status:** Not Started

**Site No:** 1141

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

**Subject No:** 11411143

**Subject Initials:** ---

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

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

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**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 - Unscheduled Visit on Sep/22/2020  
**Form:** VITAL SIGNS - PULSE OX ROOM AIR  
**Form Version:** 21-Aug-2020 02:51  
**Form Status:** Not Started  
**Site No:** 1141  
**Site Name:** (1141) University of Iowa Hospital and Clinics  
**Subject No:** 11411143  
**Subject Initials:** ---  
**Generated By:** (b) (4)  
**Generated Time (GMT):** 29-Mar-2021 11:44

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Vital Signs		
1.	Date:	//
Vital Signs Details		
2.	Record Identifier:	
	SPO2 Pulse Oximetry %	[ ]

090177e196ae408e\Final\Final On: 01-Apr-2021 05:42 (GMT)

**Header Text:** c4591001

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

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

**Site No:** 1141

**Subject No:** 11411143

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

**Form:** OXYGENATION PARAMETERS

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

**Subject Initials:** ---

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

#	Date Time of Assessment	Arterial Blood Gases PaO2	FiO2 (Fraction of Inhaled Oxygen)	Form Instance
1.				<a href="#">Repeating Pages</a>

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on  
Sep/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:** 11411143

**Subject Initials:** ---

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

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

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**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:** 11411143 **Subject Initials:** ---  
**Generated By:** (b) (4) **Generated Time (GMT):** 29-Mar-2021 11:44

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

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Sep/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:** 11411143

**Subject Initials:** ---

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

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

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**Concomitant Medications**

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

090177e196ae408e\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:** 11411143

**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>

**Header Text:** c4591001  
**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Sep/22/2020  
**Form:** IMAGING  
**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:** 11411143  
**Subject Initials:** ---  
**Generated By:** (b) (4)  
**Generated Time (GMT):** 29-Mar-2021 11:44

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

**Header Text:** c4591001  
**Visit:** POT\_COVID\_CONVA - New Unscheduled Visit    **Form:** DATE OF VISIT - ILLNESS CONVALESCENT  
**Form Version:** 22-Apr-2020 21:04    **Form Status:** Not Started  
**Site No:** 1141    **Site Name:** (1141) University of Iowa Hospital and Clinics  
**Subject No:** 11411143    **Subject Initials:** ---  
**Generated By:** (b) (4)    **Generated Time (GMT):** 29-Mar-2021 11:44

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



**Header Text:** c4591001  
**Visit:** POT\_COVID\_CONVA - New Unscheduled Visit    **Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY  
**Form Version:** 22-Apr-2020 21:03    **Form Status:** Not Started  
**Site No:** 1141    **Site Name:** (1141) University of Iowa Hospital and Clinics  
**Subject No:** 11411143    **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 1 - Unscheduled Visit on Sep/22/2020    **Form:** DATE OF VISIT

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

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

**Site No:** 1141

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

**Subject No:** 11411143

**Subject Initials:** ---

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

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

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**Date of Visit**

1.	Date of Visit	Sep/22/2020
2.	Erroneous Visit	

**Header Text:** c4591001  
**Visit:** Unplanned 1 - Unscheduled Visit on Sep/22/2020    **Form:** UNPLANNED VISIT  
**Form Version:** 22-Apr-2020 21:04    **Form Status:** Data Complete, Locked, Frozen, Verified  
**Site No:** 1141    **Site Name:** (1141) University of Iowa Hospital and Clinics  
**Subject No:** 11411143    **Subject Initials:** ---  
**Generated By:** (b) (4)    **Generated Time (GMT):** 29-Mar-2021 11:44

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Unplanned Assessments		
1.	Assessments	CONTACT OUTCOME

**Header Text:** c4591001  
**Visit:** Unplanned 1 - Unscheduled Visit on Sep/22/2020    **Form:** CONTACT OUTCOME - UNPLANNED  
**Form Version:** 22-Apr-2020 21:04    **Form Status:** Data Complete, Locked, Frozen, Verified  
**Site No:** 1141    **Site Name:** (1141) University of Iowa Hospital and Clinics  
**Subject No:** 11411143    **Subject Initials:** ---  
**Generated By:** (b) (4)    **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: Sep/22/2020  Contact Outcome: VISIT NOT REQUIRED, INVESTIGATOR DECISION
3.	Comments:	[Subject reported Covid illness symptom on Illness Diary. Subject had headache, chills, fatigue, reports improvement in symptoms. Vaccine related per PI.]

**Header Text:** c4591001

**Visit:** End of Treatment - Unscheduled

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

**Site No:** 1141

**Subject No:** 11411143

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

**Form:** DISPOSITION - TREATMENT

**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 - Treatment**

1.	Date of Completion/Discontinuation /Death :	Oct/19/2020
2.	Phase of Disposition:	VACCINATION
3.	Status:	COMPLETED
4.	Specify Status:	[ ]

<b>Header Text:</b> c4591001	<b>Form:</b> DISPOSITION - FOLLOW-UP
<b>Visit:</b> Follow-Up - Unscheduled	<b>Form Status:</b> Not Started
<b>Form Version:</b> 15-Sep-2020 21:53	<b>Site Name:</b> (1141) University of Iowa Hospital and Clinics
<b>Site No:</b> 1141	<b>Subject Initials:</b> ---
<b>Subject No:</b> 11411143	<b>Generated Time (GMT):</b> 29-Mar-2021 11:44
<b>Generated By:</b> (b) (4)	

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

**Header Text:** c4591001

**Visit:** POT\_COVID\_REPEAT\_SWAB - New  
Unscheduled Visit

**Form:** DATE OF VISIT - REPEAT SWAB

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

**Form Status:** Not Started

**Site No:** 1141

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

**Subject No:** 11411143

**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:	
----	-----------------------	--

090177e196ae408e\Final\Final On: 01-Apr-2021 05:42 (GMT)

**Header Text:** c4591001  
**Visit:** POT\_COVID\_REPEAT\_SWAB - New  
 Unscheduled Visit  
**Form Version:** 10-Oct-2020 15:57  
**Site No:** 1141  
**Subject No:** 11411143  
**Generated By:** (b) (4)

**Form:** ELECTRONIC SAMPLE TRACKING - REPEAT SWAB  
**Form Status:** Not Started  
**Site Name:** (1141) University of Iowa Hospital and Clinics  
**Subject Initials:** ---  
**Generated Time (GMT):** 29-Mar-2021 11:44

**Electronic Sample Tracking**

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

**Aliquot**

Please enter barcode for each aliquot.

5.	Sample ID	[ ]
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090177e196ae408e\Final\Final On: 01-Apr-2021 05:42 (GMT)



**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:** 11411143

**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	Headache	Sep/19/2020 03:00	NO End Date Time:  Sep/20/2020 08:00	<a href="#">Repeating Pages</a>
2.	ADVERSE EVENT	2	Chills	Sep/19/2020 03:00	NO End Date Time:  Sep/20/2020 08:00	<a href="#">Repeating Pages</a>
3.	ADVERSE EVENT	3	Fatigue	Sep/19/2020 09:00	NO End Date Time:  Sep/20/2020 08:00	<a href="#">Repeating Pages</a>

090177e196ae408e\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: 11411143

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

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

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

Subject Initials: ---

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

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[Form Audit Trail](#)

**Adverse Event Report**

1.	Category:	ADVERSE EVENT
2.	AE ID:	[1]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[Headache]
4.	Start Date Time:	Sep/19/2020 03:00
5.	Is the adverse event still ongoing?	NO End Date Time: Sep/20/2020 08:00
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
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	[ ]

090177e196ae408e\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:** 11411143

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

**Form:** ADVERSE EVENT REPORT

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

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

**Subject Initials:** ---

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

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[Form Audit Trail](#)

**Adverse Event Report**

1.	Category:	ADVERSE EVENT
2.	AE ID:	[2]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[Chills]
4.	Start Date Time:	Sep/19/2020 03:00
5.	Is the adverse event still ongoing?	NO End Date Time: Sep/20/2020 08:00
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
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	[ ]

090177e196ae408e\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:** 11411143

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

**Form:** ADVERSE EVENT REPORT

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

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

**Subject Initials:** ---

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

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**Adverse Event Report**

1.	Category:	ADVERSE EVENT
2.	AE ID:	[3]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[Fatigue]
4.	Start Date Time:	Sep/19/2020 09:00
5.	Is the adverse event still ongoing?	NO End Date Time: Sep/20/2020 08:00
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
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	[ ]

090177e196ae408e\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:** 11411143

**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>

090177e196ae408e\Final\Final On: 01-Apr-2021 05:42 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1141

**Subject No:** 11411143

**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

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**Medication Error**

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

090177e196ae408e\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:** 11411143 **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>

090177e196ae408e\Final\Final On: 01-Apr-2021 05:42 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1141

**Subject No:** 11411143

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

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

**Form Status:** Not Started

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

**Subject Initials:** ---

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

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**Concomitant Medications**

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



**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:** 11411143

**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>

090177e196ae408e\Final\Final On: 01-Apr-2021 05:42 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1141

**Subject No:** 11411143

**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

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**Concomitant Medications**

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

090177e196ae408e\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:** 11411143

**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>

090177e196ae408e\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:** 11411143

**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

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**Radiation Treatment**

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

**Header Text:** c4591001

**Visit:** Logs

**Form:** TRANSFUSIONS

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

**Site No:** 1141

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

**Subject No:** 11411143

**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>

090177e196ae408e\Final\Final On: 01-Apr-2021 05:42 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1141

**Subject No:** 11411143

**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

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

**Header Text:** c4591001

**Visit:** Unplanned Vaccination - Unscheduled

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

**Site No:** 1141

**Subject No:** 11411143

**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	

<b>Header Text:</b> c4591001	<b>Form:</b> VITAL SIGNS - TEMP
<b>Visit:</b> Unplanned Vaccination - Unscheduled	<b>Form Status:</b> Not Started
<b>Form Version:</b> 20-Feb-2021 02:16	<b>Site Name:</b> (1141) University of Iowa Hospital and Clinics
<b>Site No:</b> 1141	<b>Subject Initials:</b> ---
<b>Subject No:</b> 11411143	<b>Generated Time (GMT):</b> 29-Mar-2021 11:44
<b>Generated By:</b> (b) (4)	

**Vital Signs**

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

**Vital Signs Details**

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



**Header Text:** c4591001  
**Visit:** Unplanned Vaccination - Unscheduled  
**Form Version:** 20-Feb-2021 02:14  
**Site No:** 1141  
**Subject No:** 11411143  
**Generated By:** (b) (4)

**Form:** LAB URINALYSIS - PREGNANCY TEST  
**Form Status:** Not Started  
**Site Name:** (1141) University of Iowa Hospital and Clinics  
**Subject Initials:** ---  
**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:	

090177e196ae408e\Final\Final On: 01-Apr-2021 05:42 (GMT)

**Header Text:** c4591001  
**Visit:** Unplanned Vaccination - Unscheduled  
**Form Version:** 10-Dec-2020 02:26  
**Site No:** 1141  
**Subject No:** 11411143  
**Generated By:** (b) (4)

**Form:** VACCINATION  
**Form Status:** Not Started  
**Site Name:** (1141) University of Iowa Hospital and Clinics  
**Subject Initials:** ---  
**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?	

**Header Text:** c4591001  
**Visit:** Unplanned Vaccination - Unscheduled  
**Form Version:** 10-Oct-2020 15:57  
**Site No:** 1141  
**Subject No:** 11411143  
**Generated By:** (b) (4)

**Form:** CONTACT OUTCOME - MONTH 1  
**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:	[ ]

090177e196ae408e\Final\Final On: 01-Apr-2021 05:42 (GMT)

<b>Header Text:</b> c4591001	<b>Form:</b> CONTACT OUTCOME - MONTH 6
<b>Visit:</b> Unplanned Vaccination - Unscheduled	<b>Form Status:</b> Not Started
<b>Form Version:</b> 10-Oct-2020 16:01	<b>Site Name:</b> (1141) University of Iowa Hospital and Clinics
<b>Site No:</b> 1141	<b>Subject Initials:</b> ---
<b>Subject No:</b> 11411143	<b>Generated Time (GMT):</b> 29-Mar-2021 11:44
<b>Generated By:</b> (b) (4)	

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

**Header Text:** c4591001

**Visit:** V201\_SURVEIL\_CONSENT - 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:** 11411143

**Subject Initials:** ---

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

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

**Date of Visit**

1.	Date of Visit	//
2.	Erroneous Visit	

<b>Header Text:</b> c4591001		<b>Form:</b> INFORMED CONSENT - ASYMPTOMATIC SURVEILLANCE
<b>Visit:</b> V201_SURVEIL_CONSENT - Unscheduled		<b>Form Status:</b> Not Started
<b>Form Version:</b> 14-Jan-2021 02:29		<b>Site Name:</b> (1141) University of Iowa Hospital and Clinics
<b>Site No:</b> 1141		<b>Subject Initials:</b> ---
<b>Subject No:</b> 11411143		<b>Generated Time (GMT):</b> 29-Mar-2021 11:44
<b>Generated By:</b> (b) (4)		
<b>Informed Consent - Asymptomatic Surveillance</b>		
1.	Consent Was:	

090177e196ae408e\Final\Final On: 01-Apr-2021 05:42 (GMT)

**Header Text:** c4591001  
**Visit:** V201\_SURVEIL\_CONSENT - Unscheduled      **Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY  
**Form Version:** 22-Apr-2020 21:03      **Form Status:** Not Started  
**Site No:** 1141      **Site Name:** (1141) University of Iowa Hospital and Clinics  
**Subject No:** 11411143      **Subject Initials:** ---  
**Generated By:** (b) (4)      **Generated Time (GMT):** 29-Mar-2021 11:44

**Electronic Sample Tracking**

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

**Aliquot**

Please enter barcode for each aliquot.

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

**Header Text:** c4591001  
**Visit:** V201\_SURVEIL\_CONSENT - Unscheduled      **Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB  
**Form Version:** 22-Apr-2020 21:03      **Form Status:** Not Started  
**Site No:** 1141      **Site Name:** (1141) University of Iowa Hospital and Clinics  
**Subject No:** 11411143      **Subject Initials:** ---  
**Generated By:** (b) (4)      **Generated Time (GMT):** 29-Mar-2021 11:44

**Electronic Sample Tracking**

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

**Aliquot**

Please enter barcode for each aliquot.

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



**Header Text:** c4591001

**Visit:** 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:** 11411143

**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/19/2021
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:** 11411143      **Subject Initials:** ---  
**Generated By:** (b) (4)      **Generated Time (GMT):** 29-Mar-2021 11:44

[eCRF Audit Trail History](#)

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

**Header Text:** c4591001

**Visit:** Disposition - Unscheduled

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

**Site No:** 1141

**Subject No:** 11411143

**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/19/2021
2.	Primary Reason for Unblinding:	ASSESS ELIGIBILITY FOR ADDITIONAL VACCINATION

<b>Header Text:</b> c4591001		<b>Form:</b> WITHDRAWAL OF CONSENT
<b>Visit:</b> Disposition - Unscheduled		<b>Form Status:</b> Not Started
<b>Form Version:</b> 22-Apr-2020 21:03		<b>Site Name:</b> (1141) University of Iowa Hospital and Clinics
<b>Site No:</b> 1141		<b>Subject Initials:</b> ---
<b>Subject No:</b> 11411143		<b>Generated Time (GMT):</b> 29-Mar-2021 11:44
<b>Generated By:</b> (b) (4)		
<b>Withdrawal Of Consent</b>		
1.	Withdrawal of Consent Date :	//

<b>Header Text:</b> c4591001	<b>Form:</b> DEATH DETAILS CODED
<b>Visit:</b> Disposition - Unscheduled	<b>Form Status:</b> Not Started
<b>Form Version:</b> 22-Apr-2020 21:03	<b>Site Name:</b> (1141) University of Iowa Hospital and Clinics
<b>Site No:</b> 1141	<b>Subject Initials:</b> ---
<b>Subject No:</b> 11411143	<b>Generated Time (GMT):</b> 29-Mar-2021 11:44
<b>Generated By:</b> (b) (4)	

**Death Details**

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

**Cause of Death**

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

**Header Text:** c4591001

**Visit:** Subject Status - Unscheduled

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

**Site No:** 1141

**Subject No:** 11411143

**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	Oct/19/2020

**Header Text:** c4591001

**Visit:** Investigator Signature - Unscheduled

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

**Site No:** 1141

**Subject No:** 11411143

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

**Form:** CASEBOOK SIGNATURE FORM

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

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

**Subject Initials:** ---

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

[eCRF Audit Trail History](#)

**Casebook Signature Form**

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

090177e196ae408e\Final\Final On: 01-Apr-2021 05:42 (GMT)

**Header Text:** c4591001

**Visit:** Investigator Signature - Unscheduled

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

**Site No:** 1141

**Subject No:** 11411143

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

**Form:** CASEBOOK SIGNATURE FORM

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

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

**Subject Initials:** ---

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

[Audit Trail](#)

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

- CRF\_Sign

Name	Signature Meaning	Date	Type	Action
Patricia Winokur	Approved	Feb-12-2021 12:57:52 (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:** 30-Jul-2020 21:29

**Site No:** 1141

**Subject No:** 11411143

**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

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Item	Date	User	Comment
Form	Aug-28-2020 05:26:35 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

**Header Text:** c4591001

**Visit:** Investigator Signature - Unscheduled

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

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

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

**Site No:** 1141

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

**Subject No:** 11411143

**Subject Initials:** ---

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

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

[Back to Form](#)

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

- CRF\_Sign

Name	Signature Meaning	Date	Type	Action
Patricia Winokur	Approved	Feb-12-2021 12:57:52 (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	Feb-09-2021 10:50:10 (UTC-06:00) Central Time (US & Canada)		Edit - All signatures invalidated
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**Affidavit:**

N/A

Patricia Winokur	Approved	Feb-01-2021 11:19:05 (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	Jan-28-2021 11:02:11 (UTC-06:00) Central Time (US & Canada)		Edit - All signatures invalidated
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**Affidavit:**

N/A

Patricia Winokur	Approved	Oct-30-2020 18:12:20 (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.

090177e196ae408e\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:** 11411143      **Subject Initials:** ---  
**Generated By:** (b) (4)      **Generated Time (GMT):** 29-Mar-2021 11:44

(b) (6)	N/A	Oct-30-2020 15:29:08 (UTC-06:00) Central Time (US & Canada)		Edit - All signatures invalidated
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**Affidavit:**  
N/A

Patricia Winokur	Approved	Oct-30-2020 10:36:57 (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.

090177e196ae408e\Final\Final On: 01-Apr-2021 05:42 (GMT)

**Header Text:** c4591001  
**Visit:** COHORT\_SELECTION  
**Form Version:** 30-Jul-2020 21:29  
**Site No:** 1141  
**Subject No:** 11411143  
**Generated By:** (b) (4)

**Form:** COHORT SELECTION - eCRF Audit Trail History  
**Form Status:** Data Complete, Locked, Frozen, Verified  
**Site Name:** (1141) University of Iowa Hospital and Clinics  
**Subject Initials:** ---  
**Generated Time (GMT):** 29-Mar-2021 11:44

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*1. Select appropriate response - Protocol version*

Date	Location	User	Value	Reason
Aug-28-2020 05:26:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	<b>Data Entry:</b> 24 JUL 2020	Initial Entry

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

Date	Location	User	Value	Reason
Aug-28-2020 05:26:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	<b>Data Entry:</b> STAGE 3 COHORTS	Initial Entry

**Header Text:** c4591001

**Visit:** COHORT\_SELECTION

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

**Site No:** 1141

**Subject No:** 11411143

**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](#)

*I. Consent Was:*

Date	Location	User	Value	Reason
Aug-28-2020 05:26:06 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> OBTAINED Date Written Consent Obtained  Aug/27/2020	Initial Entry

090177e196ae408e\Final\Final On: 01-Apr-2021 05:42 (GMT)

**Header Text:** c4591001  
**Visit:** COHORT\_SELECTION **Form:** DEMOGRAPHY - eCRF Audit Trail History  
**Form Version:** 06-Jul-2020 21:55 **Form Status:** Data Complete, Locked, Frozen, Verified  
**Site No:** 1141 **Site Name:** (1141) University of Iowa Hospital and Clinics  
**Subject No:** 11411143 **Subject Initials:** ---  
**Generated By:** (b) (4) **Generated Time (GMT):** 29-Mar-2021 11:44

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**1. Subject ID**

Date	Location	User	Value	Reason
Aug-28-2020 05:25:53 (UTC-06:00) Central Time (US & Canada)	ACVOPFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 11411143	Item copied from previous form

**2. Birth Date:**

Date	Location	User	Value	Reason
Aug-28-2020 05:25:50 (UTC-06:00) Central Time (US & Canada)	ACVOPFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> (b) (6)/1964	Enrollment Entry

**3. Sex:**

Date	Location	User	Value	Reason
Aug-28-2020 05:26:15 (UTC-06:00) Central Time (US & Canada)	ACVOPFEINFP6000	(b) (4), (b) (6) [REDACTED]	<b>Data Entry:</b> FEMALE	Initial Entry

**4. Ethnicity:**

Date	Location	User	Value	Reason
Aug-28-2020 05:26:15 (UTC-06:00) Central Time (US & Canada)	ACVOPFEINFP6000	(b) (4), (b) (6) [REDACTED]	<b>Data Entry:</b> NOT HISPANIC OR LATINO(A) OR OF SPANISH ORIGIN	Initial Entry

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

Date	Location	User	Value	Reason
Aug-28-2020 05:26:15 (UTC-06:00) Central Time (US & Canada)	ACVOPFEINFP6000	(b) (4), (b) (6) [REDACTED]	<b>Data Entry:</b> WHITE	Initial Entry

090177e196ae408e\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:** 11411143

**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](#)

*I. Date of Visit*

Date	Location	User	Value	Reason
Aug-28-2020 05:26:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Aug/27/2020	Initial Entry

090177e196ae408e\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:** 11411143  
**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

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

Date	Location	User	Value	Reason
Aug-28-2020 05:26:46 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Aug/27/2020	Initial Entry

**2. Phase of Disposition:**

Date	Location	User	Value	Reason
Aug-28-2020 05:26:46 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SCREENING	Initial Entry

**3. Status:**

Date	Location	User	Value	Reason
Aug-28-2020 05:26:46 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> COMPLETED	Initial Entry

090177e196ae408e\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: 11411143

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

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**I.a**

Date	Location	User	Value	Reason
Aug-28-2020 05:27:24 (UTC-06:00) Central Time (US & Canada)	ACVOPFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Line/MH Number:</b> 1 <b>Medical History Term:</b> hypertension <b>Start Date:</b> UNK/UNK/2010 <b>Ongoing:</b> YES	Initial Entry

**I.a Line/MH Number:**

Date	Location	User	Value	Reason
Aug-28-2020 05:27:24 (UTC-06:00) Central Time (US & Canada)	ACVOPFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 1	Initial Entry

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

Date	Location	User	Value	Reason
Aug-28-2020 05:27:24 (UTC-06:00) Central Time (US & Canada)	ACVOPFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> hypertension	Initial Entry

**I.a Start Date:**

Date	Location	User	Value	Reason
Aug-28-2020 05:27:24 (UTC-06:00) Central Time (US & Canada)	ACVOPFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> UNK/UNK/2010	Initial Entry

**I.a Ongoing:**

Date	Location	User	Value	Reason
Aug-28-2020 05:27:24 (UTC-06:00) Central Time (US & Canada)	ACVOPFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

**I.b**

Date	Location	User	Value	Reason
Aug-28-2020 05:27:51 (UTC-06:00) Central Time (US & Canada)	ACVOPFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Line/MH Number:</b> 2 <b>Medical History Term:</b> seasonal affective disorder <b>Start Date:</b> UNK/UNK/1999 <b>Ongoing:</b> YES	Initial Entry

090177e196ae408e\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: 11411143

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
Aug-28-2020 05:27:51 (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
Aug-28-2020 05:27:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> seasonal affective disorder	Initial Entry

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

Date	Location	User	Value	Reason
Aug-28-2020 05:27:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> UNK/UNK/1999	Initial Entry

***1.b Ongoing:***

Date	Location	User	Value	Reason
Aug-28-2020 05:27:51 (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
Aug-28-2020 05:28:09 (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> insomnia <b>Start Date:</b> UNK/UNK/2000 <b>Ongoing:</b> YES	Initial Entry

090177e196ae408e\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: 11411143

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

**I.c Line/MH Number:**

Date	Location	User	Value	Reason
Aug-28-2020 05:28:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> 3	Initial Entry

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

Date	Location	User	Value	Reason
Aug-28-2020 05:28:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> insomnia	Initial Entry

**I.c Start Date:**

Date	Location	User	Value	Reason
Aug-28-2020 05:28:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> UNK/UNK/2000	Initial Entry

**I.c Ongoing:**

Date	Location	User	Value	Reason
Aug-28-2020 05:28:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> YES	Initial Entry

**I.d**

Date	Location	User	Value	Reason
Aug-28-2020 05:28:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> Line/MH Number: 4 Medical History Term: generalized pain Start Date: UNK/UNK/1980 Ongoing: YES	Initial Entry

090177e196ae408e\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: 11411143

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

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

Date	Location	User	Value	Reason
Aug-28-2020 05:28:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 4	Initial Entry

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

Date	Location	User	Value	Reason
Aug-28-2020 05:28:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> generalized pain	Initial Entry

**I.d Start Date:**

Date	Location	User	Value	Reason
Aug-28-2020 05:28:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> UNK/UNK/1980	Initial Entry

**I.d Ongoing:**

Date	Location	User	Value	Reason
Aug-28-2020 05:28:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

**I.e**

Date	Location	User	Value	Reason
Aug-28-2020 05:28:46 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> Line/MH Number: 5 Medical History Term: nearsighted Start Date: UNK/UNK/1975 Ongoing: YES	Initial Entry

090177e196ae408e\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: 11411143

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

*I.e Line/MH Number:*

Date	Location	User	Value	Reason
Aug-28-2020 05:28:46 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> 5	Initial Entry

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

Date	Location	User	Value	Reason
Aug-28-2020 05:28:46 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> nearsighted	Initial Entry

*I.e Start Date:*

Date	Location	User	Value	Reason
Aug-28-2020 05:28:46 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> UNK/UNK/1975	Initial Entry

*I.e Ongoing:*

Date	Location	User	Value	Reason
Aug-28-2020 05:28:46 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> YES	Initial Entry

*I.f*

Date	Location	User	Value	Reason
Aug-28-2020 05:29:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Line/MH Number: 6 Medical History Term: right hip osteoarthritis Start Date: Apr/UNK/2018 Ongoing: NO End Date: May/29/2018	Transcription Error
Aug-28-2020 05:29:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Line/MH Number: 6 Medical History Term: right hip osteoarthritis Start Date: Apr/UNK/2018 Ongoing: NO End Date: May/19/2018	Transcription Error
Aug-28-2020 05:29:27	ACV0PFEINFP6000	auto calc	<u>Data Entry:</u>	Initial Entry

090177e196ae408e\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:** 11411143

**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)

**Line/MH Number:** 6

**Medical History Term:** right hip osteoarthritis

**Start Date:** Apr/UNK/2018

**Ongoing:** NO

End Date:

May/19/2010

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 22-Apr-2020 21:03

Site No: 1141

Subject No: 11411143

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

**If Line/MH Number:**

Date	Location	User	Value	Reason
Aug-28-2020 05:29:27 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> 6	Initial Entry

**If Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:**

Date	Location	User	Value	Reason
Aug-28-2020 05:29:27 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> right hip osteoarthritis	Initial Entry

**If Start Date:**

Date	Location	User	Value	Reason
Aug-28-2020 05:29:27 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Apr/UNK/2018	Initial Entry

**If Ongoing:**

Date	Location	User	Value	Reason
Aug-28-2020 05:29:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO End Date: May/29/2018	Transcription Error
Aug-28-2020 05:29:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Aug-28-2020 05:29:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO End Date: May/19/2018	Transcription Error
Aug-28-2020 05:29:27 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	For Term right hip osteoarthritis End Date is prior to Start Date.
Aug-28-2020 05:29:27 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO End Date: May/19/2010	Initial Entry

**I.g**

Date	Location	User	Value	Reason
Aug-28-2020 05:30:37 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u>	Initial Entry

090177e196ae408e\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: 11411143

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

& Canada)			<b>Line/MH Number:</b> 7 <b>Medical History Term:</b> right hip replacement <b>Start Date:</b> May/29/2018 <b>Ongoing:</b> NO End Date: May/29/2018	
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**I.g Line/MH Number:**

Date	Location	User	Value	Reason
Aug-28-2020 05:30:37 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 7	Initial Entry

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

Date	Location	User	Value	Reason
Aug-28-2020 05:30:37 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> right hip replacement	Initial Entry

**I.g Start Date:**

Date	Location	User	Value	Reason
Aug-28-2020 05:30:37 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> May/29/2018	Initial Entry

**I.g Ongoing:**

Date	Location	User	Value	Reason
Aug-28-2020 05:30:37 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO End Date: May/29/2018	Initial Entry

**I.h**

Date	Location	User	Value	Reason
Aug-28-2020 05:31:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 8 <b>Line/MH Number:</b> <b>Medical History Term:</b> degenerative disk disease - back <b>Start Date:</b> Jan/UNK/2007 <b>Ongoing:</b> NO End Date: Mar/29/2007	Initial Entry

090177e196ae408e\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: 11411143

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

**I.h Line/MH Number:**

Date	Location	User	Value	Reason
Aug-28-2020 05:31:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 8	Initial Entry

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

Date	Location	User	Value	Reason
Aug-28-2020 05:31:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> degenerative disk disease- back	Initial Entry

**I.h Start Date:**

Date	Location	User	Value	Reason
Aug-28-2020 05:31:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Jan/UNK/2007	Initial Entry

**I.h Ongoing:**

Date	Location	User	Value	Reason
Aug-28-2020 05:31:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO End Date:  Mar/29/2007	Initial Entry

**I.i**

Date	Location	User	Value	Reason
Aug-28-2020 05:32:06 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Line/MH Number:</b> 9 <b>Medical History Term</b> Rods placed in bac : k <b>Start Date:</b> Mar/29/2007 <b>Ongoing:</b> NO End Date:  Mar/29/2007	Initial Entry

090177e196ae408e\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:** 11411143

**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

***I.i Line/MH Number:***

Date	Location	User	Value	Reason
Aug-28-2020 05:32:06 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 9	Initial Entry

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

Date	Location	User	Value	Reason
Aug-28-2020 05:32:06 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Rods placed in back	Initial Entry

***I.i Start Date:***

Date	Location	User	Value	Reason
Aug-28-2020 05:32:06 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Mar/29/2007	Initial Entry

090177e196ae408e\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: 11411143

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

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***L.i Ongoing:***

Date	Location	User	Value	Reason
Aug-28-2020 05:32:06 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO End Date:  Mar/29/2007	Initial Entry

***L.j***

Date	Location	User	Value	Reason
Aug-28-2020 05:32:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Line/MH Number:</b> 10 <b>Medical History Term:</b> tummy tuck <b>Start Date:</b> Apr/UNK/2017 <b>Ongoing:</b> NO End Date:  Apr/UNK/2017	Initial Entry

***L.j Line/MH Number:***

Date	Location	User	Value	Reason
Aug-28-2020 05:32:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 10	Initial Entry

***L.j Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:***

Date	Location	User	Value	Reason
Aug-28-2020 05:32:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> tummy tuck	Initial Entry

***L.j Start Date:***

Date	Location	User	Value	Reason
Aug-28-2020 05:32:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Apr/UNK/2017	Initial Entry

***L.j Ongoing:***

Date	Location	User	Value	Reason
Aug-28-2020 05:32:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO End Date:  Apr/UNK/2017	Initial Entry

090177e196ae408e\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: 11411143

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

I.k

Date	Location	User	Value	Reason
Aug-28-2020 05:33:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Line/MH Number:</b> 11 <b>Medical History Term:</b> abdominal apron <b>Start Date:</b> UNK/UNK/1999 <b>Ongoing:</b> NO End Date: Apr/UNK/2017	Initial Entry

I.k Line/MH Number:

Date	Location	User	Value	Reason
Aug-28-2020 05:33:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 11	Initial Entry

I.k Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:

Date	Location	User	Value	Reason
Aug-28-2020 05:33:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> abdominal apron	Initial Entry

I.k Start Date:

Date	Location	User	Value	Reason
Aug-28-2020 05:33:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> UNK/UNK/1999	Initial Entry

I.k Ongoing:

Date	Location	User	Value	Reason
Aug-28-2020 05:33:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO End Date: Apr/UNK/2017	Initial Entry

I.l

Date	Location	User	Value	Reason
Aug-28-2020 05:33:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Line/MH Number</b> 12 : <b>Medical History Term:</b> lower back pain (L5 R egion) <b>Start Date:</b> UNK/UNK/2007	Initial Entry

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Header Text: c4591001

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Site No: 1141

Subject No: 11411143

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

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

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			Ongoing:	YES
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**1.l Line/MH Number:**

Date	Location	User	Value	Reason
Aug-28-2020 05:33:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 12	Initial Entry

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

Date	Location	User	Value	Reason
Aug-28-2020 05:33:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> lower back pain (L5 Region)	Initial Entry

**1.l Start Date:**

Date	Location	User	Value	Reason
Aug-28-2020 05:33:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> UNK/UNK/2007	Initial Entry

**1.l Ongoing:**

Date	Location	User	Value	Reason
Aug-28-2020 05:33:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

**1.m**

Date	Location	User	Value	Reason
Aug-28-2020 05:33:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Line/MH Number:</b> 13 <b>Medical History Term:</b> post menopausal <b>Start Date:</b> UNK/UNK/2018 <b>Ongoing:</b> YES	Initial Entry

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Header Text: c4591001

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Site No: 1141

Subject No: 11411143

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.m Line/MH Number:***

Date	Location	User	Value	Reason
Aug-28-2020 05:33:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 13	Initial Entry

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

Date	Location	User	Value	Reason
Aug-28-2020 05:33:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> post menopausal	Initial Entry

***1.m Start Date:***

Date	Location	User	Value	Reason
Aug-28-2020 05:33:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> UNK/UNK/2018	Initial Entry

***1.m Ongoing:***

Date	Location	User	Value	Reason
Aug-28-2020 05:33:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

090177e196ae408e\Final\Final On: 01-Apr-2021 05:42 (GMT)

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 21-Aug-2020 02:51

Site No: 1141

Subject No: 11411143

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

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**1. Date:**

Date	Location	User	Value	Reason
Aug-28-2020 05:34:30 (UTC-06:00) Central Time (US & Canada)	ACVOPFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Aug/27/2020	Initial Entry

**2. Weight:**

Date	Location	User	Value	Reason
Aug-28-2020 05:34:30 (UTC-06:00) Central Time (US & Canada)	ACVOPFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 86.0	Initial Entry

**3. Unit:**

Date	Location	User	Value	Reason
Aug-28-2020 05:34:30 (UTC-06:00) Central Time (US & Canada)	ACVOPFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> kg	Initial Entry

**4. Height:**

Date	Location	User	Value	Reason
Aug-28-2020 05:34:30 (UTC-06:00) Central Time (US & Canada)	ACVOPFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 157.0	Initial Entry

**5. Unit:**

Date	Location	User	Value	Reason
Aug-28-2020 05:34:30 (UTC-06:00) Central Time (US & Canada)	ACVOPFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> cm	Initial Entry

**6. Body Mass Index:**

Date	Location	User	Value	Reason
Aug-28-2020 05:34:30 (UTC-06:00) Central Time (US & Canada)	ACVOPFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 34.9	Initial Entry

**7.a**

Date	Location	User	Value	Reason
Aug-28-2020 05:34:30 (UTC-06:00) Central Time (US & Canada)	ACVOPFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Record Identifier::</b> 1 <b>Temperature:</b> 96.1 <b>Temperature Unit:</b> F	Initial Entry

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Header Text: c4591001

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Form Version: 21-Aug-2020 02:51

Site No: 1141

Subject No: 11411143

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

Temperature Location:: ORAL CAVITY

7.a Record Identifier:

Date	Location	User	Value	Reason
Aug-28-2020 05:34:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> 1	Initial Entry

7.a Temperature:

Date	Location	User	Value	Reason
Aug-31-2020 04:45:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Aug-28-2020 08:10:46 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Original value is correct
Aug-28-2020 07:24:54 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued:Opened	DM: Confirmation on the out of range value as clinically significant or not is expected. Please review and confirm. Thank you.
Aug-28-2020 05:35:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Original value is correct
Aug-28-2020 05:34:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	Temperature 96.1 F is outside of Normal Range 97 - 99.5 F.
Aug-28-2020 05:34:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> 96.1	Initial Entry

7.a Unit:

Date	Location	User	Value	Reason
Aug-28-2020 05:34:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> F	Initial Entry

7.a Temperature Location:

Date	Location	User	Value	Reason
Aug-28-2020 05:34:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> ORAL CAVITY	Initial Entry

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Header Text: c4591001

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Site No: 1141

Subject No: 11411143

Generated By: (b) (4)

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

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

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**1. Lab Panel:**

Date	Location	User	Value	Reason
Aug-28-2020 05:34:41 (UTC-06:00) Central Time (US & Canada)	ACVOPFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> URINALYSIS	Initial Entry

**2. Lab Sub-Panel:**

Date	Location	User	Value	Reason
Aug-28-2020 05:34:41 (UTC-06:00) Central Time (US & Canada)	ACVOPFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> PREGNANCY	Initial Entry

**3. Collection Date:**

Date	Location	User	Value	Reason
Aug-28-2020 05:34:41 (UTC-06:00) Central Time (US & Canada)	ACVOPFEINFP6000	(b) (4), (b) (6) [Redacted]	<b>Data Entry:</b> Aug/27/2020	Initial Entry

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

Date	Location	User	Value	Reason
Aug-28-2020 05:34:41 (UTC-06:00) Central Time (US & Canada)	ACVOPFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> STUDY SITE	Initial Entry

**5. Specimen Type:**

Date	Location	User	Value	Reason
Aug-28-2020 05:34:41 (UTC-06:00) Central Time (US & Canada)	ACVOPFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> URINE	Initial Entry

**6.a**

Date	Location	User	Value	Reason
Aug-28-2020 05:34:41 (UTC-06:00) Central Time (US & Canada)	ACVOPFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> Sponsor-Defined I 113 dentifier: Test:: Choriogonadotropin B eta_PX113 Result:: Not Done:: NOT DONE	Initial Entry

**6.a Sponsor ID:**

Date	Location	User	Value	Reason
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090177e196ae408e\Final\Final On: 01-Apr-2021 05:42 (GMT)

**Header Text:** c4591001

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

**Form Version:** 21-Aug-2020 02:49

**Site No:** 1141

**Subject No:** 11411143

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

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

Aug-28-2020 05:34:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 113	Initial Entry
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**6.a Test:**

Date	Location	User	Value	Reason
Aug-28-2020 05:34:41 (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
Aug-28-2020 05:34:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NOT DONE	Initial Entry

**Header Text:** c4591001  
**Visit:** V1\_DAY1\_VAX1\_L  
**Form Version:** 22-Apr-2020 21:03  
**Site No:** 1141  
**Subject No:** 11411143  
**Generated By:** (b) (4)

**Form:** RANDOMIZATION - eCRF Audit Trail History  
**Form Status:** Data Complete, Locked, Frozen, Verified  
**Site Name:** (1141) University of Iowa Hospital and Clinics  
**Subject Initials:** ---  
**Generated Time (GMT):** 29-Mar-2021 11:44

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**1. Randomization Date :**

Date	Location	User	Value	Reason
Aug-28-2020 05:34:57 (UTC-06:00) Central Time (US & Canada)	ACVOPFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Aug/27/2020	Initial Entry

**2. Randomization Number:**

Date	Location	User	Value	Reason
Aug-28-2020 05:34:57 (UTC-06:00) Central Time (US & Canada)	ACVOPFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 241295	Initial Entry

**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:** 11411143**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
Aug-28-2020 05:35:04 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SITE	Initial Entry

**2. Sample Type**

Date	Location	User	Value	Reason
Aug-28-2020 05:35:04 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SERUM	Initial Entry

**3. Sample Collected?**

Date	Location	User	Value	Reason
Aug-28-2020 06:06:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Aug-28-2020 05:35:04 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Aug-28-2020 05:35:04 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES Date of Collection:  Aug/27/2020	Initial Entry

**5.a**

Date	Location	User	Value	Reason
Aug-28-2020 06:06:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sample ID: BM88SV	Initial Entry

**5.a Sample ID**

Date	Location	User	Value	Reason
Aug-28-2020 06:06:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BM88SV	Initial Entry

**5.b**

Date	Location	User	Value	Reason
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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: 11411143

Subject Initials: ---

Generated By: (b) (4)

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

Aug-28-2020 06:06:17 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample ID:</b> BM88SW	Initial Entry
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5.b Sample ID

Date	Location	User	Value	Reason
Aug-28-2020 06:06:17 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BM88SW	Initial Entry

5.c

Date	Location	User	Value	Reason
Aug-28-2020 06:06:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample ID:</b> BM88SX	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Aug-28-2020 06:06:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BM88SX	Initial Entry

5.d

Date	Location	User	Value	Reason
Aug-28-2020 06:06:37 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample ID:</b> BLC9C3	Initial Entry

5.d Sample ID

Date	Location	User	Value	Reason
Aug-28-2020 06:06:37 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BLC9C3	Initial Entry

5.e

Date	Location	User	Value	Reason
Aug-28-2020 06:06:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample ID:</b> BLC9C2	Initial Entry

090177e196ae408e\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:** 11411143

**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.e Sample ID**

<b>Date</b>	<b>Location</b>	<b>User</b>	<b>Value</b>	<b>Reason</b>
Aug-28-2020 06:06:44 (UTC-06:00) Central Time (US & Canada)	ACVOPFEINFP6000	(b) (4), (b) (6) [REDACTED]	<b>Data Entry:</b> BLC9C2	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:** 11411143**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
Aug-28-2020 05:35:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SITE	Initial Entry

**2. Sample Type**

Date	Location	User	Value	Reason
Aug-28-2020 05:35:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> NASAL_SWAB	Initial Entry

**3. Sample Collected?**

Date	Location	User	Value	Reason
Aug-28-2020 06:06:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Aug-28-2020 05:35:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Aug-28-2020 05:35:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES Date of Collection:  Aug/27/2020	Initial Entry

**5.a**

Date	Location	User	Value	Reason
Aug-28-2020 06:06:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sample ID: BM88SP	Initial Entry

**5.a Sample ID**

Date	Location	User	Value	Reason
Aug-28-2020 06:06:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BM88SP	Initial Entry

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 22-Apr-2020 21:04

Site No: 1141

Subject No: 11411143

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

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

Date	Location	User	Value	Reason
Aug-28-2020 05:35:44 (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
Aug-28-2020 05:35:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> BLINDED THERAPY	Initial Entry

**3. Formulation:**

Date	Location	User	Value	Reason
Aug-28-2020 05:35:44 (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
Aug-28-2020 05:35:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Aug/27/2020 15:09	Initial Entry

**5. Anatomical Location:**

Date	Location	User	Value	Reason
Aug-28-2020 05:35:44 (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
Aug-28-2020 05:35:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> LEFT	Initial Entry

**7. Route:**

Date	Location	User	Value	Reason
Aug-28-2020 05:35:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> INTRAMUSCULAR	Initial Entry

090177e196ae408e\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:** 11411143

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

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

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

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

**Subject Initials:** ---

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

**10. Timeframe Subject Was Observed**

Date	Location	User	Value	Reason
Aug-28-2020 05:35:44 (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
Aug-28-2020 05:35:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

**Header Text:** c4591001

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

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

**Site No:** 1141

**Subject No:** 11411143

**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

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*1. Select appropriate response - Reactogenicity diary collection*

Date	Location	User	Value	Reason
Aug-28-2020 05:35:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	<b>Data Entry:</b> NO - REACTOGENICITY E-DIARY NOT COLLECTED FOR THIS SUBJECT	Initial Entry

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1141

**Subject No:** 11411143

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

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

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

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

**Subject Initials:** ---

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

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*I. Date of Visit*

Date	Location	User	Value	Reason
Sep-18-2020 13:27:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Sep/18/2020	Initial Entry

Header Text: c4591001

Visit: V2\_VAX2\_L

Form Version: 15-Sep-2020 21:54

Site No: 1141

Subject No: 11411143

Generated By: (b) (4)

Form: VITAL SIGNS - TEMP - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

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**1. Date:**

Date	Location	User	Value	Reason
Sep-18-2020 13:27:32 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sep/18/2020	Initial Entry

**2.a**

Date	Location	User	Value	Reason
Sep-18-2020 13:27:32 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Record Identifier::</b> 1 <b>Temperature:</b> 99.0 <b>Temperature Unit:</b> F <b>Temperature Location::</b> ORAL CAVITY	Initial Entry

**2.a Record Identifier:**

Date	Location	User	Value	Reason
Sep-18-2020 13:27:32 (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
Sep-18-2020 13:27:32 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 99.0	Initial Entry

**2.a Unit:**

Date	Location	User	Value	Reason
Sep-18-2020 13:27:32 (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
Sep-18-2020 13:27:32 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> ORAL CAVITY	Initial Entry

090177e196ae408e\Final\Final On: 01-Apr-2021 05:42 (GMT)

Header Text: c4591001

Visit: V2\_VAX2\_L

Form Version: 21-Aug-2020 02:49

Site No: 1141

Subject No: 11411143

Generated By: (b) (4)

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

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

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**1. Lab Panel:**

Date	Location	User	Value	Reason
Sep-18-2020 13:27:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> URINALYSIS	Initial Entry

**2. Lab Sub-Panel:**

Date	Location	User	Value	Reason
Sep-18-2020 13:27:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> PREGNANCY	Initial Entry

**3. Collection Date:**

Date	Location	User	Value	Reason
Sep-18-2020 13:27:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [Redacted]	<b>Data Entry:</b> Sep/18/2020	Initial Entry

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

Date	Location	User	Value	Reason
Sep-18-2020 13:27:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> STUDY SITE	Initial Entry

**5. Specimen Type:**

Date	Location	User	Value	Reason
Sep-18-2020 13:27:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> URINE	Initial Entry

**6.a**

Date	Location	User	Value	Reason
Sep-18-2020 13:27:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> Sponsor-Defined I 113 dentifier: Test:: Choriogonadotropin B eta_PX113 Result:: Not Done:: NOT DONE	Initial Entry

**6.a Sponsor ID:**

Date	Location	User	Value	Reason
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090177e196ae408e\Final\Final On: 01-Apr-2021 05:42 (GMT)

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

**Form Version:** 21-Aug-2020 02:49

**Site No:** 1141

**Subject No:** 11411143

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

**Form:** LAB URINALYSIS - PREGNANCY TEST - 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-18-2020 13:27:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 113	Initial Entry
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**6.a Test:**

Date	Location	User	Value	Reason
Sep-18-2020 13:27:51 (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
Sep-18-2020 13:27:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NOT DONE	Initial Entry

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: 11411143

Subject Initials: ---

Generated By: (b) (4)

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

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**1. Data Origin**

Date	Location	User	Value	Reason
Sep-18-2020 12:09:46 (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-18-2020 12:09:46 (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-18-2020 12:09:54 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Sep-18-2020 12:09:46 (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-18-2020 12:09:46 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES Date of Collection:  Sep/18/2020	Initial Entry

**5.a**

Date	Location	User	Value	Reason
Sep-18-2020 12:09:54 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sample ID: BM6J0X	Initial Entry

**5.a Sample ID**

Date	Location	User	Value	Reason
Sep-18-2020 12:09:54 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BM6J0X	Initial Entry

090177e196ae408e\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: 11411143

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

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

Date	Location	User	Value	Reason
Sep-18-2020 13:28:08 (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-18-2020 13:28:08 (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-18-2020 13:28:08 (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-18-2020 13:28:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sep/18/2020 10:50	Initial Entry

**5. Anatomical Location:**

Date	Location	User	Value	Reason
Sep-18-2020 13:28:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> DELTOID MUSCLE	Initial Entry

**6. Body Side:**

Date	Location	User	Value	Reason
Sep-18-2020 13:28:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> LEFT	Initial Entry

**7. Route:**

Date	Location	User	Value	Reason
Sep-18-2020 13:28:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> INTRAMUSCULAR	Initial Entry

090177e196ae408e\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:** 11411143

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

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

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

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

**Subject Initials:** ---

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

**10. Timeframe Subject Was Observed**

Date	Location	User	Value	Reason
Sep-18-2020 13:28:08 (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-18-2020 13:28:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

**Header Text:** c4591001

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

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

**Site No:** 1141

**Subject No:** 11411143

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

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

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

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

**Subject Initials:** ---

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

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*I. Date of Visit*

Date	Location	User	Value	Reason
Oct-19-2020 16:14:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Oct/19/2020	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:** 11411143**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-19-2020 16:14:17 (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-19-2020 16:14:17 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SERUM	Initial Entry

**3. Sample Collected?**

Date	Location	User	Value	Reason
Oct-20-2020 06:22:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Oct-19-2020 16:14:17 (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-19-2020 16:14:17 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES Date of Collection:  Oct/19/2020	Initial Entry

**5.a**

Date	Location	User	Value	Reason
Oct-20-2020 06:22:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample ID:</b> BP9M91	Initial Entry

**5.a Sample ID**

Date	Location	User	Value	Reason
Oct-20-2020 06:22:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BP9M91	Initial Entry

**5.b**

Date	Location	User	Value	Reason
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Header Text: c4591001

Visit: V3\_MONTH1\_POSTVAX2\_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1141

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

Subject No: 11411143

Subject Initials: ---

Generated By: (b) (4)

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

Oct-20-2020 06:22:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample ID:</b> BRX71W	Initial Entry
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5.b Sample ID

Date	Location	User	Value	Reason
Oct-20-2020 06:22:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BRX71W	Initial Entry

5.c

Date	Location	User	Value	Reason
Oct-20-2020 06:22:46 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <del>BRX71W</del>	Transcription Error (DELETED)
Oct-20-2020 06:22:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample ID:</b> BRX71W	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Oct-20-2020 06:22:46 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <del>BRX71W</del>	Transcription Error (DELETED)
Oct-20-2020 06:22:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BRX71W	Initial Entry

5.d

Date	Location	User	Value	Reason
Oct-20-2020 06:22:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample ID:</b> BRX71X	Initial Entry

5.d Sample ID

Date	Location	User	Value	Reason
Oct-20-2020 06:22:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BRX71X	Initial Entry

090177e196ae408e\Final\Final On: 01-Apr-2021 05:42 (GMT)

Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Sep/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: 11411143

Subject Initials: ---

Generated By: (b) (4)

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

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*1. Date of Visit*

Date	Location	User	Value	Reason
Oct-01-2020 00:47:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Deleted	Per SITE response 'This was entered in error. The erroneous visit was ticked'
Oct-01-2020 00:45:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Data updated.
Sep-30-2020 11:55:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	This was entered in error. The erroneous visit was ticked
Sep-30-2020 11:54:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 3: Candidate	Erroneous Visit is marked, but date of visit is entered. Please check whether other assessments are performed at this visit.
Sep-27-2020 02:56:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Closed	Response satisfies query
Sep-27-2020 02:55:54 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued:Opened	RQ-1: As this visit is entered in error, Please tick the radio button to indicate that the visit entry is erroneous
Sep-26-2020 09:51:23 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Please advise how to delete this entry, this was entered in error thanks
Sep-26-2020 09:49:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Answered	This Covid entry was entered in error please advise how to go in and delete this on database.
Sep-26-2020 04:12:04 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	DM: 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. Thank you.
Sep-26-2020 04:11:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Opened	DM: Date of Visit is completed but Date of Assessment in the Signs and Symptoms form is missing. Please review

090177e196ae408e\Final\Final On: 01-Apr-2021 05:42 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Sep/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:** 11411143

**Subject Initials:** ---

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

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

				and update as appropriate. Thank you.
Sep-25-2020 12:43:19 (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.
Sep-25-2020 12:43:19 (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.
Sep-25-2020 12:43:19 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sep/22/2020	Initial Entry

**2. Erroneous Visit**

Date	Location	User	Value	Reason
Sep-30-2020 11:54:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> ERRONEOUS VISIT	Initial Entry

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

Date	Location	User	Value	Reason
Sep-25-2020 12:43:19 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> COVID_A	Initial Entry

090177e196ae408e\Final\Final On: 01-Apr-2021 05:42 (GMT)

Header Text: c4591001

Visit: Unplanned 1 - Unscheduled Visit on Sep/22/2020

Form: DATE OF VISIT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1141

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

Subject No: 11411143

Subject Initials: ---

Generated By: (b) (4)

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

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*I. Date of Visit*

Date	Location	User	Value	Reason
Oct-31-2020 03:31:37 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Closed	Response satisfies query
Oct-30-2020 16:03:37 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Answered	contact clinic note was documented in chart, created an unplanned source document as well to reflect this contact.
Oct-27-2020 02:39:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Opened	DM: Per earlier query response, it seems this visit initiate in error. If correct select this visit as Erroneous visit, else update UNPL form. Thank you.
Oct-26-2020 05:48:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Oct-25-2020 10:28:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Entered in error please advise how to delete thanks
Oct-12-2020 22:47:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	DM: Please update UNPL form or else clarify. Thank you.
Sep-24-2020 10:54:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sep/22/2020	Initial Entry

090177e196ae408e\Final\Final On: 01-Apr-2021 05:42 (GMT)

Header Text: c4591001

Visit: Unplanned 1 - Unscheduled Visit on Sep/22/2020

Form: UNPLANNED VISIT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1141

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

Subject No: 11411143

Subject Initials: ---

Generated By: (b) (4)

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

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**I. Assessments**

Date	Location	User	Value	Reason
Oct-30-2020 16:02:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 3: Deleted	Close Auto Query
Oct-30-2020 15:29:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 3: Candidate	'Contact Outcome is ticked however 'CONTACT OUTCOME' form is not entered. Please review and update as appropriate.
Oct-30-2020 15:29:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> CONTACT OUTCOME	Initial Entry
Oct-20-2020 11:51:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Deleted	Close Auto Query
Oct-20-2020 11:51:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	Changed Information
Oct-20-2020 11:49:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Candidate	'Contact Outcome is ticked however 'CONTACT OUTCOME' form is not entered. Please review and update as appropriate.
Oct-20-2020 11:49:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> CONTACT OUTCOME	Initial Entry
Sep-25-2020 12:42:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Sep-25-2020 12:42:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	Transcription Error
Sep-25-2020 06:55:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	'Contact Outcome is ticked however 'CONTACT OUTCOME' form is not entered. Please review and update as appropriate.
Sep-24-2020 10:54:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Contact Outcome is ticked however 'CONTACT OUTCOME' form is not entered.

090177e196ae408e\Final\Final On: 01-Apr-2021 05:42 (GMT)



<b>Header Text:</b> c4591001 <b>Visit:</b> Unplanned 1 - Unscheduled Visit on Sep/22/2020 <b>Form:</b> UNPLANNED VISIT - eCRF Audit Trail History <b>Form Version:</b> 22-Apr-2020 21:04 <b>Form Status:</b> Data Complete, Locked, Frozen, Verified <b>Site No:</b> 1141 <b>Site Name:</b> (1141) University of Iowa Hospital and Clinics <b>Subject No:</b> 11411143 <b>Subject Initials:</b> --- <b>Generated By:</b> (b) (4) <b>Generated Time (GMT):</b> 29-Mar-2021 11:44				
				Please review and update as appropriate.
Sep-24-2020 10:54:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> CONTACT OUTCOME	Initial Entry

090177e196ae408e\Final\Final On: 01-Apr-2021 05:42 (GMT)

Header Text: c4591001

Visit: Unplanned 1 - Unscheduled Visit on Sep/22/2020

Form: CONTACT OUTCOME - UNPLANNED - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1141

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

Subject No: 11411143

Subject Initials: ---

Generated By: (b) (4)

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

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1. Contact Type:

Date	Location	User	Value	Reason
Oct-30-2020 16:02:56 (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
Oct-30-2020 16:02:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES Date of Contact:  Sep/22/2020  Contact Outcome:  VISIT NOT REQUIRED, INVESTIGAT OR DECISION	Initial Entry

3. Comments:

Date	Location	User	Value	Reason
Nov-15-2020 12:58:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Deleted	Query is invalid or does not apply
Nov-07-2020 14:53:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Can didate	We can leave the unplanned contact outcome. AEs have been recorded in the correct location. A covid illness visit needs to be scheduled and symptoms will need to be added to the ed diary when the patient comes in. Hold query (b) (6) discuss further
Nov-07-2020 14:51:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Nov-07-2020 12:14:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued: Opened	DM Query: We can leave the unplanned contact outcome. AEs have been recorded in the correct location. A covid illness visit needs to be scheduled and symptoms will need to be added to the ed diary when the patient comes in.
Nov-06-2020	ACV0PFEINFP6000	(b) (4), (b) (6)	Query	this is recorded in AE section please advise

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Header Text: c4591001

Visit: Unplanned 1 - Unscheduled Visit on Sep/22/2020

Form: CONTACT OUTCOME - UNPLANNED - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1141

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

Subject No: 11411143

Subject Initials: ---

Generated By: (b) (4)

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

15:14:33 (UTC-06:00) Central Time (US & Canada)		(b) (4), (b) (6)	1: Answered	how to reconcile delete this unplanned contact eCRF? thanks
Nov-05-2020 12:04:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	PFE SDQ PROD (b) (4)	Query 1: Opened	The following text was indicated in the comment field [Covid illness symptom,headache,chills,fatigue,improvement in symptoms]. For any symptoms, AEs, or other key data should be collected on the appropriate page or eDiary. If this is already in the predefined list above please choose the appropriate value. Please review and update as necessary. (b) (4) (b) (4)
Oct-30-2020 16:02:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry</b> : Subject reported Covid illness symptom on Illness Diary. Subject had headache, chills, fatigue, reports improvement in symptoms. Vaccine related per PI.	Initial Entry

090177e196ae408e\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:** 11411143

**Subject Initials:** ---

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

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

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

Date	Location	User	Value	Reason
Oct-19-2020 16:14:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Oct/19/2020	Initial Entry

**2. Phase of Disposition:**

Date	Location	User	Value	Reason
Oct-19-2020 16:14:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> VACCINATION	Initial Entry

**3. Status:**

Date	Location	User	Value	Reason
Oct-19-2020 16:14:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> COMPLETED	Initial Entry

090177e196ae408e\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:** 11411143

**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

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Date	Location	User	Value	Reason
Oct-19-2020 16:15:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

090177e196ae408e\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:** 11411143

**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

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Date	Location	User	Value	Reason
Oct-19-2020 16:15:58 (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:** 11411143

**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

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Date	Location	User	Value	Reason
Oct-19-2020 16:16:34 (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:** 11411143**Generated By:** (b) (4)**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History**Form Status:** Data Complete, Locked, Frozen, Not 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
Oct-19-2020 16:15:15 (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
Oct-19-2020 16:15:15 (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
Oct-19-2020 16:15:15 (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
Oct-19-2020 16:15:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sep/19/2020 03:00	Initial Entry

**5. Is the adverse event still ongoing?**

Date	Location	User	Value	Reason
Oct-19-2020 16:15:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO End Date Time: Sep/20/2020 08:00	Initial Entry

**6. Toxicity Grade:**

Date	Location	User	Value	Reason
Oct-19-2020 16:15:15 (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*



Header Text: c4591001

Visit: Logs - Unscheduled

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Site No: 1141

Subject No: 11411143

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

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

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

Subject Initials: ---

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

prevent above outcomes).

Date	Location	User	Value	Reason
Oct-19-2020 16:15:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

8. Is this adverse event the result of a study Medication Error?  
If Yes, record the type of medication error on the Medication Error Log.

Date	Location	User	Value	Reason
Oct-19-2020 16:15:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Oct-25-2020 05:55:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Oct-24-2020 11:22:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	New Information
Oct-24-2020 11:22:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> RELATED	New Information
Oct-21-2020 00:25:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	DM: The response for "Is this event related to study treatment" is missing. Kindly review and update.

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Oct-19-2020 16:15:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NOT APPLICABLE	Initial Entry

11. Was a Concomitant Medication given?

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

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
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**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1141

**Subject No:** 11411143

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

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

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

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

**Subject Initials:** ---

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

Oct-19-2020 16:15:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry
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**13. What was the outcome of this adverse event?:**

Date	Location	User	Value	Reason
Oct-19-2020 16:15:15 (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
Oct-19-2020 16:15:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1141

Subject No: 11411143

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

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

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

Subject Initials: ---

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

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**1. Category:**

Date	Location	User	Value	Reason
Oct-19-2020 16:15:58 (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
Oct-19-2020 16:15:58 (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
Oct-19-2020 16:15:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Chills	Initial Entry

**4. Start Date Time:**

Date	Location	User	Value	Reason
Oct-19-2020 16:15:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sep/19/2020 03:00	Initial Entry

**5. Is the adverse event still ongoing?**

Date	Location	User	Value	Reason
Oct-19-2020 16:15:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO End Date Time: Sep/20/2020 08:00	Initial Entry

**6. Toxicity Grade:**

Date	Location	User	Value	Reason
Oct-19-2020 16:15:58 (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;**

090177e196ae408e\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: 11411143

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

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

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

Subject Initials: ---

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

*Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).*

Date	Location	User	Value	Reason
Oct-19-2020 16:15:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

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

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

Date	Location	User	Value	Reason
Oct-19-2020 16:15:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

**9. Is this event related to study treatment:**

Date	Location	User	Value	Reason
Oct-25-2020 05:55:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Oct-24-2020 11:29:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	New Information
Oct-24-2020 11:29:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> RELATED	New Information
Oct-21-2020 00:25:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	DM: The response for "Is this event related to study treatment" is missing. Kindly review and update.

**10. Latest Action Taken with Study Treatment:**

Date	Location	User	Value	Reason
Oct-19-2020 16:15:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NOT APPLICABLE	Initial Entry

**11. Was a Concomitant Medication given?**

Date	Location	User	Value	Reason
Oct-19-2020 16:15:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

**12. Was a Non-Drug Treatment given?**

Date	Location	User	Value	Reason
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090177e196ae408e\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:** 11411143

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

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

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

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

**Subject Initials:** ---

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

Oct-19-2020 16:15:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry
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**13. What was the outcome of this adverse event?:**

Date	Location	User	Value	Reason
Oct-19-2020 16:15:58 (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
Oct-19-2020 16:15:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1141

Subject No: 11411143

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

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

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

Subject Initials: ---

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

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**1. Category:**

Date	Location	User	Value	Reason
Oct-19-2020 16:16:34 (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
Oct-19-2020 16:16:34 (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
Oct-19-2020 16:16:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Fatigue	Initial Entry

**4. Start Date Time:**

Date	Location	User	Value	Reason
Oct-19-2020 16:16:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sep/19/2020 09:00	Initial Entry

**5. Is the adverse event still ongoing?**

Date	Location	User	Value	Reason
Oct-19-2020 16:16:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO End Date Time: Sep/20/2020 08:00	Initial Entry

**6. Toxicity Grade:**

Date	Location	User	Value	Reason
Oct-19-2020 16:16:34 (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;**

090177e196ae408e\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: 11411143

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

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

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

Subject Initials: ---

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

*Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).*

Date	Location	User	Value	Reason
Oct-19-2020 16:16:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

**8. Is this adverse event the result of a study Medication Error?**  
*If Yes, record the type of medication error on the Medication Error Log.*

Date	Location	User	Value	Reason
Oct-19-2020 16:16:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

**9. Is this event related to study treatment:**

Date	Location	User	Value	Reason
Oct-25-2020 05:56:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Oct-24-2020 11:29:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Initial Entry
Oct-24-2020 11:29:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> RELATED	Initial Entry
Oct-21-2020 00:25:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	DM: The response for "Is this event related to study treatment" is missing. Kindly review and update.

**10. Latest Action Taken with Study Treatment:**

Date	Location	User	Value	Reason
Oct-19-2020 16:16:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NOT APPLICABLE	Initial Entry

**11. Was a Concomitant Medication given?**

Date	Location	User	Value	Reason
Oct-19-2020 16:16:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

**12. Was a Non-Drug Treatment given?**

Date	Location	User	Value	Reason
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090177e196ae408e\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:** 11411143

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

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

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

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

**Subject Initials:** ---

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

Oct-19-2020 16:16:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry
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**13. What was the outcome of this adverse event?:**

Date	Location	User	Value	Reason
Oct-19-2020 16:16:34 (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
Oct-19-2020 16:16:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry



**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:** 11411143

**Subject Initials:** ---

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

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

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*I. Date of Visit*

Date	Location	User	Value	Reason
Jan-28-2021 11:02:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Jan/19/2021	Initial Entry

Header Text: c4591001

Visit: Potential ReVax Initial Contact - Unscheduled

Form: FURTHER VACCINATION CONFIRMATION - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:25

Form Status: Data Complete, Frozen

Site No: 1141

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

Subject No: 11411143

Subject Initials: ---

Generated By: (b) (4)

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

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

Date	Location	User	Value	Reason
Feb-09-2021 10:50:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Jan-28-2021 21:18:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	The response indicates participant was unblinded, however the TREATMENT UNBLINDED date is missing in the DISP visit. Please complete this date.
Jan-28-2021 11:02:17 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	The response indicates participant was unblinded, however the TREATMENT UNBLINDED date is missing in the DISP visit. Please complete this date.
Jan-28-2021 11:02:17 (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 and NOT confirmed to have received only placebo at Vaccination 1/2	Initial Entry

090177e196ae408e\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:** 11411143

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

**Form:** TREATMENT UNBLINDED - 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

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**1. Date Treatment Unblinded :**

Date	Location	User	Value	Reason
Feb-09-2021 10:50:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Jan/19/2021	Initial Entry

**2. Primary Reason for Unblinding:**

Date	Location	User	Value	Reason
Feb-09-2021 10:50:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> ASSESS ELIGIBILITY FOR ADDITIONAL VACCINATION	Initial Entry

**Header Text:** c4591001

**Visit:** Subject Status - Unscheduled

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

**Site No:** 1141

**Subject No:** 11411143

**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

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**1. Subject Status**

Date	Location	User	Value	Reason
Oct-19-2020 16:14:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> FOLLOW-UP	Initial Entry
Aug-28-2020 05:34:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> ENROLLED/RANDOMIZED	Initial Entry
Aug-28-2020 05:26:46 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SCREENED	Initial Entry

**2. Subject Status Date**

Date	Location	User	Value	Reason
Oct-19-2020 16:14:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> Oct/19/2020	Initial Entry
Aug-28-2020 05:34:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> Aug/27/2020	Initial Entry
Aug-28-2020 05:26:46 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> Aug/27/2020	Initial Entry

090177e196ae408e\Final\Final On: 01-Apr-2021 05:42 (GMT)

**Header Text:** c4591001

**Visit:** Investigator Signature - Unscheduled

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

**Site No:** 1141

**Subject No:** 11411143

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

**Form:** CASEBOOK SIGNATURE FORM - eCRF Audit Trail History

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

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

**Subject Initials:** ---

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

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*I. Casebook Signature*

Date	Location	User	Value	Reason
Oct-30-2020 05:54:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Click Here to Enable	Initial Entry

090177e196ae408e\Final\Final On: 01-Apr-2021 05:42 (GMT)