

**Header Text:** c4591001

**Visit:** COHORT\_SELECTION

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

**Site No:** 1117

**Subject No:** 11171121

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

**Form:** COHORT\_SELECTION

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

**Site Name:** (1117) Sundance Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 21-Apr-2021 18:02

[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:** 1117

**Subject No:** 11171121

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

**Form:** MAIN INFORMED CONSENT

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

**Site Name:** (1117) Sundance Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 21-Apr-2021 18:02

[eCRF Audit Trail History](#)

**Informed Consent**

1.	Consent Was:	OBTAINED Date Written Consent Obtained Sep/15/2020
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**Header Text:** c4591001

**Visit:** COHORT\_SELECTION

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

**Site No:** 1117

**Subject No:** 11171121

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

**Form:** DEMOGRAPHY

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

**Site Name:** (1117) Sundance Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 21-Apr-2021 18:02

[eCRF Audit Trail History](#)

**Demography**

1.	Subject ID	[11171121]
2.	Birth Date:	(b) (6)/1986
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:** 1117

**Subject No:** 11171121

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

**Form:** DATE OF VISIT

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

**Site Name:** (1117) Sundance Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 21-Apr-2021 18:02

[eCRF Audit Trail History](#)

**Date of Visit**

1.	Date of Visit	Sep/15/2020	
2.	Erroneous Visit	Not Applicable	<a href="#">Comments</a>

**Header Text:** c4591001

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

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

**Site No:** 1117

**Subject No:** 11171121

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

**Form:** INCLUSION/EXCLUSION CRITERIA

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

**Site Name:** (1117) Sundance Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 21-Apr-2021 18:02

**Form Comments**

**Inclusion Criteria Not Met**

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

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

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

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

**Site No:** 1117

**Subject No:** 11171121

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

**Form:** DISPOSITION - SCREENING

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

**Site Name:** (1117) Sundance Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 21-Apr-2021 18:02

[eCRF Audit Trail History](#)

**Disposition - Screening**

1.	Date of Completion/Discontinuation /Death	Sep/15/2020	
2.	Phase of Disposition:	SCREENING	
3.	Status:	COMPLETED	
4.	Specify Status:	Not Applicable [ ]	<a href="#">Comments</a>

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 22-Apr-2020 21:03

Site No: 1117

Subject No: 11171121

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1117) Sundance Clinical Research

Subject Initials: ---

Generated Time (GMT): 21-Apr-2021 18:02

[eCRF Audit Trail History](#)

**Medical History Details**

1.a	Line/MH Number:	[1]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[anxiety]
	Start Date:	UNK/UNK/2015
	Ongoing:	YES
1.b	Line/MH Number:	[2]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Demerol induced anaphylaxis]
	Start Date:	UNK/UNK/1991
	Ongoing:	NO End Date: UNK/UNK/1991
1.c	Line/MH Number:	[3]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Allergy, Demerol]
	Start Date:	UNK/UNK/1991
	Ongoing:	YES
1.d	Line/MH Number:	[4]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Radial head fracture, Left, non-displaced]
	Start Date:	Jul/22/2020
	Ongoing:	YES

090177e196d8902a\Final\Final On: 22-Apr-2021 02:13 (GMT)

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 22-Apr-2020 21:03

Site No: 1117

Subject No: 11171121

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1117) Sundance Clinical Research

Subject Initials: ---

Generated Time (GMT): 21-Apr-2021 18:02

1.e	Line/MH Number:	[5]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Pain, elbow, left]
	Start Date:	Jul/25/2020
	Ongoing:	YES
1.f	Line/MH Number:	[6]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[hypertension]
	Start Date:	Jan/UNK/2020
	Ongoing:	YES
1.g	Line/MH Number:	[7]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[C-Section]
	Start Date:	Oct/15/2016
	Ongoing:	NO End Date: Oct/15/2016
1.h	Line/MH Number:	[8]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Hip scope, right]
	Start Date:	Dec/UNK/2005
	Ongoing:	NO End Date: Dec/UNK/2005

090177e196d8902a\Final\Final On: 22-Apr-2021 02:13 (GMT)



Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 22-Apr-2020 21:03

Site No: 1117

Subject No: 11171121

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1117) Sundance Clinical Research

Subject Initials: ---

Generated Time (GMT): 21-Apr-2021 18:02

1.i	Line/MH Number:	[9]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[hip fracture, right]
	Start Date:	Dec/UNK/2005
	Ongoing:	NO End Date: Dec/UNK/2005
1.j	Line/MH Number:	[10]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Elbow, left, displaced fracture]
	Start Date:	UNK/UNK/1991
	Ongoing:	NO End Date: UNK/UNK/1991
1.k	Line/MH Number:	[11]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[elbow repair, left]
	Start Date:	UNK/UNK/1991
	Ongoing:	NO End Date: UNK/UNK/1991
1.l	Line/MH Number:	[12]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[appendicitis]
	Start Date:	UNK/UNK/1996
	Ongoing:	NO End Date: UNK/UNK/1996

090177e196d8902a\Final\Final On: 22-Apr-2021 02:13 (GMT)

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 22-Apr-2020 21:03

Site No: 1117

Subject No: 11171121

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1117) Sundance Clinical Research

Subject Initials: ---

Generated Time (GMT): 21-Apr-2021 18:02

1.m	Line/MH Number:	[13]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[appendectomy]
	Start Date:	UNK/UNK/1996
	Ongoing:	NO End Date: UNK/UNK/1996
1.n	Line/MH Number:	[14]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Tooth extraction, wisdom]
	Start Date:	UNK/UNK/2002
	Ongoing:	NO End Date: UNK/UNK/2002
1.o	Line/MH Number:	[15]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Pain, tooth]
	Start Date:	UNK/UNK/2002
	Ongoing:	NO End Date: UNK/UNK/2002
1.p	Line/MH Number:	[16]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Allergy, seasonal]
	Start Date:	UNK/UNK/2001
	Ongoing:	YES

090177e196d8902a\Final\Final On: 22-Apr-2021 02:13 (GMT)

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 22-Apr-2020 21:03

Site No: 1117

Subject No: 11171121

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1117) Sundance Clinical Research

Subject Initials: ---

Generated Time (GMT): 21-Apr-2021 18:02

1.q	Line/MH Number:	[17]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Myopia, bilateral]
	Start Date:	UNK/UNK/1993
	Ongoing:	YES
1.r	Line/MH Number:	[18]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Sinusitis, chronic]
	Start Date:	UNK/UNK/2005
	Ongoing:	YES
1.s	Line/MH Number:	[19]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[pneumonia]
	Start Date:	UNK/UNK/2018
	Ongoing:	NO End Date: UNK/UNK/2018
1.t	Line/MH Number:	[20]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[pneumonia]
	Start Date:	UNK/UNK/2016
	Ongoing:	NO End Date: UNK/UNK/2016
1.u	Line/MH Number:	[21]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Alcohol use, 2/week]
	Start Date:	UNK/UNK/2005
	Ongoing:	YES

090177e196d8902a\Final\Final On: 22-Apr-2021 02:13 (GMT)

**Header Text:** c4591001

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

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

**Site No:** 1117

**Subject No:** 11171121

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

**Form:** VITAL SIGNS - BASELINE

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

**Site Name:** (1117) Sundance Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 21-Apr-2021 18:02

[eCRF Audit Trail History](#)

**Vital Signs**

1.	Date:	Sep/15/2020
2.	Weight:	[232.6]
3.	Unit:	LB
4.	Height:	[67.8]
5.	Unit:	in
6.	Body Mass Index:	[35.6]

**Vital Signs Details**

7.a	Record Identifier:	1
	Temperature:	[97.9]
	Unit:	F
	Temperature Location:	ORAL CAVITY

090177e196d8902a\Final\Final On: 22-Apr-2021 02:13 (GMT)

**Header Text:** c4591001

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

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

**Site No:** 1117

**Subject No:** 11171121

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

**Form:** LAB URINALYSIS - PREGNANCY TEST

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

**Site Name:** (1117) Sundance Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 21-Apr-2021 18:02

[eCRF Audit Trail History](#)

**Lab Urinalysis**

1.	Lab Panel:	URINALYSIS
2.	Lab Sub-Panel:	PREGNANCY
3.	Collection Date:	Sep/15/2020
4.	Laboratory Name and Address (Derived)	[STUDY SITE]
5.	Specimen Type:	URINE

**Lab Result**

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

090177e196d8902a\Final\Final On: 22-Apr-2021 02:13 (GMT)

**Header Text:** c4591001

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

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

**Site No:** 1117

**Subject No:** 11171121

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

**Form:** RANDOMIZATION

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

**Site Name:** (1117) Sundance Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 21-Apr-2021 18:02

[eCRF Audit Trail History](#)

**Disposition**

1.	Randomization Date :	Sep/15/2020
2.	Randomization Number:	[88144]
3.	Randomization Group:	[ ]

**Header Text:** c4591001

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

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

**Site No:** 1117

**Subject No:** 11171121

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

**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

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

**Site Name:** (1117) Sundance Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 21-Apr-2021 18:02

[eCRF Audit Trail History](#)

**Electronic Sample Tracking**

1.	Data Origin	SITE	
2.	Sample Type	SERUM	
3.	Sample Collected?	YES Date of Collection: Sep/15/2020	
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	Not Applicable _____ [ ]	<a href="#">Comments</a>

**Aliquot**

Please enter barcode for each aliquot.

5.a	Sample ID	[BPRV3J]
5.b	Sample ID	[BPRV3K]
5.c	Sample ID	[BM8YKX]
5.d	Sample ID	[BM8YKY]
5.e	Sample ID	[BM8YKZ]

090177e196d8902a\Final\Final On: 22-Apr-2021 02:13 (GMT)

**Header Text:** c4591001

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

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

**Site No:** 1117

**Subject No:** 11171121

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

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

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

**Site Name:** (1117) Sundance Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 21-Apr-2021 18:02

[eCRF Audit Trail History](#)

**Electronic Sample Tracking**

1.	Data Origin	SITE	
2.	Sample Type	NASAL_SWAB	
3.	Sample Collected?	YES Date of Collection: Sep/15/2020	
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	Not Applicable _____ [ ]	<a href="#">Comments</a>

**Aliquot**

Please enter barcode for each aliquot.

5.a	Sample ID	[BM8YJ1]
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090177e196d8902a\Final\Final On: 22-Apr-2021 02:13 (GMT)



**Header Text:** c4591001

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

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

**Site No:** 1117

**Subject No:** 11171121

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

**Form:** VACCINATION

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

**Site Name:** (1117) Sundance Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 21-Apr-2021 18:02

[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/15/2020 10:06
5.	Anatomical Location:	DELTOID MUSCLE
6.	Body Side:	RIGHT
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

090177e196d8902a\Final\Final On: 22-Apr-2021 02:13 (GMT)

**Header Text:** c4591001

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

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

**Site No:** 1117

**Subject No:** 11171121

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

**Form:** REACTOGENICITY DIARY

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

**Site Name:** (1117) Sundance Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 21-Apr-2021 18:02

[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:** 1117

**Subject No:** 11171121

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

**Form:** DATE OF VISIT

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

**Site Name:** (1117) Sundance Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 21-Apr-2021 18:02

[eCRF Audit Trail History](#)

**Date of Visit**

1.	Date of Visit	Oct/6/2020
2.	Erroneous Visit	

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1117

**Subject No:** 11171121

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

**Form:** VITAL SIGNS - TEMP

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

**Site Name:** (1117) Sundance Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 21-Apr-2021 18:02

[eCRF Audit Trail History](#)

**Vital Signs**

1.	Date:	Oct/6/2020
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**Vital Signs Details**

2.a	Record Identifier:	1
	Temperature:	[98.8]
	Unit:	F
	Temperature Location:	ORAL CAVITY

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1117

**Subject No:** 11171121

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

**Form:** LAB URINALYSIS - PREGNANCY TEST

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

**Site Name:** (1117) Sundance Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 21-Apr-2021 18:02

[eCRF Audit Trail History](#)

**Lab Urinalysis**

1.	Lab Panel:	URINALYSIS
2.	Lab Sub-Panel:	PREGNANCY
3.	Collection Date:	Oct/6/2020
4.	Laboratory Name and Address (Derived)	[STUDY SITE]
5.	Specimen Type:	URINE

**Lab Result**

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

090177e196d8902a\Final\Final On: 22-Apr-2021 02:13 (GMT)

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1117

**Subject No:** 11171121

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

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

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

**Site Name:** (1117) Sundance Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 21-Apr-2021 18:02

[eCRF Audit Trail History](#)

**Electronic Sample Tracking**

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Oct/6/2020
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	[BRJ89L]
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090177e196d8902a\Final\Final On: 22-Apr-2021 02:13 (GMT)

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1117

**Subject No:** 11171121

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

**Form:** VACCINATION

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

**Site Name:** (1117) Sundance Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 21-Apr-2021 18:02

[eCRF Audit Trail History](#)

**Vaccination**

1.	Was there a temporary delay of vaccination?	NO
2.	Treatment Name	[BLINDED THERAPY]
3.	Formulation:	INJECTION
4.	Dose Date Time:	Oct/6/2020 17:09
5.	Anatomical Location:	DELTOID MUSCLE
6.	Body Side:	RIGHT
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

090177e196d8902a\Final\Final On: 22-Apr-2021 02:13 (GMT)

**Header Text:** c4591001

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

**Form:** DATE OF VISIT

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

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

**Site No:** 1117

**Site Name:** (1117) Sundance Clinical Research

**Subject No:** 11171121

**Subject Initials:** ---

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

**Generated Time (GMT):** 21-Apr-2021 18:02

[eCRF Audit Trail History](#)

**Date of Visit**

1.	Date of Visit	Nov/5/2020
2.	Erroneous Visit	



**Header Text:** c4591001

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

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

**Site No:** 1117

**Subject No:** 11171121

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

**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

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

**Site Name:** (1117) Sundance Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 21-Apr-2021 18:02

[eCRF Audit Trail History](#)

**Electronic Sample Tracking**

1.	Data Origin	SITE
2.	Sample Type	SERUM
3.	Sample Collected?	YES Date of Collection: Nov/5/2020
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	[BP58YY]
5.b	Sample ID	[BP58YZ]
5.c	Sample ID	[BP58Z0]
5.d	Sample ID	[BRSRT0]
5.e	Sample ID	[BRSRT1]

090177e196d8902a\Final\Final On: 22-Apr-2021 02:13 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on **Form:** DATE OF VISIT - ILLNESS ONSET  
Nov/23/2020

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

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

**Site No:** 1117

**Site Name:** (1117) Sundance Clinical Research

**Subject No:** 11171121

**Subject Initials:** ---

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

**Generated Time (GMT):** 21-Apr-2021 18:02

[eCRF Audit Trail History](#)

**Date of Visit**

1.	Date of Visit	Nov/23/2020
2.	Erroneous Visit	

**COVID-19 Illness Visit**

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

Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Form: SIGNS AND SYMPTOMS OF POTENTIAL COVID-19  
Nov/23/2020

Form Version: 10-Oct-2020 16:02

Form Status: Data Complete, Frozen, Verified

Site No: 1117

Site Name: (1117) Sundance Clinical Research

Subject No: 11171121

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 21-Apr-2021 18:02

[eCRF Audit Trail History](#)

**Signs and Symptoms**

1.	Date of Assessment:	Nov/23/2020
2.	Date of First Symptom Started:	Nov/16/2020
3.	Symptoms Ongoing?	NO Date of Last Symptom Resolved: Jan/11/2021

**Symptoms**

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

**Symptoms - Other**

090177e196d8902a\Final\Final On: 22-Apr-2021 02:13 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on **Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19  
Nov/23/2020

**Form Version:** 10-Oct-2020 16:02

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

**Site No:** 1117

**Site Name:** (1117) Sundance Clinical Research

**Subject No:** 11171121

**Subject Initials:** ---

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

**Generated Time (GMT):** 21-Apr-2021 18:02

5.a	Symptoms - Other Text:	[RHINORRHEA]
5.b	Symptoms - Other Text:	[HEADACHE]
5.c	Symptoms - Other Text:	[FATIGUE]
5.d	Symptoms - Other Text:	[NASAL CONGESTION]

**Header Text:** c4591001

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

**Form:** MICROBIOLOGY SPECIMEN

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

**Site No:** 1117

**Site Name:** (1117) Sundance Clinical Research

**Subject No:** 11171121

**Subject Initials:** ---

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

**Generated Time (GMT):** 21-Apr-2021 18:02

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

090177e196d8902a\Final\Final On: 22-Apr-2021 02:13 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on **Form:** MICROBIOLOGY SPECIMEN  
Nov/23/2020

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

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

**Site No:** 1117

**Site Name:** (1117) Sundance Clinical Research

**Subject No:** 11171121

**Subject Initials:** ---

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

**Generated Time (GMT):** 21-Apr-2021 18:02

[Back to Form](#)

[eCRF Audit Trail History](#)

[Form Audit Trail](#)

**Microbiology Specimen**

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

090177e196d8902a\Final\Final On: 22-Apr-2021 02:13 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on **Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB SELF  
Nov/23/2020

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

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

**Site No:** 1117

**Site Name:** (1117) Sundance Clinical Research

**Subject No:** 11171121

**Subject Initials:** ---

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

**Generated Time (GMT):** 21-Apr-2021 18:02

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**Electronic Sample Tracking**

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB_SELF
3.	Sample Collected?	YES Date of Collection: Nov/22/2020
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[ ]

**Aliquot**

Please enter barcode for each aliquot.

5.a	Sample ID	[CV05746]
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090177e196d8902a\Final\Final On: 22-Apr-2021 02:13 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on **Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB  
Nov/23/2020

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

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

**Site No:** 1117

**Site Name:** (1117) Sundance Clinical Research

**Subject No:** 11171121

**Subject Initials:** ---

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

**Generated Time (GMT):** 21-Apr-2021 18:02

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**Electronic Sample Tracking**

1.	Data Origin	SITE	
2.	Sample Type	NASAL_SWAB	
3.	Sample Collected?	NO	<a href="#">Comments</a>
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[TELEHEALTH VISIT, SEE SELF SWAB]	

**Aliquot**

Please enter barcode for each aliquot.

5.	Sample ID	[ ]
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090177e196d8902a\Final\Final On: 22-Apr-2021 02:13 (GMT)



Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Form: HEALTH CARE UTILIZATION  
Nov/23/2020

Form Version: 10-Oct-2020 15:59

Form Status: Data Complete, Frozen, Verified

Site No: 1117

Site Name: (1117) Sundance Clinical Research

Subject No: 11171121

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 21-Apr-2021 18:02

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**Health Care Utilization**

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

**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?	NO
----	--	----

090177e196d8902a\Final\Final On: 22-Apr-2021 02:13 (GMT)

**Header Text:** c4591001

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

**Form:** RESPIRATORY TREATMENT

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

**Site No:** 1117

**Site Name:** (1117) Sundance Clinical Research

**Subject No:** 11171121

**Subject Initials:** ---

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

**Generated Time (GMT):** 21-Apr-2021 18:02

#	Treatment Identifier	Con Non-Drug Treatments Pre-specified	Treatment	Treatment	Start Date	Form Instance
1.	Not Done	Not Done	Not Done	Not Done	Not Done	<a href="#">Repeating Pages</a>

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on **Form:** RESPIRATORY TREATMENT  
Nov/23/2020

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

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

**Site No:** 1117

**Site Name:** (1117) Sundance Clinical Research

**Subject No:** 11171121

**Subject Initials:** ---

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

**Generated Time (GMT):** 21-Apr-2021 18:02

[Back to Form](#)

[Form Comments](#)

[eCRF Audit Trail History](#)

**Respiratory Treatment**

1.	What is the treatment Identifier?	Not Done _____ [ ]	<a href="#">Comments</a>
2.	Concomitant Non-drug Treatment Pre-specified:	Not Done _____	<a href="#">Comments</a>
3.	Treatment:	Not Done _____	<a href="#">Comments</a>
4.	Treatment:	Not Done _____ [ ]	<a href="#">Comments</a>
5.	Start Date:	Not Done _____ //	<a href="#">Comments</a>
6.	Ongoing?	Not Done _____	<a href="#">Comments</a>

090177e196d8902a\Final\Final On: 22-Apr-2021 02:13 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on **Form:** ILLNESS DETAILS  
Nov/23/2020

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

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

**Site No:** 1117

**Site Name:** (1117) Sundance Clinical Research

**Subject No:** 11171121

**Subject Initials:** ---

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

**Generated Time (GMT):** 21-Apr-2021 18:02

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**Illness Details**

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

**Header Text:** c4591001

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

**Form:** ILLNESS DETAILS - SEVERE

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

**Site No:** 1117

**Site Name:** (1117) Sundance Clinical Research

**Subject No:** 11171121

**Subject Initials:** ---

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

**Generated Time (GMT):** 21-Apr-2021 18:02

#	Category of Clinical Event:	Subcategory of Clinical Event	Diagnosis Obtained	Toxicity Grade	Form Instance
1.	Not Done	Not Done	Not Done	Not Done	<a href="#">Repeating Pages</a>

090177e196d8902a\Final\Final On: 22-Apr-2021 02:13 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on **Form:** ILLNESS DETAILS - SEVERE  
Nov/23/2020

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

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

**Site No:** 1117

**Site Name:** (1117) Sundance Clinical Research

**Subject No:** 11171121

**Subject Initials:** ---

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

**Generated Time (GMT):** 21-Apr-2021 18:02

[Back to Form](#)

[Form Comments](#)

[eCRF Audit Trail History](#)

**Illness Details**

1.	Category of Clinical Event:	Not Done _____	<a href="#">Comments</a>
2.	Subcategory of Clinical Event:	Not Done _____	<a href="#">Comments</a>
3.	Was a diagnosis obtained?	Not Done _____	<a href="#">Comments</a>
4.	Toxicity Grade:	Not Done _____	<a href="#">Comments</a>

Header Text: c4591001

Visit: POT\_COVID\_ILL 1

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY

Form Version: 15-Sep-2020 21:51

Site No: 1117

Site Name: (1117) Sundance Clinical Research

Subject No: 11171121

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 21-Apr-2021 18:02

#	Category for Lab Test	Vendor Name	Collection Date:	Specimen Type	Lab Result			Form Instance
1.	Not Done	Not Done	Not Done	Not Done	<b>Sponsor-Defined Identifier</b>	<b>Test:</b>	<b>Result:</b>	<a href="#">Repeating Pages</a>
					Not Done	Not Done	Not Done	
					Not Done	Not Done	Not Done	
					Not Done	Not Done	Not Done	
					Not Done	Not Done	Not Done	
					Not Done	Not Done	Not Done	
					Not Done	Not Done	Not Done	
					Not Done	Not Done	Not Done	

090177e196d8902a\Final\Final On: 22-Apr-2021 02:13 (GMT)

Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY  
Nov/23/2020

Form Version: 15-Sep-2020 21:51

Form Status: Data Complete, Frozen, Verified

Site No: 1117

Site Name: (1117) Sundance Clinical Research

Subject No: 11171121

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 21-Apr-2021 18:02

[Back to Form](#)

[Form Comments](#)

[eCRF Audit Trail History](#)

**Lab Chemistry Details**

1.	Lab Panel:	Not Done _____	<a href="#">Comments</a>
2.	Laboratory Name and Address	Not Done _____ [ ]	<a href="#">Comments</a>
3.	Collection Date:	Not Done _____ //	<a href="#">Comments</a>
4.	Specimen Type:	Not Done _____	<a href="#">Comments</a>

**Lab Result**

5.a	Sponsor ID:	Not Done _____ [ ]	<a href="#">Comments</a>
	Test:	C Reactive Protein_PX329	
	Result:	Not Done _____ [ ]	<a href="#">Comments</a>
	Not Done:	Not Done _____	<a href="#">Comments</a>
	LNMT	Not Done _____ Low [ ] High [ ] Unit	<a href="#">Comments</a>

090177e196d8902a\Final\Final On: 22-Apr-2021 02:13 (GMT)



**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on **Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY  
Nov/23/2020

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

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

**Site No:** 1117

**Site Name:** (1117) Sundance Clinical Research

**Subject No:** 11171121

**Subject Initials:** ---

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

**Generated Time (GMT):** 21-Apr-2021 18:02

5.b	Sponsor ID:	Not Done _____ [ ]	<a href="#">Comments</a>
	Test:	Alanine Aminotransferase_PX30	
	Result:	Not Done _____ [ ]	<a href="#">Comments</a>
	Not Done:	Not Done _____	<a href="#">Comments</a>
	LNMT	Not Done _____ Low [ ] High [ ] Unit	<a href="#">Comments</a>
5.c	Sponsor ID:	Not Done _____ [ ]	<a href="#">Comments</a>
	Test:	Aspartate Aminotransferase_PX28	
	Result:	Not Done _____ [ ]	<a href="#">Comments</a>
	Not Done:	Not Done _____	<a href="#">Comments</a>
	LNMT	Not Done _____ Low [ ] High [ ] Unit	<a href="#">Comments</a>

090177e196d8902a\Final\Final On: 22-Apr-2021 02:13 (GMT)

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Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY  
Nov/23/2020

Form Version: 15-Sep-2020 21:51

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Site No: 1117

Site Name: (1117) Sundance Clinical Research

Subject No: 11171121

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 21-Apr-2021 18:02

5.d	Sponsor ID:	Not Done _____ [ ]	<a href="#">Comments</a>
	Test:	Alkaline Phosphatase_PX35	
	Result:	Not Done _____ [ ]	<a href="#">Comments</a>
	Not Done:	Not Done _____	<a href="#">Comments</a>
	LNMT	Not Done _____ Low [ ] High [ ] Unit	<a href="#">Comments</a>
5.e	Sponsor ID:	Not Done _____ [ ]	<a href="#">Comments</a>
	Test:	Bilirubin_PX21	
	Result:	Not Done _____ [ ]	<a href="#">Comments</a>
	Not Done:	Not Done _____	<a href="#">Comments</a>
	LNMT	Not Done _____ Low [ ] High [ ] Unit	<a href="#">Comments</a>

090177e196d8902a\Final\Final On: 22-Apr-2021 02:13 (GMT)

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Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY  
Nov/23/2020

Form Version: 15-Sep-2020 21:51

Form Status: Data Complete, Frozen, Verified

Site No: 1117

Site Name: (1117) Sundance Clinical Research

Subject No: 11171121

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 21-Apr-2021 18:02

5 f	Sponsor ID:	Not Done _____ [ ]	<a href="#">Comments</a>
	Test:	Blood Urea Nitrogen_PX47	
	Result:	Not Done _____ [ ]	<a href="#">Comments</a>
	Not Done:	Not Done _____	<a href="#">Comments</a>
	LNMT	Not Done _____ Low [ ] High [ ] Unit	<a href="#">Comments</a>

5.g	Sponsor ID:	Not Done _____ [ ]	<a href="#">Comments</a>
	Test:	Creatinine_PX48	
	Result:	Not Done _____ [ ]	<a href="#">Comments</a>
	Not Done:	Not Done _____	<a href="#">Comments</a>
	LNMT	Not Done _____ Low [ ] High [ ] Unit	<a href="#">Comments</a>

090177e196d8902a\Final\Final On: 22-Apr-2021 02:13 (GMT)

Header Text: c4591001

Visit: POT\_COVID\_ILL 1

Form: LOCAL LABORATORY DATA - REPEATING Hematology

Form Version: 15-Sep-2020 21:55

Site No: 1117

Site Name: (1117) Sundance Clinical Research

Subject No: 11171121

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 21-Apr-2021 18:02

#	Category for Lab Test	Vendor Name (DE RIVED)	Collection Date:	Specimen Type	Lab Result			Form Instance
1.	Not Done	Not Done	Not Done	Not Done	<b>Sponsor-Defined Identifier</b>	<b>Test:</b>	<b>Result :</b>	<a href="#">Repeating Pages</a>
					Not Done	Not Done	Not Done	
					Not Done	Not Done	Not Done	
					Not Done	Not Done	Not Done	
					Not Done	Not Done	Not Done	
					Not Done	Not Done	Not Done	
					Not Done	Not Done	Not Done	
					Not Done	Not Done	Not Done	
					Not Done	Not Done	Not Done	
					Not Done	Not Done	Not Done	
					Not Done	Not Done	Not Done	
					Not Done	Not Done	Not Done	

090177e196d8902a\Final\Final On: 22-Apr-2021 02:13 (GMT)

Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Form: LOCAL LABORATORY DATA - REPEATING Hematology  
Nov/23/2020

Form Version: 15-Sep-2020 21:55

Form Status: Data Complete, Frozen, Verified

Site No: 1117

Site Name: (1117) Sundance Clinical Research

Subject No: 11171121

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 21-Apr-2021 18:02

[Back to Form](#)

[Form Comments](#)

[eCRF Audit Trail History](#)

**Laboratory Data Hematology**

1.	Lab Panel:	Not Done _____	<a href="#">Comments</a>
2.	Laboratory Name and Address	Not Done _____ [ ]	<a href="#">Comments</a>
3.	Collection Date:	Not Done _____ //	<a href="#">Comments</a>
4.	Specimen Type:	Not Done _____	<a href="#">Comments</a>

**Lab Result**

5.a	Sponsor ID:	Not Done _____ [ ]	<a href="#">Comments</a>
	Test:	Hemoglobin_PX1	
	Result:	Not Done _____ [ ]	<a href="#">Comments</a>
	Not Done:	Not Done _____	<a href="#">Comments</a>
	LNMT	Not Done _____ Low [ ] High [ ] Unit	<a href="#">Comments</a>

090177e196d8902a\Final\Final On: 22-Apr-2021 02:13 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on **Form:** LOCAL LABORATORY DATA - REPEATING Hematology  
Nov/23/2020

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

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

**Site No:** 1117

**Site Name:** (1117) Sundance Clinical Research

**Subject No:** 11171121

**Subject Initials:** ---

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

**Generated Time (GMT):** 21-Apr-2021 18:02

5.b	Sponsor ID:	Not Done _____ [ ]	<a href="#">Comments</a>
	Test:	Hematocrit_PX2	
	Result:	Not Done _____ [ ]	<a href="#">Comments</a>
	Not Done:	Not Done _____	<a href="#">Comments</a>
	LNMT	Not Done _____ Low [ ] High [ ] Unit	<a href="#">Comments</a>
5.c	Sponsor ID:	Not Done _____ [ ]	<a href="#">Comments</a>
	Test:	Erythrocytes_PX3	
	Result:	Not Done _____ [ ]	<a href="#">Comments</a>
	Not Done:	Not Done _____	<a href="#">Comments</a>
	LNMT	Not Done _____ Low [ ] High [ ] Unit	<a href="#">Comments</a>

090177e196d8902a\Final\Final On: 22-Apr-2021 02:13 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on **Form:** LOCAL LABORATORY DATA - REPEATING Hematology  
Nov/23/2020

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

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

**Site No:** 1117

**Site Name:** (1117) Sundance Clinical Research

**Subject No:** 11171121

**Subject Initials:** ---

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

**Generated Time (GMT):** 21-Apr-2021 18:02

5.d	Sponsor ID:	Not Done _____ [ ]	<a href="#">Comments</a>
	Test:	Platelets_PX5	
	Result:	Not Done _____ [ ]	<a href="#">Comments</a>
	Not Done:	Not Done _____	<a href="#">Comments</a>
	LNMT	Not Done _____ Low [ ] High [ ] Unit	<a href="#">Comments</a>
5.e	Sponsor ID:	Not Done _____ [ ]	<a href="#">Comments</a>
	Test:	Leukocytes_PX7	
	Result:	Not Done _____ [ ]	<a href="#">Comments</a>
	Not Done:	Not Done _____	<a href="#">Comments</a>
	LNMT	Not Done _____ Low [ ] High [ ] Unit	<a href="#">Comments</a>

090177e196d8902a\Final\Final On: 22-Apr-2021 02:13 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on **Form:** LOCAL LABORATORY DATA - REPEATING Hematology  
Nov/23/2020

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

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

**Site No:** 1117

**Site Name:** (1117) Sundance Clinical Research

**Subject No:** 11171121

**Subject Initials:** ---

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

**Generated Time (GMT):** 21-Apr-2021 18:02

5 f	Sponsor ID:	Not Done _____	<a href="#">Comments</a>
		[ ]	
	Test:	Neutrophils_PX608	
	Result:	Not Done _____	<a href="#">Comments</a>
		[ ]	
Not Done:	Not Done _____	<a href="#">Comments</a>	
LNMT	Not Done _____	<a href="#">Comments</a>	
	Low [ ] High [ ] Unit		

5.g	Sponsor ID:	Not Done _____	<a href="#">Comments</a>
		[ ]	
	Test:	Eosinophils_PX609	
	Result:	Not Done _____	<a href="#">Comments</a>
		[ ]	
Not Done:	Not Done _____	<a href="#">Comments</a>	
LNMT	Not Done _____	<a href="#">Comments</a>	
	Low [ ] High [ ] Unit		

090177e196d8902a\Final\Final On: 22-Apr-2021 02:13 (GMT)



**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on **Form:** LOCAL LABORATORY DATA - REPEATING Hematology  
Nov/23/2020

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

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

**Site No:** 1117

**Site Name:** (1117) Sundance Clinical Research

**Subject No:** 11171121

**Subject Initials:** ---

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

**Generated Time (GMT):** 21-Apr-2021 18:02

5.h	Sponsor ID:	Not Done _____ [ ]	<a href="#">Comments</a>
	Test:	Monocytes_PX612	
	Result:	Not Done _____ [ ]	<a href="#">Comments</a>
	Not Done:	Not Done _____	<a href="#">Comments</a>
	LNMT	Not Done _____ Low [ ] High [ ] Unit	<a href="#">Comments</a>
5.i	Sponsor ID:	Not Done _____ [ ]	<a href="#">Comments</a>
	Test:	Basophils_PX610	
	Result:	Not Done _____ [ ]	<a href="#">Comments</a>
	Not Done:	Not Done _____	<a href="#">Comments</a>
	LNMT	Not Done _____ Low [ ] High [ ] Unit	<a href="#">Comments</a>

090177e196d8902a\Final\Final On: 22-Apr-2021 02:13 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on **Form:** LOCAL LABORATORY DATA - REPEATING Hematology  
Nov/23/2020

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

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

**Site No:** 1117

**Site Name:** (1117) Sundance Clinical Research

**Subject No:** 11171121

**Subject Initials:** ---

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

**Generated Time (GMT):** 21-Apr-2021 18:02

5.j	Sponsor ID:	Not Done _____ [ ]	<a href="#">Comments</a>
	Test:	Lymphocytes_PX611	
	Result:	Not Done _____ [ ]	<a href="#">Comments</a>
	Not Done:	Not Done _____	<a href="#">Comments</a>
	LNMT	Not Done _____ Low [ ] High [ ] Unit	<a href="#">Comments</a>

090177e196d8902a\Final\Final On: 22-Apr-2021 02:13 (GMT)

**Header Text:** c4591001

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

**Form:** VITAL SIGNS - COVID

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

**Site No:** 1117

**Site Name:** (1117) Sundance Clinical Research

**Subject No:** 11171121

**Subject Initials:** ---

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

**Generated Time (GMT):** 21-Apr-2021 18:02

#	Date:	Vital Signs Details			Form Instance
1.	Not Done	<b>Record Identifier:</b>	<b>Systolic:</b>	<b>Diastolic:</b>	<a href="#">Repeating Pages</a>
		Not Done	Not Done	Not Done	

090177e196d8902a\Final\Final On: 22-Apr-2021 02:13 (GMT)

Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Form: VITAL SIGNS - COVID  
Nov/23/2020

Form Version: 15-Sep-2020 21:52

Form Status: Data Complete, Frozen, Verified

Site No: 1117

Site Name: (1117) Sundance Clinical Research

Subject No: 11171121

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 21-Apr-2021 18:02

[Back to Form](#)

[Form Comments](#)

[eCRF Audit Trail History](#)

**Vital Signs**

1.	Date:	Not Done _____ //	<a href="#">Comments</a>
----	-------	-------------------------	--------------------------

**Vital Signs Details**

2.a	Record Identifier:	Not Done _____ 1	
	Systolic:	Not Done _____ [ ]	<a href="#">Comments</a>
	Diastolic:	Not Done _____ [ ]	<a href="#">Comments</a>
	Respiratory Rate in respirations/minute:	Not Done _____ [ ]	<a href="#">Comments</a>
	Heart Rate in beats/minute:	Not Done _____ [ ]	<a href="#">Comments</a>

090177e196d8902a\Final\Final On: 22-Apr-2021 02:13 (GMT)

**Header Text:** c4591001

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

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

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

**Site No:** 1117

**Site Name:** (1117) Sundance Clinical Research

**Subject No:** 11171121

**Subject Initials:** ---

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

**Generated Time (GMT):** 21-Apr-2021 18:02

#	Date:	Vital Signs Details		Form Instance
1.	Not Done	<b>Record Identifier:</b>	<b>Oxygen Saturation</b>	<a href="#">Repeating Pages</a>
		Not Done	Not Done	

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on **Form:** VITAL SIGNS - PULSE OX ROOM AIR  
Nov/23/2020

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

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

**Site No:** 1117

**Site Name:** (1117) Sundance Clinical Research

**Subject No:** 11171121

**Subject Initials:** ---

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

**Generated Time (GMT):** 21-Apr-2021 18:02

[Back to Form](#)

[Form Comments](#)

[eCRF Audit Trail History](#)

**Vital Signs**

1.	Date:	Not Done _____ //	<a href="#">Comments</a>
----	-------	-------------------------	--------------------------

**Vital Signs Details**

2.a	Record Identifier:	Not Done _____ 1	
	SPO2 Pulse Oximetry %	Not Done _____ [ ]	<a href="#">Comments</a>

**Header Text:** c4591001

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

**Form:** OXYGENATION PARAMETERS

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

**Site No:** 1117

**Site Name:** (1117) Sundance Clinical Research

**Subject No:** 11171121

**Subject Initials:** ---

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

**Generated Time (GMT):** 21-Apr-2021 18:02

#	Date Time of Assessment	Arterial Blood Gases PaO2	FiO2 (Fraction of Inhaled Oxygen)	Form Instance
1.	Not Done	Not Done	Not Done	<a href="#">Repeating Pages</a>

090177e196d8902a\Final\Final On: 22-Apr-2021 02:13 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on **Form:** OXYGENATION PARAMETERS  
Nov/23/2020

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

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

**Site No:** 1117

**Site Name:** (1117) Sundance Clinical Research

**Subject No:** 11171121

**Subject Initials:** ---

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

**Generated Time (GMT):** 21-Apr-2021 18:02

[Back to Form](#)

[Form Comments](#)

[eCRF Audit Trail History](#)

**Oxygenation Parameters**

1.	Date Time of Assessment:	Not Done _____ //	<a href="#">Comments</a>
2.	Arterial Blood Gases PaO2 (mmHg):	Not Done _____ [ ]	<a href="#">Comments</a>
3.	FiO2 (Fraction of Inhaled Oxygen):	Not Done _____ [ ]	<a href="#">Comments</a>



**Header Text:** c4591001

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

**Form:** CONCOMITANT MEDICATIONS - VASOPRESSORS

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

**Site No:** 1117

**Site Name:** (1117) Sundance Clinical Research

**Subject No:** 11171121

**Subject Initials:** ---

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

**Generated Time (GMT):** 21-Apr-2021 18:02

#	Sponsor-Defined Identifier	Category for Medication	Concomitant Medications Pre-specified	Name of Medication	Start Date	Form Instance
1.	Not Done	Not Done	Not Done	Not Done	Not Done	<a href="#">Repeating Pages</a>

090177e196d8902a\Final\Final On: 22-Apr-2021 02:13 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on **Form:** CONCOMITANT MEDICATIONS - VASOPRESSORS  
Nov/23/2020

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

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

**Site No:** 1117

**Site Name:** (1117) Sundance Clinical Research

**Subject No:** 11171121

**Subject Initials:** ---

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

**Generated Time (GMT):** 21-Apr-2021 18:02

[Back to Form](#)

[Form Comments](#)

[eCRF Audit Trail History](#)

**Concomitant Medications**

1.	What is the medication identifier?	Not Done _____ [ ]	<a href="#">Comments</a>
2.	Category:	Not Done _____	<a href="#">Comments</a>
3.	Concomitant Medications Pre-specified:	Not Done _____	<a href="#">Comments</a>
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).	Not Done _____ [ ]	<a href="#">Comments</a>
5.	Start Date:	Not Done _____ //	<a href="#">Comments</a>
6.	Ongoing?	Not Done _____	<a href="#">Comments</a>

090177e196d8902a\Final\Final On: 22-Apr-2021 02:13 (GMT)

**Header Text:** c4591001

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

**Form:** IMAGING

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

**Site No:** 1117

**Site Name:** (1117) Sundance Clinical Research

**Subject No:** 11171121

**Subject Initials:** ---

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

**Generated Time (GMT):** 21-Apr-2021 18:02

#	Date of Assessment	Location of Assessment	Imaging Method	Overall Assessment	Form Instance
1.	Not Done	Not Done	Not Done	Not Done	<a href="#">Repeating Pages</a>

090177e196d8902a\Final\Final On: 22-Apr-2021 02:13 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on **Form:** IMAGING  
Nov/23/2020

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

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

**Site No:** 1117

**Site Name:** (1117) Sundance Clinical Research

**Subject No:** 11171121

**Subject Initials:** ---

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

**Generated Time (GMT):** 21-Apr-2021 18:02

[Back to Form](#)

[Form Comments](#)

[eCRF Audit Trail History](#)

**Imaging**

1.	Date of Assessment:	Not Done _____ //	<a href="#">Comments</a>
2.	Location of Assessment:	Not Done _____	<a href="#">Comments</a>
3.	Type of Imaging Exam:	Not Done _____	<a href="#">Comments</a>
4.	Assessment:	Not Done _____	<a href="#">Comments</a>

**Header Text:** c4591001

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

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

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

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

**Site No:** 1117

**Site Name:** (1117) Sundance Clinical Research

**Subject No:** 11171121

**Subject Initials:** ---

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

**Generated Time (GMT):** 21-Apr-2021 18:02

[eCRF Audit Trail History](#)

**Date of Visit**

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

**COVID-19 Illness Visit**

3.	COVID-19 Illness Visit:	Not Applicable	<a href="#">Comments</a>
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**Header Text:** c4591001

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

**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

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

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

**Site No:** 1117

**Site Name:** (1117) Sundance Clinical Research

**Subject No:** 11171121

**Subject Initials:** ---

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

**Generated Time (GMT):** 21-Apr-2021 18:02

[Form Comments](#)

[eCRF Audit Trail History](#)

**Electronic Sample Tracking**

1.	Data Origin	Not Applicable _____	<a href="#">Comments</a>
2.	Sample Type	Not Applicable _____	<a href="#">Comments</a>
3.	Sample Collected?	Not Applicable _____	<a href="#">Comments</a>
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	Not Applicable [ ]	<a href="#">Comments</a>

**Aliquot**

Please enter barcode for each aliquot.

5.a	Sample ID	[ ]
5.b	Sample ID	[ ]
5.c	Sample ID	[ ]
5.d	Sample ID	[ ]
5.e	Sample ID	[ ]

090177e196d8902a\Final\Final On: 22-Apr-2021 02:13 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_CONVA 2 - Unscheduled  
Visit on Jan/21/2021

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

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

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

**Site No:** 1117

**Site Name:** (1117) Sundance Clinical Research

**Subject No:** 11171121

**Subject Initials:** ---

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

**Generated Time (GMT):** 21-Apr-2021 18:02

[eCRF Audit Trail History](#)

**Date of Visit**

1.	Date of Visit	Jan/21/2021
2.	Erroneous Visit	

**COVID-19 Illness Visit**

3.	COVID-19 Illness Visit:	COVID_A1
----	-------------------------	----------

**Header Text:** c4591001

**Visit:** POT\_COVID\_CONVA 2 - Unscheduled  
Visit on Jan/21/2021

**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

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

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

**Site No:** 1117

**Site Name:** (1117) Sundance Clinical Research

**Subject No:** 11171121

**Subject Initials:** ---

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

**Generated Time (GMT):** 21-Apr-2021 18:02

[eCRF Audit Trail History](#)

**Electronic Sample Tracking**

1.	Data Origin	SITE
2.	Sample Type	SERUM
3.	Sample Collected?	YES Date of Collection: Jan/21/2021
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[ ]

**Aliquot**

Please enter barcode for each aliquot.

5.a	Sample ID	[BRSRJK]
5.b	Sample ID	[BRSR JL]
5.c	Sample ID	[BP5907]
5.d	Sample ID	[BP5908]
5.e	Sample ID	[BP5909]

090177e196d8902a\Final\Final On: 22-Apr-2021 02:13 (GMT)



**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:** 1117

**Site Name:** (1117) Sundance Clinical Research

**Subject No:** 11171121

**Subject Initials:** ---

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

**Generated Time (GMT):** 21-Apr-2021 18:02

**Date of Visit**

1.	Date of Visit	//
2.	Erroneous Visit	

**COVID-19 Repeat Swab**

3.	COVID-19 Repeat Swab:	
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**Header Text:** c4591001

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

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

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

**Form Status:** Not Started

**Site No:** 1117

**Site Name:** (1117) Sundance Clinical Research

**Subject No:** 11171121

**Subject Initials:** ---

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

**Generated Time (GMT):** 21-Apr-2021 18:02

**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:** Unplanned - New Unscheduled Visit

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

**Site No:** 1117

**Subject No:** 11171121

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

**Form:** DATE OF VISIT

**Form Status:** Not Started

**Site Name:** (1117) Sundance Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 21-Apr-2021 18:02

**Date of Visit**

1.	Date of Visit	//
2.	Erroneous Visit	

**Header Text:** c4591001

**Visit:** Unplanned - New Unscheduled Visit

**Form:** UNPLANNED VISIT

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

**Form Status:** Not Started

**Site No:** 1117

**Site Name:** (1117) Sundance Clinical Research

**Subject No:** 11171121

**Subject Initials:** ---

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

**Generated Time (GMT):** 21-Apr-2021 18:02

**Unplanned Assessments**

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

**Header Text:** c4591001

**Visit:** Logs

**Form:** ADVERSE EVENT REPORT

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

**Site No:** 1117

**Site Name:** (1117) Sundance Clinical Research

**Subject No:** 11171121

**Subject Initials:** ---

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

**Generated Time (GMT):** 21-Apr-2021 18:02

#	Category	AE Identifier	Adverse Event	Start Date	Is the Adverse Event Still Ongoing	Form Instance
1.	ADVERSE EVENT	1	ANGIOEDEMA	Oct/31/2020 08:00	NO End Date Time:  Nov/3/2020 UNK:UNK	<a href="#">Repeating Pages</a>

090177e196d8902a\Final\Final On: 22-Apr-2021 02:13 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1117

Subject No: 11171121

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Locked, Frozen

Site Name: (1117) Sundance Clinical Research

Subject Initials: ---

Generated Time (GMT): 21-Apr-2021 18:02

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

**Adverse Event Report**

1.	Category:	ADVERSE EVENT
2.	AE ID:	[1]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[ANGIOEDEMA]
4.	Start Date Time:	Oct/31/2020 08:00
5.	Is the adverse event still ongoing?	NO End Date Time: Nov/3/2020 UNK:UNK
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:	NOT RELATED If Not Related to study treatment(s), this event is due to: OTHER If Other, specify: [CONMED REACTION, LISINOPRIL]
10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE
11.	Was a Concomitant Medication given?	YES

090177e196d8902a\Final\Final On: 22-Apr-2021 02:13 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1117

**Subject No:** 11171121

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

**Form:** ADVERSE EVENT REPORT

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

**Site Name:** (1117) Sundance Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 21-Apr-2021 18:02

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	[ ]

**Header Text:** c4591001

**Visit:** Logs

**Form:** MEDICATION ERROR

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

**Site No:** 1117

**Site Name:** (1117) Sundance Clinical Research

**Subject No:** 11171121

**Subject Initials:** ---

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

**Generated Time (GMT):** 21-Apr-2021 18:02

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



**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1117

**Subject No:** 11171121

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

**Form:** MEDICATION ERROR

**Form Status:** Not Started

**Site Name:** (1117) Sundance Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 21-Apr-2021 18:02

[Back to Form](#)

**Medication Error**

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

090177e196d8902a\Final\Final On: 22-Apr-2021 02:13 (GMT)

Header Text: c4591001

Visit: Logs

Form: CONCOMITANT MEDICATIONS - NON STUDY VACCINATIONS

Form Version: 22-Apr-2020 21:03

Site No: 1117

Site Name: (1117) Sundance Clinical Research

Subject No: 11171121

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 21-Apr-2021 18:02

#	Sponsor-Defined Identifier	Category for Medication	Concomitant Medications Pre-specified	Name of Medication	Start Date	Form Instance
1.	1	VACCINATIONS	NO	FLU VACCINE	Sep/1/2020	<a href="#">Repeating Pages</a>

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1117

**Subject No:** 11171121

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

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

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

**Site Name:** (1117) Sundance Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 21-Apr-2021 18:02

[Back to Form](#)

[eCRF Audit Trail History](#)

[Form Audit Trail](#)

**Concomitant Medications**

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

090177e196d8902a\Final\Final On: 22-Apr-2021 02:13 (GMT)

**Header Text:** c4591001

**Visit:** Logs

**Form:** CONCOMITANT MEDICATIONS - PROHIBITED

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

**Site No:** 1117

**Site Name:** (1117) Sundance Clinical Research

**Subject No:** 11171121

**Subject Initials:** ---

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

**Generated Time (GMT):** 21-Apr-2021 18:02

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

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1117

**Subject No:** 11171121

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

**Form:** CONCOMITANT MEDICATIONS - PROHIBITED

**Form Status:** Not Started

**Site Name:** (1117) Sundance Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 21-Apr-2021 18:02

[Back to Form](#)

**Concomitant Medications**

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

090177e196d8902a\Final\Final On: 22-Apr-2021 02:13 (GMT)

**Header Text:** c4591001

**Visit:** Logs

**Form:** RADIATION TREATMENT

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

**Site No:** 1117

**Site Name:** (1117) Sundance Clinical Research

**Subject No:** 11171121

**Subject Initials:** ---

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

**Generated Time (GMT):** 21-Apr-2021 18:02

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

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1117

**Subject No:** 11171121

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

**Form:** RADIATION TREATMENT

**Form Status:** Not Started

**Site Name:** (1117) Sundance Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 21-Apr-2021 18:02

[Back to Form](#)

**Radiation Treatment**

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

**Header Text:** c4591001

**Visit:** Logs

**Form:** TRANSFUSIONS

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

**Site No:** 1117

**Site Name:** (1117) Sundance Clinical Research

**Subject No:** 11171121

**Subject Initials:** ---

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

**Generated Time (GMT):** 21-Apr-2021 18:02

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



**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1117

**Subject No:** 11171121

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

**Form:** TRANSFUSIONS

**Form Status:** Not Started

**Site Name:** (1117) Sundance Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 21-Apr-2021 18:02

[Back to Form](#)

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

**Header Text:** c4591001

**Visit:** End of Treatment - Unscheduled

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

**Site No:** 1117

**Subject No:** 11171121

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

**Form:** DISPOSITION - TREATMENT

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

**Site Name:** (1117) Sundance Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 21-Apr-2021 18:02

[eCRF Audit Trail History](#)

**Disposition - Treatment**

1.	Date of Completion/Discontinuation /Death :	Nov/5/2020
2.	Phase of Disposition:	VACCINATION
3.	Status:	COMPLETED
4.	Specify Status:	[ ]

**Header Text:** c4591001

**Visit:** Unplanned Vaccination - Unscheduled

**Form:** DATE OF VISIT

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

**Form Status:** Not Started

**Site No:** 1117

**Site Name:** (1117) Sundance Clinical Research

**Subject No:** 11171121

**Subject Initials:** ---

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

**Generated Time (GMT):** 21-Apr-2021 18:02

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

**Header Text:** c4591001

**Visit:** Unplanned Vaccination - Unscheduled

**Form:** VITAL SIGNS - TEMP

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

**Form Status:** Not Started

**Site No:** 1117

**Site Name:** (1117) Sundance Clinical Research

**Subject No:** 11171121

**Subject Initials:** ---

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

**Generated Time (GMT):** 21-Apr-2021 18:02

**Vital Signs**

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

**Vital Signs Details**

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

**Header Text:** c4591001

**Visit:** Unplanned Vaccination - Unscheduled

**Form:** LAB URINALYSIS - PREGNANCY TEST

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

**Form Status:** Not Started

**Site No:** 1117

**Site Name:** (1117) Sundance Clinical Research

**Subject No:** 11171121

**Subject Initials:** ---

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

**Generated Time (GMT):** 21-Apr-2021 18:02

**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:	

090177e196d8902a\Final\Final On: 22-Apr-2021 02:13 (GMT)

**Header Text:** c4591001

**Visit:** Unplanned Vaccination - Unscheduled

**Form:** VACCINATION

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

**Form Status:** Not Started

**Site No:** 1117

**Site Name:** (1117) Sundance Clinical Research

**Subject No:** 11171121

**Subject Initials:** ---

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

**Generated Time (GMT):** 21-Apr-2021 18:02

**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?	

090177e196d8902a\Final\Final On: 22-Apr-2021 02:13 (GMT)

**Header Text:** c4591001

**Visit:** Unplanned Vaccination - Unscheduled

**Form:** CONTACT OUTCOME - MONTH 1

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

**Form Status:** Not Started

**Site No:** 1117

**Site Name:** (1117) Sundance Clinical Research

**Subject No:** 11171121

**Subject Initials:** ---

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

**Generated Time (GMT):** 21-Apr-2021 18:02

**Contact Outcome**

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

**Header Text:** c4591001

**Visit:** Unplanned Vaccination - Unscheduled

**Form:** CONTACT OUTCOME - MONTH 6

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

**Form Status:** Not Started

**Site No:** 1117

**Site Name:** (1117) Sundance Clinical Research

**Subject No:** 11171121

**Subject Initials:** ---

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

**Generated Time (GMT):** 21-Apr-2021 18:02

**Contact Outcome**

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



**Header Text:** c4591001

**Visit:** Follow-Up - Unscheduled

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

**Site No:** 1117

**Subject No:** 11171121

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

**Form:** DISPOSITION - FOLLOW-UP

**Form Status:** Not Started

**Site Name:** (1117) Sundance Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 21-Apr-2021 18:02

**Disposition - Follow-Up**

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

**Header Text:** c4591001

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

**Form:** DATE OF VISIT

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

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

**Site No:** 1117

**Site Name:** (1117) Sundance Clinical Research

**Subject No:** 11171121

**Subject Initials:** ---

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

**Generated Time (GMT):** 21-Apr-2021 18:02

[eCRF Audit Trail History](#)

**Date of Visit**

1.	Date of Visit	Jan/7/2021
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, Verified

**Site No:** 1117

**Site Name:** (1117) Sundance Clinical Research

**Subject No:** 11171121

**Subject Initials:** ---

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

**Generated Time (GMT):** 21-Apr-2021 18:02

[eCRF Audit Trail History](#)

**Further Vaccination Confirmation**

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

**Header Text:** c4591001

**Visit:** Disposition - Unscheduled

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

**Site No:** 1117

**Subject No:** 11171121

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

**Form:** TREATMENT UNBLINDED

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

**Site Name:** (1117) Sundance Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 21-Apr-2021 18:02

[eCRF Audit Trail History](#)

**Treatment Unblinded**

1.	Date Treatment Unblinded :	Jan/11/2021
2.	Primary Reason for Unblinding:	ASSESS ELIGIBILITY FOR ADDITIONAL VACCINATION

**Header Text:** c4591001

**Visit:** Disposition - Unscheduled

**Form:** WITHDRAWAL OF CONSENT

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

**Form Status:** Not Started

**Site No:** 1117

**Site Name:** (1117) Sundance Clinical Research

**Subject No:** 11171121

**Subject Initials:** ---

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

**Generated Time (GMT):** 21-Apr-2021 18:02

**Withdrawal Of Consent**

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

**Header Text:** c4591001

**Visit:** Disposition - Unscheduled

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

**Site No:** 1117

**Subject No:** 11171121

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

**Form:** DEATH DETAILS CODED

**Form Status:** Not Started

**Site Name:** (1117) Sundance Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 21-Apr-2021 18:02

**Death Details**

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

**Cause of Death**

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

**Header Text:** c4591001

**Visit:** V101\_VAX3

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

**Site No:** 1117

**Subject No:** 11171121

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

**Form:** DATE OF VISIT

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

**Site Name:** (1117) Sundance Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 21-Apr-2021 18:02

[eCRF Audit Trail History](#)

**Date of Visit**

1.	Date of Visit	Jan/18/2021
2.	Erroneous Visit	

**Header Text:** c4591001

**Visit:** V101\_VAX3

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

**Site No:** 1117

**Subject No:** 11171121

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

**Form:** INFORMED CONSENT - FURTHER VACCINATION

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

**Site Name:** (1117) Sundance Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 21-Apr-2021 18:02

[eCRF Audit Trail History](#)

**Informed Consent - Further Vaccination**

1.	Consent Was:	OBTAINED Date Written Consent Obtained Jan/18/2021
----	--------------	--



**Header Text:** c4591001

**Visit:** V101\_VAX3

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

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

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

**Site No:** 1117

**Site Name:** (1117) Sundance Clinical Research

**Subject No:** 11171121

**Subject Initials:** ---

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

**Generated Time (GMT):** 21-Apr-2021 18:02

[Form Comments](#)

**Inclusion Criteria Not Met**

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

**Exclusion Criteria Met**

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

**Header Text:** c4591001

**Visit:** V101\_VAX3

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

**Site No:** 1117

**Subject No:** 11171121

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

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

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

**Site Name:** (1117) Sundance Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 21-Apr-2021 18:02

[eCRF Audit Trail History](#)

**Disposition - Screening for Further Vaccination**

1.	Date of Completion/Discontinuation /Death :	Jan/18/2021
2.	Phase of Disposition:	REPEAT SCREENING 1
3.	Status:	COMPLETED
4.	Specify Status:	[ ]

**Header Text:** c4591001

**Visit:** V101\_VAX3

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

**Site No:** 1117

**Subject No:** 11171121

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

**Form:** LAB URINALYSIS - PREGNANCY TEST

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

**Site Name:** (1117) Sundance Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 21-Apr-2021 18:02

[eCRF Audit Trail History](#)

**Lab Urinalysis**

1.	Lab Panel:	URINALYSIS
2.	Lab Sub-Panel:	PREGNANCY
3.	Collection Date:	Jan/18/2021
4.	Laboratory Name and Address (Derived)	[STUDY SITE]
5.	Specimen Type:	URINE

**Lab Result**

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

090177e196d8902a\Final\Final On: 22-Apr-2021 02:13 (GMT)

**Header Text:** c4591001

**Visit:** V101\_VAX3

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

**Site No:** 1117

**Subject No:** 11171121

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

**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

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

**Site Name:** (1117) Sundance Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 21-Apr-2021 18:02

[eCRF Audit Trail History](#)

**Electronic Sample Tracking**

1.	Data Origin	SITE
2.	Sample Type	SERUM
3.	Sample Collected?	YES Date of Collection: Jan/18/2021
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[ ]

**Aliquot**

Please enter barcode for each aliquot.

5.a	Sample ID	[BRSRH9]
5.b	Sample ID	[BRSRHB]
5.c	Sample ID	[BRDFTS]
5.d	Sample ID	[BRDFTT]
5.e	Sample ID	[BRDFTV]

090177e196d8902a\Final\Final On: 22-Apr-2021 02:13 (GMT)

**Header Text:** c4591001

**Visit:** V101\_VAX3

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

**Site No:** 1117

**Subject No:** 11171121

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

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

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

**Site Name:** (1117) Sundance Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 21-Apr-2021 18:02

[eCRF Audit Trail History](#)

**Electronic Sample Tracking**

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Jan/18/2021
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[ ]

**Aliquot**

Please enter barcode for each aliquot.

5.a	Sample ID	[BP58ZT]
-----	-----------	----------

090177e196d8902a\Final\Final On: 22-Apr-2021 02:13 (GMT)

**Header Text:** c4591001

**Visit:** V101\_VAX3

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

**Site No:** 1117

**Subject No:** 11171121

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

**Form:** VACCINATION

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

**Site Name:** (1117) Sundance Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 21-Apr-2021 18:02

[eCRF Audit Trail History](#)

**Vaccination**

1.	Was there a temporary delay of vaccination?	NO
2.	Treatment Name	[BNT162b2]
3.	Formulation:	INJECTION
4.	Dose Date Time:	Jan/18/2021 09:58
5.	Anatomical Location:	DELTOID MUSCLE
6.	Body Side:	LEFT
7.	Route:	INTRAMUSCULAR
8.	Actual Dose:	[30.0]
9.	Unit:	ug
10.	Timeframe Subject Was Observed	30 MINUTES
11.	Was the subject observed for at least the protocol specified observation period after investigational product administration?	YES

090177e196d8902a\Final\Final On: 22-Apr-2021 02:13 (GMT)

**Header Text:** c4591001

**Visit:** V102\_VAX4

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

**Site No:** 1117

**Subject No:** 11171121

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

**Form:** DATE OF VISIT

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

**Site Name:** (1117) Sundance Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 21-Apr-2021 18:02

[eCRF Audit Trail History](#)

**Date of Visit**

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

**Header Text:** c4591001

**Visit:** V102\_VAX4

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

**Site No:** 1117

**Subject No:** 11171121

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

**Form:** LAB URINALYSIS - PREGNANCY TEST

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

**Site Name:** (1117) Sundance Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 21-Apr-2021 18:02

[eCRF Audit Trail History](#)

**Lab Urinalysis**

1.	Lab Panel:	URINALYSIS
2.	Lab Sub-Panel:	PREGNANCY
3.	Collection Date:	Feb/8/2021
4.	Laboratory Name and Address (Derived)	[STUDY SITE]
5.	Specimen Type:	URINE

**Lab Result**

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

090177e196d8902a\Final\Final On: 22-Apr-2021 02:13 (GMT)



**Header Text:** c4591001

**Visit:** V102\_VAX4

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

**Site No:** 1117

**Subject No:** 11171121

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

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

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

**Site Name:** (1117) Sundance Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 21-Apr-2021 18:02

[eCRF Audit Trail History](#)

**Electronic Sample Tracking**

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Feb/8/2021
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[ ]

**Aliquot**

Please enter barcode for each aliquot.

5.a	Sample ID	[BR6RV0]
-----	-----------	----------

090177e196d8902a\Final\Final On: 22-Apr-2021 02:13 (GMT)

**Header Text:** c4591001

**Visit:** V102\_VAX4

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

**Site No:** 1117

**Subject No:** 11171121

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

**Form:** VACCINATION

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

**Site Name:** (1117) Sundance Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 21-Apr-2021 18:02

[eCRF Audit Trail History](#)

**Vaccination**

1.	Was there a temporary delay of vaccination?	NO
2.	Treatment Name	[BNT162b2]
3.	Formulation:	INJECTION
4.	Dose Date Time:	Feb/8/2021 09:43
5.	Anatomical Location:	DELTOID MUSCLE
6.	Body Side:	LEFT
7.	Route:	INTRAMUSCULAR
8.	Actual Dose:	[30.0]
9.	Unit:	ug
10.	Timeframe Subject Was Observed	30 MINUTES
11.	Was the subject observed for at least the protocol specified observation period after investigational product administration?	YES

090177e196d8902a\Final\Final On: 22-Apr-2021 02:13 (GMT)

**Header Text:** c4591001

**Visit:** V103\_MONTH1

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

**Site No:** 1117

**Subject No:** 11171121

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

**Form:** DATE OF VISIT

**Form Status:** Not Started

**Site Name:** (1117) Sundance Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 21-Apr-2021 18:02

**Date of Visit**

1.	Date of Visit	//
2.	Erroneous Visit	

**Header Text:** c4591001

**Visit:** V103\_MONTH1

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

**Site No:** 1117

**Subject No:** 11171121

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

**Form:** CONTACT OUTCOME

**Form Status:** Not Started

**Site Name:** (1117) Sundance Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 21-Apr-2021 18:02

**Contact Outcome**

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

**Header Text:** c4591001

**Visit:** V104\_MONTH6

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

**Site No:** 1117

**Subject No:** 11171121

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

**Form:** DATE OF VISIT

**Form Status:** Not Started

**Site Name:** (1117) Sundance Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 21-Apr-2021 18:02

**Date of Visit**

1.	Date of Visit	//
2.	Erroneous Visit	

**Header Text:** c4591001

**Visit:** V104\_MONTH6

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

**Site No:** 1117

**Subject No:** 11171121

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

**Form:** CONTACT OUTCOME

**Form Status:** Not Started

**Site Name:** (1117) Sundance Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 21-Apr-2021 18:02

**Contact Outcome**

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

**Header Text:** c4591001

**Visit:** V105\_MONTH18

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

**Site No:** 1117

**Subject No:** 11171121

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

**Form:** DATE OF VISIT

**Form Status:** Not Started

**Site Name:** (1117) Sundance Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 21-Apr-2021 18:02

**Date of Visit**

1.	Date of Visit	//
2.	Erroneous Visit	

**Header Text:** c4591001

**Visit:** V105\_MONTH18

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

**Site No:** 1117

**Subject No:** 11171121

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

**Form:** CONTACT OUTCOME

**Form Status:** Not Started

**Site Name:** (1117) Sundance Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 21-Apr-2021 18:02

**Contact Outcome**

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



**Header Text:** c4591001

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

**Form:** DISPOSITION - TREATMENT

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

**Form Status:** Not Started

**Site No:** 1117

**Site Name:** (1117) Sundance Clinical Research

**Subject No:** 11171121

**Subject Initials:** ---

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

**Generated Time (GMT):** 21-Apr-2021 18:02

**Disposition - Treatment**

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

**Header Text:** c4591001

**Visit:** Subject Status - Unscheduled

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

**Site No:** 1117

**Subject No:** 11171121

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

**Form:** SUBJECT STATUS

**Form Status:** Data Complete, Verified

**Site Name:** (1117) Sundance Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 21-Apr-2021 18:02

[eCRF Audit Trail History](#)

**Subject Status**

1.	Subject Status	FOLLOW-UP
2.	Subject Status Date	Nov/5/2020

**Header Text:** c4591001

**Visit:** Investigator Signature - Unscheduled

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

**Site No:** 1117

**Subject No:** 11171121

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

**Form:** CASEBOOK SIGNATURE FORM

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

**Site Name:** (1117) Sundance Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 21-Apr-2021 18:02

[eCRF Audit Trail History](#)

**Casebook Signature Form**

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

**Header Text:** c4591001

**Visit:** Investigator Signature - Unscheduled

**Form:** CASEBOOK SIGNATURE FORM

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

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

**Site No:** 1117

**Site Name:** (1117) Sundance Clinical Research

**Subject No:** 11171121

**Subject Initials:** ---

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

**Generated Time (GMT):** 21-Apr-2021 18:02

[Audit Trail](#)

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

- CRF\_Sign

Name	Signature Meaning	Date	Type	Action
(b) (6)	Approved	Mar-10-2021 11:53:32 (UTC-06:00) Central Time (US & Canada)	BOOK	Signed

**Affidavit:**

By my dated signature below, I, (b) (6) verify that all case report form pages accurately display the results of the examinations, tests, evaluations and treatments performed on this subject.

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

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

090177e196d8902a\Final\Final On: 22-Apr-2021 02:13 (GMT)

**Header Text:** c4591001

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

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

**Site No:** 1117

**Subject No:** 11171121

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

**Form:** DATE OF VISIT - Comments

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

**Site Name:** (1117) Sundance Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 21-Apr-2021 18:02

[Back to Form](#)

Item	Date	User	Comment
2	Sep-18-2020 12:53:55 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

**Header Text:** c4591001

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

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

**Site No:** 1117

**Subject No:** 11171121

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

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

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

**Site Name:** (1117) Sundance Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 21-Apr-2021 18:02

[Back to Form](#)

Item	Date	User	Comment
Form	Sep-18-2020 12:54:23 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

**Header Text:** c4591001

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

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

**Site No:** 1117

**Subject No:** 11171121

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

**Form:** DISPOSITION - SCREENING - Comments

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

**Site Name:** (1117) Sundance Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 21-Apr-2021 18:02

[Back to Form](#)

Item	Date	User	Comment
4	Sep-18-2020 12:54:52 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

**Header Text:** c4591001

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

**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY -  
Comments

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

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

**Site No:** 1117

**Site Name:** (1117) Sundance Clinical Research

**Subject No:** 11171121

**Subject Initials:** ---

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

**Generated Time (GMT):** 21-Apr-2021 18:02

[Back to Form](#)

Item	Date	User	Comment
4	Sep-21-2020 12:25:51 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Applicable



**Header Text:** c4591001

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

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

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

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

**Site No:** 1117

**Site Name:** (1117) Sundance Clinical Research

**Subject No:** 11171121

**Subject Initials:** ---

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

**Generated Time (GMT):** 21-Apr-2021 18:02

[Back to Form](#)

Item	Date	User	Comment
4	Sep-21-2020 12:43:05 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

**Header Text:** c4591001

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

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

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

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

**Site No:** 1117

**Site Name:** (1117) Sundance Clinical Research

**Subject No:** 11171121

**Subject Initials:** ---

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

**Generated Time (GMT):** 21-Apr-2021 18:02

[Back to Form](#)

Item	Date	User	Comment
3	Nov-25-2020 11:05:58 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	TELEHEALTH VISIT, SEE SELF SWAB

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on **Form:** RESPIRATORY TREATMENT - Comments  
Nov/23/2020

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

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

**Site No:** 1117

**Site Name:** (1117) Sundance Clinical Research

**Subject No:** 11171121

**Subject Initials:** ---

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

**Generated Time (GMT):** 21-Apr-2021 18:02

[Back to Form](#)

Item	Date	User	Comment
Form	Nov-25-2020 11:06:56 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Done

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on **Form:** RESPIRATORY TREATMENT - Comments  
Nov/23/2020

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

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

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**Site Name:** (1117) Sundance Clinical Research

**Subject No:** 11171121

**Subject Initials:** ---

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

**Generated Time (GMT):** 21-Apr-2021 18:02

[Back to Form](#)

Item	Date	User	Comment
1	Nov-25-2020 11:06:56 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Done

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on **Form:** RESPIRATORY TREATMENT - Comments  
Nov/23/2020

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

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

**Site No:** 1117

**Site Name:** (1117) Sundance Clinical Research

**Subject No:** 11171121

**Subject Initials:** ---

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

**Generated Time (GMT):** 21-Apr-2021 18:02

[Back to Form](#)

Item	Date	User	Comment
2	Nov-25-2020 11:06:56 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Done

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on **Form:** RESPIRATORY TREATMENT - Comments  
Nov/23/2020

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

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

**Site No:** 1117

**Site Name:** (1117) Sundance Clinical Research

**Subject No:** 11171121

**Subject Initials:** ---

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

**Generated Time (GMT):** 21-Apr-2021 18:02

[Back to Form](#)

Item	Date	User	Comment
3	Nov-25-2020 11:06:56 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Done

**Header Text:** c4591001

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Nov/23/2020

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

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

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**Subject Initials:** ---

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**Generated Time (GMT):** 21-Apr-2021 18:02

[Back to Form](#)

Item	Date	User	Comment
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**Header Text:** c4591001

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Nov/23/2020

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

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**Site Name:** (1117) Sundance Clinical Research

**Subject No:** 11171121

**Subject Initials:** ---

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

**Generated Time (GMT):** 21-Apr-2021 18:02

[Back to Form](#)

Item	Date	User	Comment
5	Nov-25-2020 11:06:56 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Done



**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on **Form:** RESPIRATORY TREATMENT - Comments  
Nov/23/2020

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

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

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**Site Name:** (1117) Sundance Clinical Research

**Subject No:** 11171121

**Subject Initials:** ---

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

**Generated Time (GMT):** 21-Apr-2021 18:02

[Back to Form](#)

Item	Date	User	Comment
6	Nov-25-2020 11:06:56 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Done

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on **Form:** ILLNESS DETAILS - SEVERE - Comments  
Nov/23/2020

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

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

**Site No:** 1117

**Site Name:** (1117) Sundance Clinical Research

**Subject No:** 11171121

**Subject Initials:** ---

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

**Generated Time (GMT):** 21-Apr-2021 18:02

[Back to Form](#)

Item	Date	User	Comment
Form	Nov-25-2020 11:08:23 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Done

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on **Form:** ILLNESS DETAILS - SEVERE - Comments  
Nov/23/2020

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

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

**Site No:** 1117

**Site Name:** (1117) Sundance Clinical Research

**Subject No:** 11171121

**Subject Initials:** ---

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

**Generated Time (GMT):** 21-Apr-2021 18:02

[Back to Form](#)

Item	Date	User	Comment
1	Nov-25-2020 11:08:23 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Done
1	Nov-25-2020 11:08:11 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	
1	Nov-25-2020 11:07:52 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Done

**Header Text:** c4591001

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Nov/23/2020

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

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

**Site No:** 1117

**Site Name:** (1117) Sundance Clinical Research

**Subject No:** 11171121

**Subject Initials:** ---

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

**Generated Time (GMT):** 21-Apr-2021 18:02

[Back to Form](#)

Item	Date	User	Comment
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**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on **Form:** ILLNESS DETAILS - SEVERE - Comments  
Nov/23/2020

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

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

**Site No:** 1117

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**Generated Time (GMT):** 21-Apr-2021 18:02

[Back to Form](#)

Item	Date	User	Comment
3	Nov-25-2020 11:08:23 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Done

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on **Form:** ILLNESS DETAILS - SEVERE - Comments  
Nov/23/2020

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

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**Site Name:** (1117) Sundance Clinical Research

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

**Generated Time (GMT):** 21-Apr-2021 18:02

[Back to Form](#)

Item	Date	User	Comment
4	Nov-25-2020 11:08:23 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Done

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/23/2020 **Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY - Comments

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

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

**Site No:** 1117

**Site Name:** (1117) Sundance Clinical Research

**Subject No:** 11171121

**Subject Initials:** ---

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

**Generated Time (GMT):** 21-Apr-2021 18:02

[Back to Form](#)

Item	Date	User	Comment
Form	Nov-25-2020 11:08:41 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Done

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/23/2020 **Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY - Comments

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

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

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**Site Name:** (1117) Sundance Clinical Research

**Subject No:** 11171121

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**Generated Time (GMT):** 21-Apr-2021 18:02

[Back to Form](#)

Item	Date	User	Comment
1	Nov-25-2020 11:08:41 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Done



**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/23/2020 **Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY - Comments

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

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**Generated Time (GMT):** 21-Apr-2021 18:02

[Back to Form](#)

Item	Date	User	Comment
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[Back to Form](#)

Item	Date	User	Comment
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**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/23/2020 **Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY - Comments

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

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**Generated Time (GMT):** 21-Apr-2021 18:02

[Back to Form](#)

Item	Date	User	Comment
4	Nov-25-2020 11:08:41 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Done

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/23/2020 **Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY - Comments

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

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**Site No:** 1117

**Site Name:** (1117) Sundance Clinical Research

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**Generated Time (GMT):** 21-Apr-2021 18:02

[Back to Form](#)

Item	Date	User	Comment
5.a	Nov-25-2020 11:08:41 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Done

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/23/2020 **Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY - Comments

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

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

**Site No:** 1117

**Site Name:** (1117) Sundance Clinical Research

**Subject No:** 11171121

**Subject Initials:** ---

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**Generated Time (GMT):** 21-Apr-2021 18:02

[Back to Form](#)

Item	Date	User	Comment
5.a	Nov-25-2020 11:08:41 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Done

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/23/2020 **Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY - Comments

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

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

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**Site Name:** (1117) Sundance Clinical Research

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**Generated Time (GMT):** 21-Apr-2021 18:02

[Back to Form](#)

Item	Date	User	Comment
5.a	Nov-25-2020 11:08:41 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Done

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/23/2020 **Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY - Comments

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

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**Site Name:** (1117) Sundance Clinical Research

**Subject No:** 11171121

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**Generated Time (GMT):** 21-Apr-2021 18:02

[Back to Form](#)

Item	Date	User	Comment
5.a	Nov-25-2020 11:08:41 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Done

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/23/2020 **Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY - Comments

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

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**Generated Time (GMT):** 21-Apr-2021 18:02

[Back to Form](#)

Item	Date	User	Comment
5.b	Nov-25-2020 11:08:41 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Done



**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/23/2020 **Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY - Comments

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

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**Generated Time (GMT):** 21-Apr-2021 18:02

[Back to Form](#)

Item	Date	User	Comment
5.b	Nov-25-2020 11:08:41 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Done

**Header Text:** c4591001

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

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

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**Site Name:** (1117) Sundance Clinical Research

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[Back to Form](#)

Item	Date	User	Comment
5.b	Nov-25-2020 11:08:41 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Done

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/23/2020 **Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY - Comments

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

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**Generated Time (GMT):** 21-Apr-2021 18:02

[Back to Form](#)

Item	Date	User	Comment
5.b	Nov-25-2020 11:08:41 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Done

**Header Text:** c4591001

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**Subject Initials:** ---

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**Generated Time (GMT):** 21-Apr-2021 18:02

[Back to Form](#)

Item	Date	User	Comment
5.c	Nov-25-2020 11:08:41 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Done

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/23/2020 **Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY - Comments

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

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

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**Site Name:** (1117) Sundance Clinical Research

**Subject No:** 11171121

**Subject Initials:** ---

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

**Generated Time (GMT):** 21-Apr-2021 18:02

[Back to Form](#)

Item	Date	User	Comment
5.c	Nov-25-2020 11:08:41 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Done

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/23/2020 **Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY - Comments

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

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**Site Name:** (1117) Sundance Clinical Research

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**Subject Initials:** ---

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**Generated Time (GMT):** 21-Apr-2021 18:02

[Back to Form](#)

Item	Date	User	Comment
5.c	Nov-25-2020 11:08:41 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Done

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/23/2020 **Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY - Comments

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

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

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**Site Name:** (1117) Sundance Clinical Research

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**Subject Initials:** ---

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**Generated Time (GMT):** 21-Apr-2021 18:02

[Back to Form](#)

Item	Date	User	Comment
5.c	Nov-25-2020 11:08:41 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Done

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/23/2020 **Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY - Comments

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**Site Name:** (1117) Sundance Clinical Research

**Subject No:** 11171121

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**Generated Time (GMT):** 21-Apr-2021 18:02

[Back to Form](#)

Item	Date	User	Comment
5.d	Nov-25-2020 11:08:41 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Done



**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/23/2020 **Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY - Comments

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

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**Subject No:** 11171121

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**Generated Time (GMT):** 21-Apr-2021 18:02

[Back to Form](#)

Item	Date	User	Comment
5.d	Nov-25-2020 11:08:41 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Done

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/23/2020 **Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY - Comments

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**Generated Time (GMT):** 21-Apr-2021 18:02

[Back to Form](#)

Item	Date	User	Comment
5.d	Nov-25-2020 11:08:41 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Done

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/23/2020 **Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY - Comments

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**Generated Time (GMT):** 21-Apr-2021 18:02

[Back to Form](#)

Item	Date	User	Comment
5.d	Nov-25-2020 11:08:41 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Done

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/23/2020 **Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY - Comments

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

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**Subject Initials:** ---

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

**Generated Time (GMT):** 21-Apr-2021 18:02

[Back to Form](#)

Item	Date	User	Comment
5.e	Nov-25-2020 11:08:41 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Done

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/23/2020 **Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY - Comments

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

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

**Site No:** 1117

**Site Name:** (1117) Sundance Clinical Research

**Subject No:** 11171121

**Subject Initials:** ---

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

**Generated Time (GMT):** 21-Apr-2021 18:02

[Back to Form](#)

Item	Date	User	Comment
5.e	Nov-25-2020 11:08:41 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Done

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/23/2020 **Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY - Comments

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**Generated Time (GMT):** 21-Apr-2021 18:02

[Back to Form](#)

Item	Date	User	Comment
5.e	Nov-25-2020 11:08:41 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Done

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**Generated Time (GMT):** 21-Apr-2021 18:02

[Back to Form](#)

Item	Date	User	Comment
5.e	Nov-25-2020 11:08:41 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Done

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/23/2020 **Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY - Comments

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

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

**Site No:** 1117

**Site Name:** (1117) Sundance Clinical Research

**Subject No:** 11171121

**Subject Initials:** ---

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

**Generated Time (GMT):** 21-Apr-2021 18:02

[Back to Form](#)

Item	Date	User	Comment
5 f	Nov-25-2020 11:08:41 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Done



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**Generated Time (GMT):** 21-Apr-2021 18:02

[Back to Form](#)

Item	Date	User	Comment
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[Back to Form](#)

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[Back to Form](#)

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[Back to Form](#)

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[Back to Form](#)

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[Back to Form](#)

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[Back to Form](#)

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**Generated Time (GMT):** 21-Apr-2021 18:02

[Back to Form](#)

Item	Date	User	Comment
Form	Nov-25-2020 11:08:58 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Done



**Header Text:** c4591001

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**Subject No:** 11171121

**Subject Initials:** ---

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**Generated Time (GMT):** 21-Apr-2021 18:02

[Back to Form](#)

Item	Date	User	Comment
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**Subject No:** 11171121

**Subject Initials:** ---

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**Generated Time (GMT):** 21-Apr-2021 18:02

[Back to Form](#)

Item	Date	User	Comment
2	Nov-25-2020 11:08:58 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Done

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**Subject No:** 11171121

**Subject Initials:** ---

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**Generated Time (GMT):** 21-Apr-2021 18:02

[Back to Form](#)

Item	Date	User	Comment
3	Nov-25-2020 11:08:58 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Done

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**Subject No:** 11171121

**Subject Initials:** ---

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**Generated Time (GMT):** 21-Apr-2021 18:02

[Back to Form](#)

Item	Date	User	Comment
4	Nov-25-2020 11:08:58 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Done

**Header Text:** c4591001

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[Back to Form](#)

Item	Date	User	Comment
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[Back to Form](#)

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[Back to Form](#)

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[Back to Form](#)

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[Back to Form](#)

Item	Date	User	Comment
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[Back to Form](#)

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[Back to Form](#)

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**Generated Time (GMT):** 21-Apr-2021 18:02

[Back to Form](#)

Item	Date	User	Comment
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**Subject Initials:** ---

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

**Generated Time (GMT):** 21-Apr-2021 18:02

[Back to Form](#)

Item	Date	User	Comment
5.c	Nov-25-2020 11:08:58 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Done

**Header Text:** c4591001

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**Site Name:** (1117) Sundance Clinical Research

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**Subject Initials:** ---

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**Generated Time (GMT):** 21-Apr-2021 18:02

[Back to Form](#)

Item	Date	User	Comment
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**Generated Time (GMT):** 21-Apr-2021 18:02

[Back to Form](#)

Item	Date	User	Comment
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**Generated Time (GMT):** 21-Apr-2021 18:02

[Back to Form](#)

Item	Date	User	Comment
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**Subject Initials:** ---

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

**Generated Time (GMT):** 21-Apr-2021 18:02

[Back to Form](#)

Item	Date	User	Comment
5.d	Nov-25-2020 11:08:58 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Done

**Header Text:** c4591001

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**Subject Initials:** ---

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**Generated Time (GMT):** 21-Apr-2021 18:02

[Back to Form](#)

Item	Date	User	Comment
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[Back to Form](#)

Item	Date	User	Comment
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[Back to Form](#)

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[Back to Form](#)

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[Back to Form](#)

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[Back to Form](#)

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[Back to Form](#)

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[Back to Form](#)

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**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/23/2020 **Form:** LOCAL LABORATORY DATA - REPEATING Hematology - Comments

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

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

**Site No:** 1117

**Site Name:** (1117) Sundance Clinical Research

**Subject No:** 11171121

**Subject Initials:** ---

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

**Generated Time (GMT):** 21-Apr-2021 18:02

[Back to Form](#)

Item	Date	User	Comment
5.g	Nov-25-2020 11:08:58 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Done

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**Generated Time (GMT):** 21-Apr-2021 18:02

[Back to Form](#)

Item	Date	User	Comment
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**Generated Time (GMT):** 21-Apr-2021 18:02

[Back to Form](#)

Item	Date	User	Comment
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[Back to Form](#)

Item	Date	User	Comment
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[Back to Form](#)

Item	Date	User	Comment
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[Back to Form](#)

Item	Date	User	Comment
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[Back to Form](#)

Item	Date	User	Comment
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**Generated Time (GMT):** 21-Apr-2021 18:02

[Back to Form](#)

Item	Date	User	Comment
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[Back to Form](#)

Item	Date	User	Comment
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[Back to Form](#)

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[Back to Form](#)

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[Back to Form](#)

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[Back to Form](#)

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[Back to Form](#)

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[Back to Form](#)

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**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on **Form:** VITAL SIGNS - COVID - Comments  
Nov/23/2020

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

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**Site Name:** (1117) Sundance Clinical Research

**Subject No:** 11171121

**Subject Initials:** ---

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

**Generated Time (GMT):** 21-Apr-2021 18:02

[Back to Form](#)

Item	Date	User	Comment
Form	Nov-25-2020 11:09:15 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Done

**Header Text:** c4591001

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Nov/23/2020

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

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**Site Name:** (1117) Sundance Clinical Research

**Subject No:** 11171121

**Subject Initials:** ---

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**Generated Time (GMT):** 21-Apr-2021 18:02

[Back to Form](#)

Item	Date	User	Comment
1	Nov-25-2020 11:09:15 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Done

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Nov/23/2020

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**Subject Initials:** ---

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**Generated Time (GMT):** 21-Apr-2021 18:02

[Back to Form](#)

Item	Date	User	Comment
2.a	Nov-25-2020 11:09:15 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Done

**Header Text:** c4591001

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Nov/23/2020

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

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**Generated Time (GMT):** 21-Apr-2021 18:02

[Back to Form](#)

Item	Date	User	Comment
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Nov/23/2020

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[Back to Form](#)

Item	Date	User	Comment
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Nov/23/2020

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**Generated Time (GMT):** 21-Apr-2021 18:02

[Back to Form](#)

Item	Date	User	Comment
2.a	Nov-25-2020 11:09:15 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Done

**Header Text:** c4591001

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Nov/23/2020

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

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**Site Name:** (1117) Sundance Clinical Research

**Subject No:** 11171121

**Subject Initials:** ---

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

**Generated Time (GMT):** 21-Apr-2021 18:02

[Back to Form](#)

Item	Date	User	Comment
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Nov/23/2020

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

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**Site Name:** (1117) Sundance Clinical Research

**Subject No:** 11171121

**Subject Initials:** ---

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

**Generated Time (GMT):** 21-Apr-2021 18:02

[Back to Form](#)

Item	Date	User	Comment
1	Nov-25-2020 11:09:30 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Done

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Nov/23/2020

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

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**Site Name:** (1117) Sundance Clinical Research

**Subject No:** 11171121

**Subject Initials:** ---

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

**Generated Time (GMT):** 21-Apr-2021 18:02

[Back to Form](#)

Item	Date	User	Comment
2.a	Nov-25-2020 11:09:30 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Done

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on **Form:** OXYGENATION PARAMETERS - Comments  
Nov/23/2020

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

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**Site Name:** (1117) Sundance Clinical Research

**Subject No:** 11171121

**Subject Initials:** ---

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

**Generated Time (GMT):** 21-Apr-2021 18:02

[Back to Form](#)

Item	Date	User	Comment
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Nov/23/2020

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**Site Name:** (1117) Sundance Clinical Research

**Subject No:** 11171121

**Subject Initials:** ---

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

**Generated Time (GMT):** 21-Apr-2021 18:02

[Back to Form](#)

Item	Date	User	Comment
1	Nov-25-2020 11:09:45 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Done

**Header Text:** c4591001

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Nov/23/2020

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

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**Site Name:** (1117) Sundance Clinical Research

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**Subject Initials:** ---

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

**Generated Time (GMT):** 21-Apr-2021 18:02

[Back to Form](#)

Item	Date	User	Comment
2	Nov-25-2020 11:09:45 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Done



**Header Text:** c4591001

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Nov/23/2020

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

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**Site No:** 1117

**Site Name:** (1117) Sundance Clinical Research

**Subject No:** 11171121

**Subject Initials:** ---

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

**Generated Time (GMT):** 21-Apr-2021 18:02

[Back to Form](#)

Item	Date	User	Comment
3	Nov-25-2020 11:09:45 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Done

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on **Form:** CONCOMITANT MEDICATIONS - VASOPRESSORS - Comments  
Nov/23/2020

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

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

**Site No:** 1117

**Site Name:** (1117) Sundance Clinical Research

**Subject No:** 11171121

**Subject Initials:** ---

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

**Generated Time (GMT):** 21-Apr-2021 18:02

[Back to Form](#)

Item	Date	User	Comment
Form	Nov-25-2020 11:10:03 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Done

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on **Form:** CONCOMITANT MEDICATIONS - VASOPRESSORS - Comments  
Nov/23/2020

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

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

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**Site Name:** (1117) Sundance Clinical Research

**Subject No:** 11171121

**Subject Initials:** ---

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

**Generated Time (GMT):** 21-Apr-2021 18:02

[Back to Form](#)

Item	Date	User	Comment
1	Nov-25-2020 11:10:03 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Done

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Nov/23/2020

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

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

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**Site Name:** (1117) Sundance Clinical Research

**Subject No:** 11171121

**Subject Initials:** ---

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

**Generated Time (GMT):** 21-Apr-2021 18:02

[Back to Form](#)

Item	Date	User	Comment
2	Nov-25-2020 11:10:03 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Done

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on **Form:** CONCOMITANT MEDICATIONS - VASOPRESSORS - Comments  
Nov/23/2020

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

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**Generated Time (GMT):** 21-Apr-2021 18:02

[Back to Form](#)

Item	Date	User	Comment
3	Nov-25-2020 11:10:03 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Done

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Nov/23/2020

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**Subject Initials:** ---

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

**Generated Time (GMT):** 21-Apr-2021 18:02

[Back to Form](#)

Item	Date	User	Comment
4	Nov-25-2020 11:10:03 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Done

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on **Form:** CONCOMITANT MEDICATIONS - VASOPRESSORS - Comments  
Nov/23/2020

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**Subject No:** 11171121

**Subject Initials:** ---

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**Generated Time (GMT):** 21-Apr-2021 18:02

[Back to Form](#)

Item	Date	User	Comment
5	Nov-25-2020 11:10:03 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Done

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on **Form:** CONCOMITANT MEDICATIONS - VASOPRESSORS - Comments  
Nov/23/2020

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**Subject No:** 11171121

**Subject Initials:** ---

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

**Generated Time (GMT):** 21-Apr-2021 18:02

[Back to Form](#)

Item	Date	User	Comment
6	Nov-25-2020 11:10:03 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Done



**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on **Form:** IMAGING - Comments  
Nov/23/2020

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

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**Site Name:** (1117) Sundance Clinical Research

**Subject No:** 11171121

**Subject Initials:** ---

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

**Generated Time (GMT):** 21-Apr-2021 18:02

[Back to Form](#)

Item	Date	User	Comment
Form	Nov-25-2020 11:10:19 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Done

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Nov/23/2020

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

**Generated Time (GMT):** 21-Apr-2021 18:02

[Back to Form](#)

Item	Date	User	Comment
1	Nov-25-2020 11:10:19 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Done

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**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on **Form:** IMAGING - Comments  
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**Generated Time (GMT):** 21-Apr-2021 18:02

[Back to Form](#)

Item	Date	User	Comment
2	Nov-25-2020 11:10:19 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Done

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**Site No:** 1117

**Site Name:** (1117) Sundance Clinical Research

**Subject No:** 11171121

**Subject Initials:** ---

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

**Generated Time (GMT):** 21-Apr-2021 18:02

[Back to Form](#)

Item	Date	User	Comment
3	Nov-25-2020 11:10:19 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Done

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on **Form:** IMAGING - Comments  
Nov/23/2020

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

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

**Site No:** 1117

**Site Name:** (1117) Sundance Clinical Research

**Subject No:** 11171121

**Subject Initials:** ---

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

**Generated Time (GMT):** 21-Apr-2021 18:02

[Back to Form](#)

Item	Date	User	Comment
4	Nov-25-2020 11:10:19 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Done

**Header Text:** c4591001

**Visit:** POT\_COVID\_CONVA 1

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

**Site No:** 1117

**Subject No:** 11171121

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

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

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

**Site Name:** (1117) Sundance Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 21-Apr-2021 18:02

[Back to Form](#)

Item	Date	User	Comment
3	Feb-19-2021 10:46:38 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

**Header Text:** c4591001

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

**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY -  
Comments

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

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

**Site No:** 1117

**Site Name:** (1117) Sundance Clinical Research

**Subject No:** 11171121

**Subject Initials:** ---

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

**Generated Time (GMT):** 21-Apr-2021 18:02

[Back to Form](#)

Item	Date	User	Comment
Form	Feb-19-2021 10:45:45 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

**Header Text:** c4591001

**Visit:** POT\_COVID\_CONVA 1

**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY -  
Comments

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

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

**Site No:** 1117

**Site Name:** (1117) Sundance Clinical Research

**Subject No:** 11171121

**Subject Initials:** ---

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

**Generated Time (GMT):** 21-Apr-2021 18:02

[Back to Form](#)

Item	Date	User	Comment
1	Feb-19-2021 10:45:45 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Applicable



**Header Text:** c4591001

**Visit:** POT\_COVID\_CONVA 1

**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY -  
Comments

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

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

**Site No:** 1117

**Site Name:** (1117) Sundance Clinical Research

**Subject No:** 11171121

**Subject Initials:** ---

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

**Generated Time (GMT):** 21-Apr-2021 18:02

[Back to Form](#)

Item	Date	User	Comment
2	Feb-19-2021 10:45:45 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

**Header Text:** c4591001

**Visit:** POT\_COVID\_CONVA 1

**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY -  
Comments

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

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

**Site No:** 1117

**Site Name:** (1117) Sundance Clinical Research

**Subject No:** 11171121

**Subject Initials:** ---

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

**Generated Time (GMT):** 21-Apr-2021 18:02

[Back to Form](#)

Item	Date	User	Comment
3	Feb-19-2021 10:45:45 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

**Header Text:** c4591001

**Visit:** POT\_COVID\_CONVA 1

**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY -  
Comments

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

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

**Site No:** 1117

**Site Name:** (1117) Sundance Clinical Research

**Subject No:** 11171121

**Subject Initials:** ---

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

**Generated Time (GMT):** 21-Apr-2021 18:02

[Back to Form](#)

Item	Date	User	Comment
4	Feb-19-2021 10:45:45 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

**Header Text:** c4591001

**Visit:** V101\_VAX3

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

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

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

**Site No:** 1117

**Site Name:** (1117) Sundance Clinical Research

**Subject No:** 11171121

**Subject Initials:** ---

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

**Generated Time (GMT):** 21-Apr-2021 18:02

[Back to Form](#)

Item	Date	User	Comment
Form	Jan-22-2021 15:13:30 (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: 1117

Site Name: (1117) Sundance Clinical Research

Subject No: 11171121

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 21-Apr-2021 18:02

[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
(b) (6)	Approved	Mar-10-2021 11:53:32 (UTC-06:00) Central Time (US & Canada)	BOOK	Signed

**Affidavit:**

By my dated signature below, I, (b) (6), verify that all case report form pages accurately display the results of the examinations, tests, evaluations and treatments performed on this subject.

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

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

(b) (6)	N/A	Dec-28-2020 21:28:42 (UTC-06:00) Central Time (US & Canada)		Edit - All signatures invalidated
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**Affidavit:**

N/A

(b) (6)	Approved	Dec-02-2020 13:13:31 (UTC-06:00) Central Time (US & Canada)	BOOK	Signed
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**Affidavit:**

By my dated signature below, I, (b) (6), verify that all case report form pages accurately display the results of the examinations, tests, evaluations and treatments performed on this subject.

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

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

(b) (6)	N/A	Nov-25-2020 11:01:36 (UTC-06:00) Central Time (US & Canada)		Edit - All signatures invalidated
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**Affidavit:**

N/A

(b) (6)	Approved	Nov-16-2020 16:26:02 (UTC-06:00) Central Time (US & Canada)	BOOK	Signed
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090177e196d8902a\Final\Final On: 22-Apr-2021 02:13 (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:** 1117

**Site Name:** (1117) Sundance Clinical Research

**Subject No:** 11171121

**Subject Initials:** ---

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

**Generated Time (GMT):** 21-Apr-2021 18:02

**Affidavit:**

By my dated signature below, I, (b) (6) verify that all case report form pages accurately display the results of the examinations, tests, evaluations and treatments performed on this subject.

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

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

(b) (6)	N/A	Nov-12-2020 13:05:03 (UTC-06:00) Central Time (US & Canada)		Edit - All signatures invalidated
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**Affidavit:**

N/A

(b) (6)	Approved	Nov-09-2020 16:02:50 (UTC-06:00) Central Time (US & Canada)	BOOK	Signed
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**Affidavit:**

By my dated signature below, I, (b) (6) , verify that all case report form pages accurately display the results of the examinations, tests, evaluations and treatments performed on this subject.

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

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

090177e196d8902a\Final\Final On: 22-Apr-2021 02:13 (GMT)

**Header Text:** c4591001

**Visit:** COHORT\_SELECTION

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

**Site No:** 1117

**Subject No:** 11171121

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

**Form:** COHORT\_SELECTION - eCRF Audit Trail History

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

**Site Name:** (1117) Sundance Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 21-Apr-2021 18:02

[Back to Form](#)

*1. Select appropriate response - Protocol version*

Date	Location	User	Value	Reason
Sep-16-2020 14:55:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 24 JUL 2020	Initial Entry

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

Date	Location	User	Value	Reason
Sep-16-2020 14:55:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> STAGE 3 COHORTS	Initial Entry

**Header Text:** c4591001

**Visit:** COHORT\_SELECTION

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

**Site No:** 1117

**Subject No:** 11171121

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

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

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

**Site Name:** (1117) Sundance Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 21-Apr-2021 18:02

[Back to Form](#)

*I. Consent Was:*

Date	Location	User	Value	Reason
Sep-16-2020 14:55:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> OBTAINED Date Written Consent Obtained  Sep/15/2020	Initial Entry



Header Text: c4591001

Visit: COHORT\_SELECTION

Form Version: 15-Sep-2020 21:54

Site No: 1117

Subject No: 11171121

Generated By: (b) (4)

Form: DEMOGRAPHY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1117) Sundance Clinical Research

Subject Initials: ---

Generated Time (GMT): 21-Apr-2021 18:02

[Back to Form](#)

**1. Subject ID**

Date	Location	User	Value	Reason
Sep-16-2020 14:55:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 11171121	Item copied from previous form

**2. Birth Date:**

Date	Location	User	Value	Reason
Sep-16-2020 14:55:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> (b) (6)/1986	Enrollment Entry

**3. Sex:**

Date	Location	User	Value	Reason
Sep-16-2020 14:56:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> FEMALE	Initial Entry

**4. Ethnicity:**

Date	Location	User	Value	Reason
Sep-16-2020 14:56:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NOT HISPANIC OR LATINO(A) O R OF SPANISH ORIGIN	Initial Entry

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

Date	Location	User	Value	Reason
Sep-16-2020 14:56:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> WHITE	Initial Entry

090177e196d8902a\Final\Final On: 22-Apr-2021 02:13 (GMT)

**Header Text:** c4591001

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

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

**Site No:** 1117

**Subject No:** 11171121

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

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

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

**Site Name:** (1117) Sundance Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 21-Apr-2021 18:02

[Back to Form](#)

**1. Date of Visit**

Date	Location	User	Value	Reason
Sep-18-2020 12:53:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sep/15/2020	Initial Entry

**2. Erroneous Visit**

Date	Location	User	Value	Reason
Sep-18-2020 12:53:55 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 15-Sep-2020 21:52

Site No: 1117

Subject No: 11171121

Generated By: (b) (4)

Form: DISPOSITION - SCREENING - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1117) Sundance Clinical Research

Subject Initials: ---

Generated Time (GMT): 21-Apr-2021 18:02

[Back to Form](#)

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

Date	Location	User	Value	Reason
Sep-18-2020 12:54:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sep/15/2020	Initial Entry

**2. Phase of Disposition:**

Date	Location	User	Value	Reason
Sep-18-2020 12:54:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SCREENING	Initial Entry

**3. Status:**

Date	Location	User	Value	Reason
Sep-18-2020 12:54:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> COMPLETED	Initial Entry

**4. Specify Status:**

Date	Location	User	Value	Reason
Sep-18-2020 12:54:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

090177e196d8902a\Final\Final On: 22-Apr-2021 02:13 (GMT)

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 22-Apr-2020 21:03

Site No: 1117

Subject No: 11171121

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1117) Sundance Clinical Research

Subject Initials: ---

Generated Time (GMT): 21-Apr-2021 18:02

[Back to Form](#)

*I.a*

Date	Location	User	Value	Reason
Sep-18-2020 12:56:17 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Line/MH Number:</b> 1 <b>Medical History Term:</b> anxiety <b>Start Date:</b> UNK/UNK/2015 <b>Ongoing:</b> YES	Initial Entry

*I.a Line/MH Number:*

Date	Location	User	Value	Reason
Sep-18-2020 12:56:17 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	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
Sep-18-2020 12:56:17 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> anxiety	Initial Entry

*I.a Start Date:*

Date	Location	User	Value	Reason
Sep-18-2020 12:56:17 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> UNK/UNK/2015	Initial Entry

*I.a Ongoing:*

Date	Location	User	Value	Reason
Sep-18-2020 12:56:17 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

*I.b*

Date	Location	User	Value	Reason
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090177e196d8902a\Final\Final On: 22-Apr-2021 02:13 (GMT)

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1117

Site Name: (1117) Sundance Clinical Research

Subject No: 11171121

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 21-Apr-2021 18:02

Sep-18-2020 12:56:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Line/MH Num</b> 2 <b>ber:</b> <b>Medical Histor</b> Demerol induced an <b>y Term:</b> apyhlaxis <b>Start Date:</b> UNK/UNK/1991 <b>Ongoing:</b> NO End Date:  UNK/UNK/1991 1	Initial Entry
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**I.b Line/MH Number:**

Date	Location	User	Value	Reason
Sep-18-2020 12:56:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 2	Initial Entry

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

Date	Location	User	Value	Reason
Sep-18-2020 12:56:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Demerol induced anaphylaxis	Initial Entry

**I.b Start Date:**

Date	Location	User	Value	Reason
Sep-18-2020 12:56:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> UNK/UNK/1991	Initial Entry

**I.b Ongoing:**

Date	Location	User	Value	Reason
Sep-18-2020 12:56:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO End Date:  UNK/UNK/1991	Initial Entry

**I.c**

Date	Location	User	Value	Reason
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090177e196d8902a\Final\Final On: 22-Apr-2021 02:13 (GMT)

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 22-Apr-2020 21:03

Site No: 1117

Subject No: 11171121

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1117) Sundance Clinical Research

Subject Initials: ---

Generated Time (GMT): 21-Apr-2021 18:02

Sep-18-2020 12:57:19 (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> Allergy, Demerol <b>Start Date:</b> UNK/UNK/1991 <b>Ongoing:</b> YES	Initial Entry
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*I.c Line/MH Number:*

Date	Location	User	Value	Reason
Sep-18-2020 12:57:19 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 3	Initial Entry

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

Date	Location	User	Value	Reason
Sep-18-2020 12:57:19 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Allergy, Demerol	Initial Entry

*I.c Start Date:*

Date	Location	User	Value	Reason
Sep-18-2020 12:57:19 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> UNK/UNK/1991	Initial Entry

*I.c Ongoing:*

Date	Location	User	Value	Reason
Sep-18-2020 12:57:19 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

*I.d*

Date	Location	User	Value	Reason
Sep-18-2020 12:58:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Line/MH Number:</b> 4 <b>Medical History Term:</b> Radial head fracture, <b>Primary Term:</b> Left, non-displaced	Initial Entry

090177e196d8902a\Final\Final On: 22-Apr-2021 02:13 (GMT)

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 22-Apr-2020 21:03

Site No: 1117

Subject No: 11171121

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1117) Sundance Clinical Research

Subject Initials: ---

Generated Time (GMT): 21-Apr-2021 18:02

			<b>Start Date:</b> Jul/22/2020	
			<b>Ongoing:</b> YES	

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

Date	Location	User	Value	Reason
Sep-18-2020 12:58:05 (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
Sep-18-2020 12:58:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Radial head fracture, Left, non-displaced	Initial Entry

**I.d Start Date:**

Date	Location	User	Value	Reason
Sep-18-2020 12:58:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Jul/22/2020	Initial Entry

**I.d Ongoing:**

Date	Location	User	Value	Reason
Sep-18-2020 12:58:05 (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
Sep-18-2020 12:58:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Line/MH Number:</b> 5 <b>Medical History Term:</b> Pain, elbow, left <b>Start Date:</b> Jul/25/2020 <b>Ongoing:</b> YES	Initial Entry

090177e196d8902a\Final\Final On: 22-Apr-2021 02:13 (GMT)

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 22-Apr-2020 21:03

Site No: 1117

Subject No: 11171121

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1117) Sundance Clinical Research

Subject Initials: ---

Generated Time (GMT): 21-Apr-2021 18:02

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

Date	Location	User	Value	Reason
Sep-18-2020 12:58:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 5	Initial Entry

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

Date	Location	User	Value	Reason
Sep-18-2020 12:58:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Pain, elbow, left	Initial Entry

**I.e Start Date:**

Date	Location	User	Value	Reason
Sep-18-2020 12:58:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Jul/25/2020	Initial Entry

**I.e Ongoing:**

Date	Location	User	Value	Reason
Sep-18-2020 12:58:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

**I.f**

Date	Location	User	Value	Reason
Sep-18-2020 12:58:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Line/MH Number:</b> 6 <b>Medical History Term:</b> hypertension <b>Start Date:</b> Jan/UNK/2020 <b>Ongoing:</b> YES	Initial Entry

090177e196d8902a\Final\Final On: 22-Apr-2021 02:13 (GMT)



Header Text: c4591001

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Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1117

Site Name: (1117) Sundance Clinical Research

Subject No: 11171121

Subject Initials: ---

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Generated Time (GMT): 21-Apr-2021 18:02

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

Date	Location	User	Value	Reason
Sep-18-2020 12:58:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 6	Initial Entry

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

Date	Location	User	Value	Reason
Sep-18-2020 12:58:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> hypertension	Initial Entry

***I.f Start Date:***

Date	Location	User	Value	Reason
Sep-18-2020 12:58:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Jan/UNK/2020	Initial Entry

***I.f Ongoing:***

Date	Location	User	Value	Reason
Sep-18-2020 12:58:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

***I.g***

Date	Location	User	Value	Reason
Sep-18-2020 12:59:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Line/MH Number:</b> 7 <b>Medical History Term:</b> <b>Start Date:</b> Oct/15/2016 <b>Ongoing:</b> NO End Date: Oct/15/2016	Initial Entry

090177e196d8902a\Final\Final On: 22-Apr-2021 02:13 (GMT)

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

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Site No: 1117

Site Name: (1117) Sundance Clinical Research

Subject No: 11171121

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 21-Apr-2021 18:02

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

Date	Location	User	Value	Reason
Sep-18-2020 12:59:22 (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
Sep-18-2020 12:59:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> C-Section	Initial Entry

**I.g Start Date:**

Date	Location	User	Value	Reason
Sep-18-2020 12:59:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Oct/15/2016	Initial Entry

**I.g Ongoing:**

Date	Location	User	Value	Reason
Sep-18-2020 12:59:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO End Date: Oct/15/2016	Initial Entry

**I.h**

Date	Location	User	Value	Reason
Sep-18-2020 13:00:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> Line/MH Number 8 : Medical History T Hip scope, right erm: Start Date: Dec/UNK/2005 Ongoing: NO End Date: Dec/UNK/2005	Initial Entry

090177e196d8902a\Final\Final On: 22-Apr-2021 02:13 (GMT)

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1117

Site Name: (1117) Sundance Clinical Research

Subject No: 11171121

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 21-Apr-2021 18:02

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

Date	Location	User	Value	Reason
Sep-18-2020 13:00:41 (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
Sep-18-2020 13:00:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Hip scope, right	Initial Entry

**I.h Start Date:**

Date	Location	User	Value	Reason
Sep-18-2020 13:00:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Dec/UNK/2005	Initial Entry

**I.h Ongoing:**

Date	Location	User	Value	Reason
Sep-18-2020 13:00:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO End Date:  Dec/UNK/2005	Initial Entry

**I.i**

Date	Location	User	Value	Reason
Sep-18-2020 13:04:14 (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> hip fracture, right <b>Start Date:</b> Dec/UNK/2005 <b>Ongoing:</b> NO End Date:  Dec/UNK/2005	Initial Entry

090177e196d8902a\Final\Final On: 22-Apr-2021 02:13 (GMT)

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

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Site No: 1117

Site Name: (1117) Sundance Clinical Research

Subject No: 11171121

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 21-Apr-2021 18:02

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

Date	Location	User	Value	Reason
Sep-18-2020 13:04:14 (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
Sep-18-2020 13:04:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> hip fracture, right	Initial Entry

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

Date	Location	User	Value	Reason
Sep-18-2020 13:04:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Dec/UNK/2005	Initial Entry

***I.i Ongoing:***

Date	Location	User	Value	Reason
Sep-18-2020 13:04:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO End Date: Dec/UNK/2005	Initial Entry

***I.j***

Date	Location	User	Value	Reason
Sep-18-2020 13:04:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Line/MH Num</b> 10 <b>ber:</b> <b>Medical History Term:</b> Elbow, left, displaced fracture <b>Start Date:</b> UNK/UNK/1991 <b>Ongoing:</b> NO End Date: UNK/UNK/1991	Initial Entry

090177e196d8902a\Final\Final On: 22-Apr-2021 02:13 (GMT)

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

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Site No: 1117

Site Name: (1117) Sundance Clinical Research

Subject No: 11171121

Subject Initials: ---

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Generated Time (GMT): 21-Apr-2021 18:02

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

Date	Location	User	Value	Reason
Sep-18-2020 13:04:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 10	Initial Entry

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

Date	Location	User	Value	Reason
Sep-18-2020 13:04:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Elbow, left, displaced fracture	Initial Entry

***I.j Start Date:***

Date	Location	User	Value	Reason
Sep-18-2020 13:04:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> UNK/UNK/1991	Initial Entry

***I.j Ongoing:***

Date	Location	User	Value	Reason
Sep-18-2020 13:04:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO End Date: UNK/UNK/1991	Initial Entry

090177e196d8902a\Final\Final On: 22-Apr-2021 02:13 (GMT)

**Header Text:** c4591001

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

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

**Site No:** 1117

**Subject No:** 11171121

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

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

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

**Site Name:** (1117) Sundance Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 21-Apr-2021 18:02

[Back to Form](#)

<i>l.k</i>				
Date	Location	User	Value	Reason
Sep-18-2020 13:05:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Line/MH Number:</b> 11 <b>r:</b> <b>Medical History:</b> elbow repair, left <b>Term:</b> t <b>Start Date:</b> UNK/UNK/1991 <b>Ongoing:</b> NO End Date: UNK/UNK/1991	Initial Entry

090177e196d8902a\Final\Final On: 22-Apr-2021 02:13 (GMT)

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 22-Apr-2020 21:03

Site No: 1117

Subject No: 11171121

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1117) Sundance Clinical Research

Subject Initials: ---

Generated Time (GMT): 21-Apr-2021 18:02

<i>1.k Line/MH Number:</i>				
Date	Location	User	Value	Reason
Sep-18-2020 13:05:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 11	Initial Entry

<i>1.k Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:</i>				
Date	Location	User	Value	Reason
Sep-18-2020 13:05:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> elbow repair, left	Initial Entry

<i>1.k Start Date:</i>				
Date	Location	User	Value	Reason
Sep-18-2020 13:05:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> UNK/UNK/1991	Initial Entry

<i>1.k Ongoing:</i>				
Date	Location	User	Value	Reason
Sep-18-2020 13:05:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO End Date:  UNK/UNK/1991	Initial Entry

<i>1.l</i>				
Date	Location	User	Value	Reason
Sep-18-2020 13:06:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Line/MH Number:</b> 12 <b>r:</b> <b>Medical History:</b> appendicitis <b>Term:</b> <b>Start Date:</b> UNK/UNK/1991 6	Initial Entry

090177e196d8902a\Final\Final On: 22-Apr-2021 02:13 (GMT)

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 22-Apr-2020 21:03

Site No: 1117

Subject No: 11171121

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1117) Sundance Clinical Research

Subject Initials: ---

Generated Time (GMT): 21-Apr-2021 18:02

			<b>Ongoing:</b>	NO	
				End Date:	
				UNK/UNK/1996	

**1.1 Line/MH Number:**

Date	Location	User	Value	Reason
Sep-18-2020 13:06:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 12	Initial Entry

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

Date	Location	User	Value	Reason
Sep-18-2020 13:06:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> appendicitis	Initial Entry

**1.1 Start Date:**

Date	Location	User	Value	Reason
Sep-18-2020 13:06:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> UNK/UNK/1996	Initial Entry

**1.1 Ongoing:**

Date	Location	User	Value	Reason
Sep-18-2020 13:06:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO End Date:  UNK/UNK/1996	Initial Entry

**1.m**

Date	Location	User	Value	Reason
Sep-18-2020 13:06:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Line/MH Number:</b> 13 <b>r:</b> <b>Medical History Term:</b> appendectomy	Initial Entry

090177e196d8902a\Final\Final On: 22-Apr-2021 02:13 (GMT)



Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 22-Apr-2020 21:03

Site No: 1117

Subject No: 11171121

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1117) Sundance Clinical Research

Subject Initials: ---

Generated Time (GMT): 21-Apr-2021 18:02

			<b>Start Date:</b> UNK/UNK/1996 <b>Ongoing:</b> NO End Date: UNK/UNK/1996
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**I.m Line/MH Number:**

Date	Location	User	Value	Reason
Sep-18-2020 13:06:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 13	Initial Entry

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

Date	Location	User	Value	Reason
Sep-18-2020 13:06:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> appendectomy	Initial Entry

**I.m Start Date:**

Date	Location	User	Value	Reason
Sep-18-2020 13:06:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> UNK/UNK/1996	Initial Entry

**I.m Ongoing:**

Date	Location	User	Value	Reason
Sep-18-2020 13:06:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO End Date: UNK/UNK/1996	Initial Entry

**I.n**

Date	Location	User	Value	Reason
Sep-18-2020 13:07:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> Line/MH Number: 14	Initial Entry

090177e196d8902a\Final\Final On: 22-Apr-2021 02:13 (GMT)

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Visit: V1\_DAY1\_VAX1\_L

Form Version: 22-Apr-2020 21:03

Site No: 1117

Subject No: 11171121

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Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1117) Sundance Clinical Research

Subject Initials: ---

Generated Time (GMT): 21-Apr-2021 18:02

			<b>Medical History Term:</b> Tooth extraction, wisdom <b>Start Date:</b> UNK/UNK/2002 <b>Ongoing:</b> NO End Date: UNK/UNK/2002	
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**1.n Line/MH Number:**

Date	Location	User	Value	Reason
Sep-18-2020 13:07:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 14	Initial Entry

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

Date	Location	User	Value	Reason
Sep-18-2020 13:07:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Tooth extraction, wisdom	Initial Entry

**1.n Start Date:**

Date	Location	User	Value	Reason
Sep-18-2020 13:07:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> UNK/UNK/2002	Initial Entry

**1.n Ongoing:**

Date	Location	User	Value	Reason
Sep-18-2020 13:07:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO End Date: UNK/UNK/2002	Initial Entry

**1.o**

Date	Location	User	Value	Reason
Sep-18-2020 13:07:47 (UTC-06:00) Central Time	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Line/MH Numbe</b> 15	Initial Entry

090177e196d8902a\Final\Final On: 22-Apr-2021 02:13 (GMT)

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 22-Apr-2020 21:03

Site No: 1117

Subject No: 11171121

Generated By: (b) (4)

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Site Name: (1117) Sundance Clinical Research

Subject Initials: ---

Generated Time (GMT): 21-Apr-2021 18:02

(US & Canada)			<b>r:</b> <b>Medical History</b> Pain, tooth <b>Term:</b> <b>Start Date:</b> UNK/UNK/2002 <b>Ongoing:</b> NO End Date: UNK/UNK/2002	
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**1.o Line/MH Number:**

Date	Location	User	Value	Reason
Sep-18-2020 13:07:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 15	Initial Entry

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

Date	Location	User	Value	Reason
Sep-18-2020 13:07:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Pain, tooth	Initial Entry

**1.o Start Date:**

Date	Location	User	Value	Reason
Sep-18-2020 13:07:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> UNK/UNK/2002	Initial Entry

**1.o Ongoing:**

Date	Location	User	Value	Reason
Sep-18-2020 13:07:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO End Date: UNK/UNK/2002	Initial Entry

**1.p**

Date	Location	User	Value	Reason
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090177e196d8902a\Final\Final On: 22-Apr-2021 02:13 (GMT)

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1117

Site Name: (1117) Sundance Clinical Research

Subject No: 11171121

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 21-Apr-2021 18:02

Sep-18-2020 13:08:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Line/MH Number:</b> 16 <b>Medical History Term:</b> Allergy, seasonal <b>Start Date:</b> UNK/UNK/2001 <b>Ongoing:</b> YES	Initial Entry
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**1.p Line/MH Number:**

Date	Location	User	Value	Reason
Sep-18-2020 13:08:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 16	Initial Entry

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

Date	Location	User	Value	Reason
Sep-18-2020 13:08:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Allergy, seasonal	Initial Entry

**1.p Start Date:**

Date	Location	User	Value	Reason
Sep-18-2020 13:08:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> UNK/UNK/2001	Initial Entry

**1.p Ongoing:**

Date	Location	User	Value	Reason
Sep-18-2020 13:08:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

**1.q**

Date	Location	User	Value	Reason
Sep-18-2020 13:08:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Line/MH Number:</b> 17 <b>Medical History Term:</b> Myopia, bilateral	Initial Entry

090177e196d8902a\Final\Final On: 22-Apr-2021 02:13 (GMT)

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 22-Apr-2020 21:03

Site No: 1117

Subject No: 11171121

Generated By: (b) (4)

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Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1117) Sundance Clinical Research

Subject Initials: ---

Generated Time (GMT): 21-Apr-2021 18:02

			<b>Start Date:</b>	UNK/UNK/1993	
			<b>Ongoing:</b>	YES	

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

Date	Location	User	Value	Reason
Sep-18-2020 13:08:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 17	Initial Entry

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

Date	Location	User	Value	Reason
Sep-18-2020 13:08:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Myopia, bilateral	Initial Entry

**1.q Start Date:**

Date	Location	User	Value	Reason
Sep-18-2020 13:08:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> UNK/UNK/1993	Initial Entry

**1.q Ongoing:**

Date	Location	User	Value	Reason
Sep-18-2020 13:08:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

**1.r**

Date	Location	User	Value	Reason
Sep-18-2020 13:10:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Line/MH Number:</b> 18 <b>Medical History Te rm:</b> Sinusitis, chronic <b>Start Date:</b> UNK/UNK/2005 <b>Ongoing:</b> YES	Initial Entry

090177e196d8902a\Final\Final On: 22-Apr-2021 02:13 (GMT)

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 22-Apr-2020 21:03

Site No: 1117

Subject No: 11171121

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1117) Sundance Clinical Research

Subject Initials: ---

Generated Time (GMT): 21-Apr-2021 18:02

<i>I.r Line/MH Number:</i>				
Date	Location	User	Value	Reason
Sep-18-2020 13:10:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 18	Initial Entry

<i>I.r Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:</i>				
Date	Location	User	Value	Reason
Sep-18-2020 13:10:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sinusitis, chronic	Initial Entry

<i>I.r Start Date:</i>				
Date	Location	User	Value	Reason
Sep-18-2020 13:10:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> UNK/UNK/2005	Initial Entry

<i>I.r Ongoing:</i>				
Date	Location	User	Value	Reason
Sep-18-2020 13:10:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

<i>I.s</i>				
Date	Location	User	Value	Reason
Sep-18-2020 13:11:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Line/MH Number:</b> 19 <b>Medical History Term:</b> pneumonia <b>Start Date:</b> UNK/UNK/2018 <b>Ongoing:</b> NO End Date: UNK/UNK/2018	Initial Entry

090177e196d8902a\Final\Final On: 22-Apr-2021 02:13 (GMT)

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 22-Apr-2020 21:03

Site No: 1117

Subject No: 11171121

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1117) Sundance Clinical Research

Subject Initials: ---

Generated Time (GMT): 21-Apr-2021 18:02

<i>I.s Line/MH Number:</i>				
Date	Location	User	Value	Reason
Sep-18-2020 13:11:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 19	Initial Entry

<i>I.s Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:</i>				
Date	Location	User	Value	Reason
Sep-18-2020 13:11:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> pneumonia	Initial Entry

<i>I.s Start Date:</i>				
Date	Location	User	Value	Reason
Sep-18-2020 13:11:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> UNK/UNK/2018	Initial Entry

<i>I.s Ongoing:</i>				
Date	Location	User	Value	Reason
Sep-18-2020 13:11:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO End Date:  UNK/UNK/2018	Initial Entry

<i>I.t</i>				
Date	Location	User	Value	Reason
Sep-18-2020 13:11:32 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Line/MH Number:</b> 20 <b>Medical History:</b> pneumonia <b>Term:</b> <b>Start Date:</b> UNK/UNK/2016	Initial Entry

090177e196d8902a\Final\Final On: 22-Apr-2021 02:13 (GMT)

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 22-Apr-2020 21:03

Site No: 1117

Subject No: 11171121

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1117) Sundance Clinical Research

Subject Initials: ---

Generated Time (GMT): 21-Apr-2021 18:02

			<b>Ongoing:</b>	NO	
				End Date:	
				UNK/UNK/2016	

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

Date	Location	User	Value	Reason
Sep-18-2020 13:11:32 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 20	Initial Entry

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

Date	Location	User	Value	Reason
Sep-18-2020 13:11:32 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> pneumonia	Initial Entry

**1.t Start Date:**

Date	Location	User	Value	Reason
Sep-18-2020 13:11:32 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> UNK/UNK/2016	Initial Entry

**1.t Ongoing:**

Date	Location	User	Value	Reason
Sep-18-2020 13:11:32 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO End Date:  UNK/UNK/2016	Initial Entry

090177e196d8902a\Final\Final On: 22-Apr-2021 02:13 (GMT)



Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 22-Apr-2020 21:03

Site No: 1117

Subject No: 11171121

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1117) Sundance Clinical Research

Subject Initials: ---

Generated Time (GMT): 21-Apr-2021 18:02

[Back to Form](#)

<i>I.u</i>				
Date	Location	User	Value	Reason
Sep-18-2020 13:12:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Line/MH Number</b> 21 : <b>Medical History T</b> Alcohol use, 2/ <b>erm:</b> week <b>Start Date:</b> UNK/UNK/200 5 <b>Ongoing:</b> YES	Initial Entry

<i>I.u Line/MH Number:</i>				
Date	Location	User	Value	Reason
Sep-18-2020 13:12:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 21	Initial Entry

<i>I.u Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:</i>				
Date	Location	User	Value	Reason
Sep-18-2020 13:12:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Alcohol use, 2/week	Initial Entry

<i>I.u Start Date:</i>				
Date	Location	User	Value	Reason
Sep-18-2020 13:12:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> UNK/UNK/2005	Initial Entry

<i>I.u Ongoing:</i>				
Date	Location	User	Value	Reason
Sep-18-2020 13:12:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

090177e196d8902a\Final\Final On: 22-Apr-2021 02:13 (GMT)

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 15-Sep-2020 21:56

Site No: 1117

Subject No: 11171121

Generated By: (b) (4)

Form: VITAL SIGNS - BASELINE - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1117) Sundance Clinical Research

Subject Initials: ---

Generated Time (GMT): 21-Apr-2021 18:02

[Back to Form](#)

**1. Date:**

Date	Location	User	Value	Reason
Sep-18-2020 13:12:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sep/15/2020	Initial Entry

**2. Weight:**

Date	Location	User	Value	Reason
Sep-18-2020 13:12:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 232.6	Initial Entry

**3. Unit:**

Date	Location	User	Value	Reason
Sep-18-2020 13:12:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> LB	Initial Entry

**4. Height:**

Date	Location	User	Value	Reason
Sep-18-2020 13:12:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 67.8	Initial Entry

**5. Unit:**

Date	Location	User	Value	Reason
Sep-18-2020 13:12:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> in	Initial Entry

**6. Body Mass Index:**

Date	Location	User	Value	Reason
Sep-18-2020 13:12:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 35.6	Initial Entry

090177e196d8902a\Final\Final On: 22-Apr-2021 02:13 (GMT)

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 15-Sep-2020 21:56

Site No: 1117

Subject No: 11171121

Generated By: (b) (4)

Form: VITAL SIGNS - BASELINE - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1117) Sundance Clinical Research

Subject Initials: ---

Generated Time (GMT): 21-Apr-2021 18:02

7.a

Date	Location	User	Value	Reason
Sep-18-2020 13:12:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Record Identifier:: 1 Temperature: 97.9 Temperature Unit: F Temperature Location:: ORAL CAVITY	Initial Entry

7.a Record Identifier:

Date	Location	User	Value	Reason
Sep-18-2020 13:12:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 1	Initial Entry

7.a Temperature:

Date	Location	User	Value	Reason
Sep-18-2020 13:12:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 97.9	Initial Entry

7.a Unit:

Date	Location	User	Value	Reason
Sep-18-2020 13:12:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> F	Initial Entry

7.a Temperature Location:

Date	Location	User	Value	Reason
Sep-18-2020 13:12:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> ORAL CAVITY	Initial Entry

090177e196d8902a\Final\Final On: 22-Apr-2021 02:13 (GMT)

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

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

Form Version: 15-Sep-2020 21:51

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1117

Site Name: (1117) Sundance Clinical Research

Subject No: 11171121

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 21-Apr-2021 18:02

[Back to Form](#)

**1. Lab Panel:**

Date	Location	User	Value	Reason
Sep-18-2020 13:14:09 (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 13:14:09 (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 13:14:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sep/15/2020	Initial Entry

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

Date	Location	User	Value	Reason
Sep-18-2020 13:14:09 (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 13:14:09 (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 13:14:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> Sponsor-Define 113 <b>d Identifier:</b>	Initial Entry

090177e196d8902a\Final\Final On: 22-Apr-2021 02:13 (GMT)

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

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

Form Version: 15-Sep-2020 21:51

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1117

Site Name: (1117) Sundance Clinical Research

Subject No: 11171121

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 21-Apr-2021 18:02

			<b>Test::</b> Choriogonadotropin Beta_PX113 <b>Result::</b> NEGATIVE <b>Not Done::</b>
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**6.a Sponsor ID:**

Date	Location	User	Value	Reason
Sep-18-2020 13:14:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 113	Initial Entry

**6.a Test:**

Date	Location	User	Value	Reason
Sep-18-2020 13:14:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Choriogonadotropin Beta_PX113	Initial Entry

**6.a Result:**

Date	Location	User	Value	Reason
Sep-18-2020 13:14:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NEGATIVE	Initial Entry

090177e196d8902a\Final\Final On: 22-Apr-2021 02:13 (GMT)

**Header Text:** c4591001

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

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

**Site No:** 1117

**Subject No:** 11171121

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

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

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

**Site Name:** (1117) Sundance Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 21-Apr-2021 18:02

[Back to Form](#)

**1. Randomization Date :**

Date	Location	User	Value	Reason
Sep-18-2020 13:14:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sep/15/2020	Initial Entry

**2. Randomization Number:**

Date	Location	User	Value	Reason
Sep-18-2020 13:14:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 88144	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: 1117

Site Name: (1117) Sundance Clinical Research

Subject No: 11171121

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 21-Apr-2021 18:02

[Back to Form](#)

**1. Data Origin**

Date	Location	User	Value	Reason
Sep-18-2020 13:14:52 (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 13:14:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SERUM	Initial Entry

**3. Sample Collected?**

Date	Location	User	Value	Reason
Sep-21-2020 12:26:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Sep-20-2020 01:26:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Sep-18-2020 13:14:52 (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 13:14:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES Date of Collection:  Sep/15/2020	Initial Entry

**4. If no sample was collected or sample was not collected according to protocol, please provide reason:**

Date	Location	User	Value	Reason
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090177e196d8902a\Final\Final On: 22-Apr-2021 02:13 (GMT)

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1117

Site Name: (1117) Sundance Clinical Research

Subject No: 11171121

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 21-Apr-2021 18:02

Sep-21-2020 12:25:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry
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5.a

Date	Location	User	Value	Reason
Sep-21-2020 12:26:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sample ID: BPRV3J	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Sep-21-2020 12:26:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BPRV3J	Initial Entry

5.b

Date	Location	User	Value	Reason
Sep-21-2020 12:26:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sample ID: BPRV3K	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Sep-21-2020 12:26:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BPRV3K	Initial Entry

5.c

Date	Location	User	Value	Reason
Sep-22-2020 12:22:46 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sample ID: BM8YKX	Initial Entry

090177e196d8902a\Final\Final On: 22-Apr-2021 02:13 (GMT)



Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1117

Site Name: (1117) Sundance Clinical Research

Subject No: 11171121

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 21-Apr-2021 18:02

5.c Sample ID

Date	Location	User	Value	Reason
Sep-22-2020 12:22:46 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> BM8YKX	Initial Entry

5.d

Date	Location	User	Value	Reason
Sep-22-2020 12:22:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Sample ID: BM8YKY	Initial Entry

5.d Sample ID

Date	Location	User	Value	Reason
Sep-22-2020 12:22:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> BM8YKY	Initial Entry

5.e

Date	Location	User	Value	Reason
Sep-22-2020 12:23:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Sample ID: BM8YKZ	Initial Entry

5.e Sample ID

Date	Location	User	Value	Reason
Sep-22-2020 12:23:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> BM8YKZ	Initial Entry

090177e196d8902a\Final\Final On: 22-Apr-2021 02:13 (GMT)

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1117

Site Name: (1117) Sundance Clinical Research

Subject No: 11171121

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 21-Apr-2021 18:02

[Back to Form](#)

**1. Data Origin**

Date	Location	User	Value	Reason
Sep-18-2020 13:15:02 (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 13:15:02 (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-21-2020 12:43:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Sep-20-2020 01:26:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Sep-18-2020 13:15:02 (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 13:15:02 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES Date of Collection:  Sep/15/2020	Initial Entry

**4. If no sample was collected or sample was not collected according to protocol, please provide reason:**

Date	Location	User	Value	Reason
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090177e196d8902a\Final\Final On: 22-Apr-2021 02:13 (GMT)

**Header Text:** c4591001

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

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

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

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

**Site No:** 1117

**Site Name:** (1117) Sundance Clinical Research

**Subject No:** 11171121

**Subject Initials:** ---

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

**Generated Time (GMT):** 21-Apr-2021 18:02

Sep-21-2020 12:43:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry
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**5.a**

Date	Location	User	Value	Reason
Sep-21-2020 12:43:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sample ID: BM8YJ1	Initial Entry

**5.a Sample ID**

Date	Location	User	Value	Reason
Sep-21-2020 12:43:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BM8YJ1	Initial Entry

090177e196d8902a\Final\Final On: 22-Apr-2021 02:13 (GMT)

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 22-Apr-2020 21:04

Site No: 1117

Subject No: 11171121

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1117) Sundance Clinical Research

Subject Initials: ---

Generated Time (GMT): 21-Apr-2021 18:02

[Back to Form](#)

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

Date	Location	User	Value	Reason
Sep-18-2020 13:15:28 (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 13:15:28 (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 13:15:28 (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 13:15:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sep/15/2020 10:06	Initial Entry

**5. Anatomical Location:**

Date	Location	User	Value	Reason
Sep-18-2020 13:15:28 (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 13:15:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> RIGHT	Initial Entry

090177e196d8902a\Final\Final On: 22-Apr-2021 02:13 (GMT)

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form: VACCINATION - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1117

Site Name: (1117) Sundance Clinical Research

Subject No: 11171121

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 21-Apr-2021 18:02

7. Route:

Date	Location	User	Value	Reason
Sep-18-2020 13:15:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> INTRAMUSCULAR	Initial Entry

10. Timeframe Subject Was Observed

Date	Location	User	Value	Reason
Sep-18-2020 13:15:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> THE PROTOCOL SPECIFIED OBS ERVATION 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 13:15:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

090177e196d8902a\Final\Final On: 22-Apr-2021 02:13 (GMT)

**Header Text:** c4591001

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

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

**Site No:** 1117

**Subject No:** 11171121

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

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

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

**Site Name:** (1117) Sundance Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 21-Apr-2021 18:02

[Back to Form](#)

*1. Select appropriate response - Reactogenicity diary collection*

Date	Location	User	Value	Reason
Sep-22-2020 11:35:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<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:** 1117

**Subject No:** 11171121

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

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

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

**Site Name:** (1117) Sundance Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 21-Apr-2021 18:02

[Back to Form](#)

*1. Date of Visit*

<b>Date</b>	<b>Location</b>	<b>User</b>	<b>Value</b>	<b>Reason</b>
Oct-15-2020 12:03:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Oct/6/2020	Initial Entry

Header Text: c4591001

Visit: V2\_VAX2\_L

Form Version: 10-Oct-2020 16:01

Site No: 1117

Subject No: 11171121

Generated By: (b) (4)

Form: VITAL SIGNS - TEMP - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1117) Sundance Clinical Research

Subject Initials: ---

Generated Time (GMT): 21-Apr-2021 18:02

[Back to Form](#)

**1. Date:**

Date	Location	User	Value	Reason
Oct-15-2020 12:03:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Oct/6/2020	Initial Entry

**2.a**

Date	Location	User	Value	Reason
Oct-15-2020 12:03:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Record Identifier::</b> 1 <b>Temperature:</b> 98.8 <b>Temperature Unit:</b> F <b>Temperature Location:</b> ORAL CAVITY	Initial Entry

**2.a Record Identifier:**

Date	Location	User	Value	Reason
Oct-15-2020 12:03:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 1	Initial Entry

**2.a Temperature:**

Date	Location	User	Value	Reason
Oct-15-2020 12:03:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 98.8	Initial Entry

**2.a Unit:**

Date	Location	User	Value	Reason
Oct-15-2020 12:03:44 (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
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090177e196d8902a\Final\Final On: 22-Apr-2021 02:13 (GMT)



**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1117

**Subject No:** 11171121

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

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

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

**Site Name:** (1117) Sundance Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 21-Apr-2021 18:02

Oct-15-2020 12:03:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> ORAL CAVITY	Initial Entry
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090177e196d8902a\Final\Final On: 22-Apr-2021 02:13 (GMT)

Header Text: c4591001

Visit: V2\_VAX2\_L

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

Form Version: 15-Sep-2020 21:51

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1117

Site Name: (1117) Sundance Clinical Research

Subject No: 11171121

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 21-Apr-2021 18:02

[Back to Form](#)

**1. Lab Panel:**

Date	Location	User	Value	Reason
Oct-15-2020 12:04:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> URINALYSIS	Initial Entry

**2. Lab Sub-Panel:**

Date	Location	User	Value	Reason
Oct-15-2020 12:04:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> PREGNANCY	Initial Entry

**3. Collection Date:**

Date	Location	User	Value	Reason
Oct-15-2020 12:04:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Oct/6/2020	Initial Entry

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

Date	Location	User	Value	Reason
Oct-15-2020 12:04:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> STUDY SITE	Initial Entry

**5. Specimen Type:**

Date	Location	User	Value	Reason
Oct-15-2020 12:04:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> URINE	Initial Entry

**6.a**

Date	Location	User	Value	Reason
Oct-15-2020 12:04:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> Sponsor-Define 113 <b>d Identifier:</b>	Initial Entry

090177e196d8902a\Final\Final On: 22-Apr-2021 02:13 (GMT)

Header Text: c4591001

Visit: V2\_VAX2\_L

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

Form Version: 15-Sep-2020 21:51

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1117

Site Name: (1117) Sundance Clinical Research

Subject No: 11171121

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 21-Apr-2021 18:02

			<b>Test::</b> Choriogonadotropin Beta_PX113 <b>Result::</b> NEGATIVE <b>Not Done::</b>
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6.a Sponsor ID:

Date	Location	User	Value	Reason
Oct-15-2020 12:04:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 113	Initial Entry

6.a Test:

Date	Location	User	Value	Reason
Oct-15-2020 12:04:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Choriogonadotropin Beta_PX113	Initial Entry

6.a Result:

Date	Location	User	Value	Reason
Oct-15-2020 12:04:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NEGATIVE	Initial Entry

090177e196d8902a\Final\Final On: 22-Apr-2021 02:13 (GMT)

Header Text: c4591001

Visit: V2\_VAX2\_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1117

Site Name: (1117) Sundance Clinical Research

Subject No: 11171121

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 21-Apr-2021 18:02

[Back to Form](#)

**1. Data Origin**

Date	Location	User	Value	Reason
Oct-09-2020 11:48:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SITE	Initial Entry

**2. Sample Type**

Date	Location	User	Value	Reason
Oct-09-2020 11:48:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> NASAL_SWAB	Initial Entry

**3. Sample Collected?**

Date	Location	User	Value	Reason
Oct-09-2020 11:48:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Oct-09-2020 11:48:38 (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-09-2020 11:48:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES Date of Collection:  Oct/6/2020	Initial Entry

**5.a**

Date	Location	User	Value	Reason
Oct-09-2020 11:48:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample ID: BRJ89L</b>	Initial Entry

**5.a Sample ID**

090177e196d8902a\Final\Final On: 22-Apr-2021 02:13 (GMT)

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

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

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

**Site No:** 1117

**Site Name:** (1117) Sundance Clinical Research

**Subject No:** 11171121

**Subject Initials:** ---

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

**Generated Time (GMT):** 21-Apr-2021 18:02

Date	Location	User	Value	Reason
Oct-09-2020 11:48:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> BRJ89L	Initial Entry

Header Text: c4591001

Visit: V2\_VAX2\_L

Form Version: 22-Apr-2020 21:04

Site No: 1117

Subject No: 11171121

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1117) Sundance Clinical Research

Subject Initials: ---

Generated Time (GMT): 21-Apr-2021 18:02

[Back to Form](#)

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

Date	Location	User	Value	Reason
Oct-15-2020 12:04:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**2. Treatment Name**

Date	Location	User	Value	Reason
Oct-15-2020 12:04:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> BLINDED THERAPY	Initial Entry

**3. Formulation:**

Date	Location	User	Value	Reason
Oct-15-2020 12:04:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> INJECTION	Initial Entry

**4. Dose Date Time:**

Date	Location	User	Value	Reason
Oct-15-2020 12:04:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Oct/6/2020 17:09	Initial Entry

**5. Anatomical Location:**

Date	Location	User	Value	Reason
Oct-15-2020 12:04:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> DELTOID MUSCLE	Initial Entry

**6. Body Side:**

Date	Location	User	Value	Reason
Oct-15-2020 12:04:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> RIGHT	Initial Entry

090177e196d8902a\Final\Final On: 22-Apr-2021 02:13 (GMT)

Header Text: c4591001

Visit: V2\_VAX2\_L

Form Version: 22-Apr-2020 21:04

Site No: 1117

Subject No: 11171121

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1117) Sundance Clinical Research

Subject Initials: ---

Generated Time (GMT): 21-Apr-2021 18:02

7. Route:

Date	Location	User	Value	Reason
Oct-15-2020 12:04:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> INTRAMUSCULAR	Initial Entry

10. Timeframe Subject Was Observed

Date	Location	User	Value	Reason
Oct-15-2020 12:04:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> THE PROTOCOL SPECIFIED OBS ERVATION PERIOD	Initial Entry

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

Date	Location	User	Value	Reason
Oct-15-2020 12:04:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

090177e196d8902a\Final\Final On: 22-Apr-2021 02:13 (GMT)

**Header Text:** c4591001

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

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

**Site No:** 1117

**Subject No:** 11171121

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

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

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

**Site Name:** (1117) Sundance Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 21-Apr-2021 18:02

[Back to Form](#)

*I. Date of Visit*

<b>Date</b>	<b>Location</b>	<b>User</b>	<b>Value</b>	<b>Reason</b>
Nov-05-2020 18:28:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Nov/5/2020	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: 1117

Site Name: (1117) Sundance Clinical Research

Subject No: 11171121

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 21-Apr-2021 18:02

[Back to Form](#)

**1. Data Origin**

Date	Location	User	Value	Reason
Nov-05-2020 18:14:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SITE	Initial Entry

**2. Sample Type**

Date	Location	User	Value	Reason
Nov-05-2020 18:14:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SERUM	Initial Entry

**3. Sample Collected?**

Date	Location	User	Value	Reason
Nov-05-2020 18:14:24 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Nov-05-2020 18:14:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Nov-05-2020 18:14:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES Date of Collection:  Nov/5/2020	Initial Entry

**5.a**

Date	Location	User	Value	Reason
Nov-05-2020 18:14:24 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample ID: BP58YY</b>	Initial Entry

**5.a Sample ID**

090177e196d8902a\Final\Final On: 22-Apr-2021 02:13 (GMT)

Header Text: c4591001

Visit: V3\_MONTH1\_POSTVAX2\_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1117

Site Name: (1117) Sundance Clinical Research

Subject No: 11171121

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 21-Apr-2021 18:02

Date	Location	User	Value	Reason
Nov-05-2020 18:14:24 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> BP58YY	Initial Entry

5.b

Date	Location	User	Value	Reason
Nov-05-2020 18:14:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Sample ID: BP58YZ	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Nov-05-2020 18:14:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> BP58YZ	Initial Entry

5.c

Date	Location	User	Value	Reason
Nov-05-2020 18:14:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Sample ID: BP58Z0	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Nov-05-2020 18:14:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> BP58Z0	Initial Entry

5.d

Date	Location	User	Value	Reason
Nov-05-2020 18:14:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Sample ID: BRSRT0	Initial Entry

090177e196d8902a\Final\Final On: 22-Apr-2021 02:13 (GMT)

Header Text: c4591001

Visit: V3\_MONTH1\_POSTVAX2\_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1117

Site Name: (1117) Sundance Clinical Research

Subject No: 11171121

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 21-Apr-2021 18:02

5.d Sample ID

Date	Location	User	Value	Reason
Nov-05-2020 18:14:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> BRSRT0	Initial Entry

5.e

Date	Location	User	Value	Reason
Nov-05-2020 18:15:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Sample ID: BRSRT1	Initial Entry

5.e Sample ID

Date	Location	User	Value	Reason
Nov-05-2020 18:15:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> BRSRT1	Initial Entry

090177e196d8902a\Final\Final On: 22-Apr-2021 02:13 (GMT)

**Header Text:** c4591001**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on **Form:** DATE OF VISIT - ILLNESS ONSET - eCRF Audit Trail History  
Nov/23/2020**Form Version:** 22-Apr-2020 21:03**Form Status:** Data Complete, Frozen, Verified**Site No:** 1117**Site Name:** (1117) Sundance Clinical Research**Subject No:** 11171121**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 21-Apr-2021 18:02[Back to Form](#)**1. Date of Visit**

Date	Location	User	Value	Reason
Nov-25-2020 11:05:06 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Nov-25-2020 11:03:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Deleted	Close Auto Query
Nov-25-2020 11:01:35 (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.
Nov-25-2020 11:01:35 (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.
Nov-25-2020 11:01:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Nov/23/2020	Initial Entry

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

Date	Location	User	Value	Reason
Nov-25-2020 11:01:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> COVID_A	Initial Entry

Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/23/2020 Form: SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF Audit Trail History

Form Version: 10-Oct-2020 16:02

Form Status: Data Complete, Frozen, Verified

Site No: 1117

Site Name: (1117) Sundance Clinical Research

Subject No: 11171121

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 21-Apr-2021 18:02

[Back to Form](#)

1. Date of Assessment:

Date	Location	User	Value	Reason
Nov-25-2020 11:03:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Nov/23/2020	Initial Entry

2. Date of First Symptom Started:

Date	Location	User	Value	Reason
Nov-25-2020 11:03:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Nov/16/2020	Initial Entry

3. Symptoms Ongoing?

Date	Location	User	Value	Reason
Jan-26-2021 12:34:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Jan-26-2021 11:48:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	New Information
Jan-26-2021 11:48:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO Date of Last Symptom Resolved:  Jan/11/2021	New Information
Jan-25-2021 13:49:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	CLINQUERY: Please clarify whether the reported symptoms are still ongoing? If symptoms have ended, please update 'Symptoms Ongoing' on to 'NO' and add Date of Last Symptom Resolved on the CRF.

090177e196d8902a\Final\Final On: 22-Apr-2021 02:13 (GMT)

Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Form: SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF  
Nov/23/2020 Audit Trail History

Form Version: 10-Oct-2020 16:02

Form Status: Data Complete, Frozen, Verified

Site No: 1117

Site Name: (1117) Sundance Clinical Research

Subject No: 11171121

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 21-Apr-2021 18:02

Jan-25-2021 06:52:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Candidate	CLINQUERY: Please clarify whether the reported symptoms are still ongoing? If symptoms have ended, please update 'Symptoms Ongoing' on to 'NO' and add Date of Last Symptom Resolved on the CRF.
Nov-25-2020 11:03:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

4.a

Date	Location	User	Value	Reason
Nov-25-2020 11:02:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptoms:</b> FEVER <b>Symptom Present:</b> NO	Initial Entry

4.a Symptoms:

Date	Location	User	Value	Reason
Nov-25-2020 11:02:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> FEVER	Initial Entry

4.a Was symptom present?

Date	Location	User	Value	Reason
Nov-25-2020 11:02:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

4.b

Date	Location	User	Value	Reason
Nov-25-2020 11:02:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptoms:</b> NEW OR INCREAS ED COUGH	Initial Entry

090177e196d8902a\Final\Final On: 22-Apr-2021 02:13 (GMT)

Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Form: SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF  
Nov/23/2020 Audit Trail History

Form Version: 10-Oct-2020 16:02

Form Status: Data Complete, Frozen, Verified

Site No: 1117

Site Name: (1117) Sundance Clinical Research

Subject No: 11171121

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 21-Apr-2021 18:02

			Symptom P YES resent:	
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4.b Symptoms:

Date	Location	User	Value	Reason
Nov-25-2020 11:02:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NEW OR INCREASED COUGH	Initial Entry

4.b Was symptom present?

Date	Location	User	Value	Reason
Nov-25-2020 11:02:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> YES	Initial Entry

4.c

Date	Location	User	Value	Reason
Nov-25-2020 11:02:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Symptom: NEW OR INCREASED SHORTNESS OF BREATH Symptom Present: NO	Initial Entry

4.c Symptoms:

Date	Location	User	Value	Reason
Nov-25-2020 11:02:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NEW OR INCREASED SHORTNESS OF BREATH	Initial Entry

4.c Was symptom present?

Date	Location	User	Value	Reason
Nov-25-2020 11:02:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

4.d

090177e196d8902a\Final\Final On: 22-Apr-2021 02:13 (GMT)

Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/23/2020 Form: SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF Audit Trail History

Form Version: 10-Oct-2020 16:02

Form Status: Data Complete, Frozen, Verified

Site No: 1117

Site Name: (1117) Sundance Clinical Research

Subject No: 11171121

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 21-Apr-2021 18:02

Date	Location	User	Value	Reason
Nov-25-2020 11:02:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptoms:</b> CHILLS <b>Symptom Present:</b> NO	Initial Entry

4.d Symptoms:

Date	Location	User	Value	Reason
Nov-25-2020 11:02:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> CHILLS	Initial Entry

4.d Was symptom present?

Date	Location	User	Value	Reason
Nov-25-2020 11:02:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

4.e

Date	Location	User	Value	Reason
Nov-25-2020 11:02:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptoms</b> NEW OR INCREASE : D MUSCLE PAIN <b>Symptom</b> YES <b>Present:</b>	Initial Entry

4.e Symptoms:

Date	Location	User	Value	Reason
Nov-25-2020 11:02:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NEW OR INCREASED MUSCLE PAIN	Initial Entry

4.e Was symptom present?

Date	Location	User	Value	Reason
Nov-25-2020 11:02:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

090177e196d8902a\Final\Final On: 22-Apr-2021 02:13 (GMT)



Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/23/2020 Form: SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF Audit Trail History

Form Version: 10-Oct-2020 16:02

Form Status: Data Complete, Frozen, Verified

Site No: 1117

Site Name: (1117) Sundance Clinical Research

Subject No: 11171121

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 21-Apr-2021 18:02

4.f

Date	Location	User	Value	Reason
Nov-25-2020 11:02:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptoms:</b> NEW LOSS OF TASTE OR SMELL <b>Symptom Present:</b> YES	Initial Entry

4.f Symptoms:

Date	Location	User	Value	Reason
Nov-25-2020 11:02:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NEW LOSS OF TASTE OR SMELL	Initial Entry

4.f Was symptom present?

Date	Location	User	Value	Reason
Nov-25-2020 11:02:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

4.g

Date	Location	User	Value	Reason
Nov-25-2020 11:02:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptoms:</b> NEW OR INCREASED SORE THROAT <b>Symptom Present:</b> YES	Initial Entry

090177e196d8902a\Final\Final On: 22-Apr-2021 02:13 (GMT)

Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Form: SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF  
Nov/23/2020 Audit Trail History

Form Version: 10-Oct-2020 16:02

Form Status: Data Complete, Frozen, Verified

Site No: 1117

Site Name: (1117) Sundance Clinical Research

Subject No: 11171121

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 21-Apr-2021 18:02

**4.g Symptoms:**

Date	Location	User	Value	Reason
Nov-25-2020 11:02:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NEW OR INCREASED SORE TH ROAT	Initial Entry

**4.g Was symptom present?**

Date	Location	User	Value	Reason
Nov-25-2020 11:02:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

**4.h**

Date	Location	User	Value	Reason
Nov-25-2020 11:02:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptoms:</b> DIARRHEA <b>Symptom Present:</b> YES	Initial Entry

**4.h Symptoms:**

Date	Location	User	Value	Reason
Nov-25-2020 11:02:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> DIARRHEA	Initial Entry

**4.h Was symptom present?**

Date	Location	User	Value	Reason
Nov-25-2020 11:02:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

**4.i**

Date	Location	User	Value	Reason
Nov-25-2020 11:02:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptoms:</b> VOMITING <b>Symptom Present:</b> NO	Initial Entry

090177e196d8902a\Final\Final On: 22-Apr-2021 02:13 (GMT)

Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/23/2020 Form: SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF Audit Trail History

Form Version: 10-Oct-2020 16:02

Form Status: Data Complete, Frozen, Verified

Site No: 1117

Site Name: (1117) Sundance Clinical Research

Subject No: 11171121

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 21-Apr-2021 18:02

4.i Symptoms:

Date	Location	User	Value	Reason
Nov-25-2020 11:02:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> VOMITING	Initial Entry

4.i Was symptom present?

Date	Location	User	Value	Reason
Nov-25-2020 11:02:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

5.a

Date	Location	User	Value	Reason
Nov-25-2020 11:02:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Symptoms - Other: RHINORRHEA	Initial Entry

5.a Symptoms - Other Text:

Date	Location	User	Value	Reason
Nov-25-2020 11:02:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> RHINORRHEA	Initial Entry

5.b

Date	Location	User	Value	Reason
Nov-25-2020 11:02:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Symptoms - Other: HEADACHE	Initial Entry

5.b Symptoms - Other Text:

Date	Location	User	Value	Reason
Nov-25-2020 11:02:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> HEADACHE	Initial Entry

5.c

090177e196d8902a\Final\Final On: 22-Apr-2021 02:13 (GMT)

Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Form: SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF  
Nov/23/2020 Audit Trail History

Form Version: 10-Oct-2020 16:02

Form Status: Data Complete, Frozen, Verified

Site No: 1117

Site Name: (1117) Sundance Clinical Research

Subject No: 11171121

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 21-Apr-2021 18:02

Date	Location	User	Value	Reason
Nov-25-2020 11:03:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Symptoms - Other: FATIGUE	Initial Entry

*5.c Symptoms - Other Text:*

Date	Location	User	Value	Reason
Nov-25-2020 11:03:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> FATIGUE	Initial Entry

*5.d*

Date	Location	User	Value	Reason
Nov-25-2020 11:03:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Symptoms - Other: NASAL CONGESTION	Initial Entry

*5.d Symptoms - Other Text:*

Date	Location	User	Value	Reason
Nov-25-2020 11:03:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NASAL CONGESTION	Initial Entry

090177e196d8902a\Final\Final On: 22-Apr-2021 02:13 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on **Form:** MICROBIOLOGY SPECIMEN - Audit Trail  
Nov/23/2020

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

**Form Status:**

**Site No:** 1117

**Site Name:** (1117) Sundance Clinical Research

**Subject No:** 11171121

**Subject Initials:** ---

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

**Generated Time (GMT):** 21-Apr-2021 18:02

[Back to Form](#)

Date	Location	User	Value	Reason
Nov-25-2020 11:04:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Form: MICROBIOLOGY SPECIMEN - eCRF Audit Trail History  
Nov/23/2020

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen, Verified

Site No: 1117

Site Name: (1117) Sundance Clinical Research

Subject No: 11171121

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 21-Apr-2021 18:02

[Back to Form](#)

**1. Actual Date of Collection:**

Date	Location	User	Value	Reason
Nov-25-2020 11:04:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Nov/22/2020	Initial Entry

**2. Specimen Type:**

Date	Location	User	Value	Reason
Nov-25-2020 11:04:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> SWABBED MATERIAL	Initial Entry

**3. Specimen Collection Location:**

Date	Location	User	Value	Reason
Nov-25-2020 11:04:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NASOPHARYNX	Initial Entry

**4. Assay Code and Description:**

Date	Location	User	Value	Reason
Nov-25-2020 11:04:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SEVERE ACUTE RESP SYNDRO ME CORONAVIRUS 2	Initial Entry

**5. Device Type:**

Date	Location	User	Value	Reason
Nov-25-2020 11:04:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SARS-COV-2 DIAGNOSTIC TEST	Initial Entry

**6. Trade Name:**

Date	Location	User	Value	Reason
Nov-25-2020 11:04:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> OTHER	Initial Entry

090177e196d8902a\Final\Final On: 22-Apr-2021 02:13 (GMT)

Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Form: MICROBIOLOGY SPECIMEN - eCRF Audit Trail History  
Nov/23/2020

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen, Verified

Site No: 1117

Site Name: (1117) Sundance Clinical Research

Subject No: 11171121

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 21-Apr-2021 18:02

7. Test Result:

Date	Location	User	Value	Reason
Nov-25-2020 11:04:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> POSITIVE	Initial Entry

8. Comments/Findings/Details:

Date	Location	User	Value	Reason
Nov-25-2020 11:04:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> CLIA ACCREDITED FACILITY	Initial Entry

9. Trade Name Other, Specify:

Date	Location	User	Value	Reason
Dec-01-2020 15:58:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Dec-01-2020 11:23:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Changed Information
Dec-01-2020 11:23:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> CLIA CERTIFIED LAB	Changed Information
Nov-27-2020 13:38:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	Clinical Query: Per CRF CRs 8.31.7, please enter if test conducted at 'CLIA-certified lab' or 'ISO 15189 accredited lab.'
Nov-25-2020 11:04:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NALT UNKNOWN	Initial Entry

090177e196d8902a\Final\Final On: 22-Apr-2021 02:13 (GMT)

Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/23/2020 Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB SELF - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1117

Site Name: (1117) Sundance Clinical Research

Subject No: 11171121

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 21-Apr-2021 18:02

[Back to Form](#)

1. Data Origin

Date	Location	User	Value	Reason
Nov-25-2020 11:05:06 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Nov-25-2020 11:05:06 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> NASAL_SWAB_SELF	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Nov-25-2020 11:05:18 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Nov-25-2020 11:05:06 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Nov-25-2020 11:05:06 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES Date of Collection:  Nov/22/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Nov-25-2020 11:05:18 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample ID:</b> CV05746	Initial Entry

5.a Sample ID

090177e196d8902a\Final\Final On: 22-Apr-2021 02:13 (GMT)



**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/23/2020 **Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB SELF - eCRF Audit Trail History

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

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

**Site No:** 1117

**Site Name:** (1117) Sundance Clinical Research

**Subject No:** 11171121

**Subject Initials:** ---

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

**Generated Time (GMT):** 21-Apr-2021 18:02

Date	Location	User	Value	Reason
Nov-25-2020 11:05:18 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> CV05746	Initial Entry

Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/23/2020 Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1117

Site Name: (1117) Sundance Clinical Research

Subject No: 11171121

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 21-Apr-2021 18:02

[Back to Form](#)

**1. Data Origin**

Date	Location	User	Value	Reason
Nov-25-2020 11:05:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SITE	Initial Entry

**2. Sample Type**

Date	Location	User	Value	Reason
Nov-25-2020 11:05:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> NASAL_SWAB	Initial Entry

**3. Sample Collected?**

Date	Location	User	Value	Reason
Nov-25-2020 11:05:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**4. If no sample was collected or sample was not collected according to protocol, please provide reason:**

Date	Location	User	Value	Reason
Nov-25-2020 11:05:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> TELEHEALTH VISIT, SEE SELF SWAB	Initial Entry

090177e196d8902a\Final\Final On: 22-Apr-2021 02:13 (GMT)

Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Form: HEALTH CARE UTILIZATION - eCRF Audit Trail History  
Nov/23/2020

Form Version: 10-Oct-2020 15:59

Form Status: Data Complete, Frozen, Verified

Site No: 1117

Site Name: (1117) Sundance Clinical Research

Subject No: 11171121

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 21-Apr-2021 18:02

[Back to Form](#)

*I.a*

Date	Location	User	Value	Reason
Nov-25-2020 11:06:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Type of Practitioner:</b> SPECIALIST <b>Occurrence of Visits or Contacts:</b> NO	Initial Entry

*I.a Physician or Healthcare Professional:*

Date	Location	User	Value	Reason
Nov-25-2020 11:06:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> SPECIALIST	Initial Entry

*I.a Occurrence of Visits or Contacts:*

Date	Location	User	Value	Reason
Nov-25-2020 11:06:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

*I.b*

Date	Location	User	Value	Reason
Nov-25-2020 11:06:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Type of Practitioner:</b> EMERGENCY ROOM <b>Occurrence of Visits or Contacts:</b> NO	Initial Entry

090177e196d8902a\Final\Final On: 22-Apr-2021 02:13 (GMT)

Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Form: HEALTH CARE UTILIZATION - eCRF Audit Trail History  
Nov/23/2020

Form Version: 10-Oct-2020 15:59

Form Status: Data Complete, Frozen, Verified

Site No: 1117

Site Name: (1117) Sundance Clinical Research

Subject No: 11171121

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 21-Apr-2021 18:02

**I.b Physician or Healthcare Professional:**

Date	Location	User	Value	Reason
Nov-25-2020 11:06:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> EMERGENCY ROOM	Initial Entry

**I.b Occurrence of Visits or Contacts:**

Date	Location	User	Value	Reason
Nov-25-2020 11:06:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**I.c**

Date	Location	User	Value	Reason
Nov-25-2020 11:06:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Type of Practitioner:</b> PRIMARY CARE PHYSICIAN <b>Occurrence of Visits or Contacts:</b> NO	Initial Entry

**I.c Physician or Healthcare Professional:**

Date	Location	User	Value	Reason
Nov-25-2020 11:06:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> PRIMARY CARE PHYSICIAN	Initial Entry

**I.c Occurrence of Visits or Contacts:**

Date	Location	User	Value	Reason
Nov-25-2020 11:06:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**I.d**

Date	Location	User	Value	Reason
Nov-25-2020 11:06:36 (UTC-06:00) Central Time	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Type of Practitioner:</b> URGENT CARE	Initial Entry

090177e196d8902a\Final\Final On: 22-Apr-2021 02:13 (GMT)

Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Form: HEALTH CARE UTILIZATION - eCRF Audit Trail History  
Nov/23/2020

Form Version: 10-Oct-2020 15:59

Form Status: Data Complete, Frozen, Verified

Site No: 1117

Site Name: (1117) Sundance Clinical Research

Subject No: 11171121

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 21-Apr-2021 18:02

(US & Canada)		(b) (4), (b) (6)	ner: E Occurrence of Visits or Contacts: YES Number of Visits or Contacts: 1
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**I.d Physician or Healthcare Professional:**

Date	Location	User	Value	Reason
Nov-25-2020 11:06:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> URGENT CARE	Initial Entry

**I.d Occurrence of Visits or Contacts:**

Date	Location	User	Value	Reason
Nov-25-2020 11:06:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES Number of Visits or Contacts: 1	Initial Entry

**I.e**

Date	Location	User	Value	Reason
Nov-25-2020 11:06:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Type of Practitioner:</b> TELEPHONE CONSULTATION <b>Occurrence of Visits or Contacts:</b> YES Number of Visits or Contacts: 1	Initial Entry

090177e196d8902a\Final\Final On: 22-Apr-2021 02:13 (GMT)

**Header Text:** c4591001**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on **Form:** HEALTH CARE UTILIZATION - eCRF Audit Trail History  
Nov/23/2020**Form Version:** 10-Oct-2020 15:59**Form Status:** Data Complete, Frozen, Verified**Site No:** 1117**Site Name:** (1117) Sundance Clinical Research**Subject No:** 11171121**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 21-Apr-2021 18:02***1.e Physician or Healthcare Professional:***

Date	Location	User	Value	Reason
Nov-25-2020 11:06:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> TELEPHONE CONSULTATION	Initial Entry

***1.e Occurrence of Visits or Contacts:***

Date	Location	User	Value	Reason
Nov-25-2020 11:06:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES <i>Number of Visits or Contacts:</i>  1	Initial Entry

***1.f***

Date	Location	User	Value	Reason
Nov-25-2020 11:06:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Type of Practitioner:</b> OTH R <b>Occurrence of Visits or C</b> NO <b>ontacts:</b>	Initial Entry

***1.f Physician or Healthcare Professional:***

Date	Location	User	Value	Reason
Nov-25-2020 11:06:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> OTHER	Initial Entry

***1.f Occurrence of Visits or Contacts:***

Date	Location	User	Value	Reason
Nov-25-2020 11:06:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

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

Date	Location	User	Value	Reason
Nov-25-2020 11:06:36	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	Initial Entry

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on **Form:** HEALTH CARE UTILIZATION - eCRF Audit Trail History  
Nov/23/2020

**Form Version:** 10-Oct-2020 15:59

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

**Site No:** 1117

**Site Name:** (1117) Sundance Clinical Research

**Subject No:** 11171121

**Subject Initials:** ---

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

**Generated Time (GMT):** 21-Apr-2021 18:02

(UTC-06:00) Central Time  
(US & Canada)

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

NO

Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Form: RESPIRATORY TREATMENT - eCRF Audit Trail History  
Nov/23/2020

Form Version: 06-Jul-2020 21:53

Form Status: Data Complete, Frozen, Verified

Site No: 1117

Site Name: (1117) Sundance Clinical Research

Subject No: 11171121

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 21-Apr-2021 18:02

[Back to Form](#)

**1. What is the treatment Identifier?**

Date	Location	User	Value	Reason
Nov-25-2020 11:06:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

**2. Concomitant Non-drug Treatment Pre-specified:**

Date	Location	User	Value	Reason
Nov-25-2020 11:06:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

**3. Treatment:**

Date	Location	User	Value	Reason
Nov-25-2020 11:06:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

**4. Treatment:**

Date	Location	User	Value	Reason
Nov-25-2020 11:06:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

**5. Start Date:**

Date	Location	User	Value	Reason
Nov-25-2020 11:06:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

**6. Ongoing?**

Date	Location	User	Value	Reason
Nov-25-2020 11:06:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

090177e196d8902a\Final\Final On: 22-Apr-2021 02:13 (GMT)



Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Form: ILLNESS DETAILS - eCRF Audit Trail History  
Nov/23/2020

Form Version: 06-Jul-2020 21:52

Form Status: Data Complete, Frozen, Verified

Site No: 1117

Site Name: (1117) Sundance Clinical Research

Subject No: 11171121

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 21-Apr-2021 18:02

[Back to Form](#)

**1. Category of Clinical Event:**

Date	Location	User	Value	Reason
Nov-25-2020 11:07:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> POTENTIAL COVID-19 ILLNESS	Initial Entry

**2. Was a diagnosis obtained for Potential COVID-19 Illness?**

Date	Location	User	Value	Reason
Nov-25-2020 11:07:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES <i>Respiratory Illness Diagnosis:</i>  COVID-19 INFECTION  Date of Diagnosis:  Nov/22/2020	Initial Entry

**3. Toxicity Grade:**

Date	Location	User	Value	Reason
Nov-25-2020 11:07:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 3	Initial Entry

090177e196d8902a\Final\Final On: 22-Apr-2021 02:13 (GMT)

Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Form: ILLNESS DETAILS - SEVERE - eCRF Audit Trail History  
Nov/23/2020

Form Version: 17-Jul-2020 21:55

Form Status: Data Complete, Frozen, Verified

Site No: 1117

Site Name: (1117) Sundance Clinical Research

Subject No: 11171121

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 21-Apr-2021 18:02

[Back to Form](#)

**1. Category of Clinical Event:**

Date	Location	User	Value	Reason
Nov-25-2020 11:08:23 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry
Nov-25-2020 11:08:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	Initial Entry
Nov-25-2020 11:07:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

**2. Subcategory of Clinical Event:**

Date	Location	User	Value	Reason
Nov-25-2020 11:08:23 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

**3. Was a diagnosis obtained?**

Date	Location	User	Value	Reason
Nov-25-2020 11:08:23 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

**4. Toxicity Grade:**

Date	Location	User	Value	Reason
Nov-25-2020 11:08:23 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

090177e196d8902a\Final\Final On: 22-Apr-2021 02:13 (GMT)

Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/23/2020 Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History

Form Version: 15-Sep-2020 21:51

Form Status: Data Complete, Frozen, Verified

Site No: 1117

Site Name: (1117) Sundance Clinical Research

Subject No: 11171121

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 21-Apr-2021 18:02

[Back to Form](#)

1. Lab Panel:

Date	Location	User	Value	Reason
Nov-25-2020 11:08:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

2. Laboratory Name and Address

Date	Location	User	Value	Reason
Nov-25-2020 11:08:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

3. Collection Date:

Date	Location	User	Value	Reason
Nov-25-2020 11:08:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

4. Specimen Type:

Date	Location	User	Value	Reason
Nov-25-2020 11:08:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

5.a

Date	Location	User	Value	Reason
Nov-25-2020 11:08:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sponsor-Defined Identifier: Not Done Test:: Not Done Result:: Not Done Not Done:: Not Done	Initial Entry

090177e196d8902a\Final\Final On: 22-Apr-2021 02:13 (GMT)

Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/23/2020 Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History

Form Version: 15-Sep-2020 21:51

Form Status: Data Complete, Frozen, Verified

Site No: 1117

Site Name: (1117) Sundance Clinical Research

Subject No: 11171121

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 21-Apr-2021 18:02

			Lab Normal Range:	Not Done
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5.a Sponsor ID:

Date	Location	User	Value	Reason
Nov-25-2020 11:08:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Done	Initial Entry

5.a Test:

Date	Location	User	Value	Reason
Nov-25-2020 11:08:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Done	Initial Entry

5.a Result:

Date	Location	User	Value	Reason
Nov-25-2020 11:08:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Done	Initial Entry

5.a Not Done:

Date	Location	User	Value	Reason
Nov-25-2020 11:08:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Done	Initial Entry

5.a LNMT

Date	Location	User	Value	Reason
Nov-25-2020 11:08:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Done	Initial Entry

5.b

Date	Location	User	Value	Reason
Nov-25-2020 11:08:41 (UTC-06:00) Central Time	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Sponsor-Defined Identif Not Don	Initial Entry

090177e196d8902a\Final\Final On: 22-Apr-2021 02:13 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/23/2020 **Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History

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

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

**Site No:** 1117

**Site Name:** (1117) Sundance Clinical Research

**Subject No:** 11171121

**Subject Initials:** ---

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

**Generated Time (GMT):** 21-Apr-2021 18:02

(US & Canada)	(b) (4), (b) (6)	<b>ier:</b> e	
		<b>Test::</b> Not Done	
		e	
		<b>Result::</b> Not Done	
		e	
		<b>Not Done::</b> Not Done	
		e	
		<b>Lab Normal Range:</b> Not Done	
		e	

Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/23/2020 Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History

Form Version: 15-Sep-2020 21:51

Form Status: Data Complete, Frozen, Verified

Site No: 1117

Site Name: (1117) Sundance Clinical Research

Subject No: 11171121

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 21-Apr-2021 18:02

**5.b Sponsor ID:**

Date	Location	User	Value	Reason
Nov-25-2020 11:08:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

**5.b Test:**

Date	Location	User	Value	Reason
Nov-25-2020 11:08:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

**5.b Result:**

Date	Location	User	Value	Reason
Nov-25-2020 11:08:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

**5.b Not Done:**

Date	Location	User	Value	Reason
Nov-25-2020 11:08:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

**5.b LNMT**

Date	Location	User	Value	Reason
Nov-25-2020 11:08:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

**5.c**

Date	Location	User	Value	Reason
Nov-25-2020 11:08:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sponsor-Defined Identifier: Not Done <b>Test::</b> Not Done	Initial Entry

090177e196d8902a\Final\Final On: 22-Apr-2021 02:13 (GMT)

Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/23/2020 Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History

Form Version: 15-Sep-2020 21:51

Form Status: Data Complete, Frozen, Verified

Site No: 1117

Site Name: (1117) Sundance Clinical Research

Subject No: 11171121

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 21-Apr-2021 18:02

			<b>Result::</b>	Not Done
			<b>Not Done::</b>	Not Done
			<b>Lab Normal Range:</b>	Not Done

5.c Sponsor ID:

Date	Location	User	Value	Reason
Nov-25-2020 11:08:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

5.c Test:

Date	Location	User	Value	Reason
Nov-25-2020 11:08:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

5.c Result:

Date	Location	User	Value	Reason
Nov-25-2020 11:08:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

5.c Not Done:

Date	Location	User	Value	Reason
Nov-25-2020 11:08:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

5.c LNMT

Date	Location	User	Value	Reason
Nov-25-2020 11:08:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

5.d

090177e196d8902a\Final\Final On: 22-Apr-2021 02:13 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/23/2020 **Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History

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

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

**Site No:** 1117

**Site Name:** (1117) Sundance Clinical Research

**Subject No:** 11171121

**Subject Initials:** ---

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

**Generated Time (GMT):** 21-Apr-2021 18:02

Date	Location	User	Value	Reason
Nov-25-2020 11:08:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sponsor-Defined Identifier:</b> Not Done <b>Test::</b> Not Done <b>Result::</b> Not Done <b>Not Done::</b> Not Done <b>Lab Normal Range:</b> Not Done	Initial Entry



Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/23/2020 Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History

Form Version: 15-Sep-2020 21:51

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Site No: 1117

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Generated Time (GMT): 21-Apr-2021 18:02

5.d Sponsor ID:

Date	Location	User	Value	Reason
Nov-25-2020 11:08:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Done	Initial Entry

5.d Test:

Date	Location	User	Value	Reason
Nov-25-2020 11:08:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Done	Initial Entry

5.d Result:

Date	Location	User	Value	Reason
Nov-25-2020 11:08:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Done	Initial Entry

5.d Not Done:

Date	Location	User	Value	Reason
Nov-25-2020 11:08:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Done	Initial Entry

5.d LNMT

Date	Location	User	Value	Reason
Nov-25-2020 11:08:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Done	Initial Entry

5.e

Date	Location	User	Value	Reason
Nov-25-2020 11:08:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Sponsor-Defined Identifier: Not Done Test:: Not Done	Initial Entry

090177e196d8902a\Final\Final On: 22-Apr-2021 02:13 (GMT)

Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/23/2020 Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History

Form Version: 15-Sep-2020 21:51

Form Status: Data Complete, Frozen, Verified

Site No: 1117

Site Name: (1117) Sundance Clinical Research

Subject No: 11171121

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 21-Apr-2021 18:02

			<b>Result::</b>	Not Done
			<b>Not Done::</b>	Not Done
			<b>Lab Normal Range:</b>	Not Done

5.e Sponsor ID:

Date	Location	User	Value	Reason
Nov-25-2020 11:08:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

5.e Test:

Date	Location	User	Value	Reason
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5.e Result:

Date	Location	User	Value	Reason
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5.e Not Done:

Date	Location	User	Value	Reason
Nov-25-2020 11:08:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

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Date	Location	User	Value	Reason
Nov-25-2020 11:08:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

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Date	Location	User	Value	Reason
Nov-25-2020 11:08:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sponsor-Defined Identifier:</b> Not Done <b>Test::</b> Not Done <b>Result::</b> Not Done <b>Not Done::</b> Not Done <b>Lab Normal Range:</b> Not Done	Initial Entry

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5.f Sponsor ID:

Date	Location	User	Value	Reason
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5.f Test:

Date	Location	User	Value	Reason
Nov-25-2020 11:08:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Done	Initial Entry

5.f Result:

Date	Location	User	Value	Reason
Nov-25-2020 11:08:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Done	Initial Entry

5.f Not Done:

Date	Location	User	Value	Reason
Nov-25-2020 11:08:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Done	Initial Entry

5.f LNMT

Date	Location	User	Value	Reason
Nov-25-2020 11:08:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Done	Initial Entry

5.g

Date	Location	User	Value	Reason
Nov-25-2020 11:08:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Sponsor-Defined Identifier: Not Done Test:: Not Done	Initial Entry

090177e196d8902a\Final\Final On: 22-Apr-2021 02:13 (GMT)

Header Text: c4591001

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Site No: 1117

Site Name: (1117) Sundance Clinical Research

Subject No: 11171121

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 21-Apr-2021 18:02

			<b>Result::</b>	Not Done
			<b>Not Done::</b>	Not Done
			<b>Lab Normal Range:</b>	Not Done

5.g Sponsor ID:

Date	Location	User	Value	Reason
Nov-25-2020 11:08:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

5.g Test:

Date	Location	User	Value	Reason
Nov-25-2020 11:08:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

5.g Result:

Date	Location	User	Value	Reason
Nov-25-2020 11:08:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

5.g Not Done:

Date	Location	User	Value	Reason
Nov-25-2020 11:08:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

5.g LNMT

Date	Location	User	Value	Reason
Nov-25-2020 11:08:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

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Form Version: 15-Sep-2020 21:55

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Site No: 1117

Site Name: (1117) Sundance Clinical Research

Subject No: 11171121

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 21-Apr-2021 18:02

[Back to Form](#)

**1. Lab Panel:**

Date	Location	User	Value	Reason
Nov-25-2020 11:08:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

**2. Laboratory Name and Address**

Date	Location	User	Value	Reason
Nov-25-2020 11:08:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

**3. Collection Date:**

Date	Location	User	Value	Reason
Nov-25-2020 11:08:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

**4. Specimen Type:**

Date	Location	User	Value	Reason
Nov-25-2020 11:08:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

**5.a**

Date	Location	User	Value	Reason
Nov-25-2020 11:08:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sponsor-Defined Identifier: Not Done Test:: Not Done Result:: Not Done Not Done:: Not Done	Initial Entry

090177e196d8902a\Final\Final On: 22-Apr-2021 02:13 (GMT)

Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF  
Nov/23/2020 Audit Trail History

Form Version: 15-Sep-2020 21:55

Form Status: Data Complete, Frozen, Verified

Site No: 1117

Site Name: (1117) Sundance Clinical Research

Subject No: 11171121

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 21-Apr-2021 18:02

			Lab Normal Range:	Not Done
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5.a Sponsor ID:

Date	Location	User	Value	Reason
Nov-25-2020 11:08:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Done	Initial Entry

5.a Test:

Date	Location	User	Value	Reason
Nov-25-2020 11:08:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Done	Initial Entry

5.a Result:

Date	Location	User	Value	Reason
Nov-25-2020 11:08:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Done	Initial Entry

5.a Not Done:

Date	Location	User	Value	Reason
Nov-25-2020 11:08:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Done	Initial Entry

5.a LNMT

Date	Location	User	Value	Reason
Nov-25-2020 11:08:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Done	Initial Entry

5.b

Date	Location	User	Value	Reason
Nov-25-2020 11:08:58 (UTC-06:00) Central Time	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Sponsor-Defined Identif Not Don	Initial Entry

090177e196d8902a\Final\Final On: 22-Apr-2021 02:13 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on **Form:** LOCAL LABORATORY DATA - REPEATING Hematology - eCRF  
Nov/23/2020 Audit Trail History

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

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**Site No:** 1117

**Site Name:** (1117) Sundance Clinical Research

**Subject No:** 11171121

**Subject Initials:** ---

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

**Generated Time (GMT):** 21-Apr-2021 18:02

(US & Canada)	(b) (4), (b) (6)	<b>ier:</b> e	
		<b>Test::</b> Not Done	
		e	
		<b>Result::</b> Not Done	
		e	
		<b>Not Done::</b> Not Done	
		e	
		<b>Lab Normal Range:</b> Not Done	
		e	



Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF  
Nov/23/2020 Audit Trail History

Form Version: 15-Sep-2020 21:55

Form Status: Data Complete, Frozen, Verified

Site No: 1117

Site Name: (1117) Sundance Clinical Research

Subject No: 11171121

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 21-Apr-2021 18:02

**5.b Sponsor ID:**

Date	Location	User	Value	Reason
Nov-25-2020 11:08:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Done	Initial Entry

**5.b Test:**

Date	Location	User	Value	Reason
Nov-25-2020 11:08:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Done	Initial Entry

**5.b Result:**

Date	Location	User	Value	Reason
Nov-25-2020 11:08:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Done	Initial Entry

**5.b Not Done:**

Date	Location	User	Value	Reason
Nov-25-2020 11:08:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Done	Initial Entry

**5.b LNMT**

Date	Location	User	Value	Reason
Nov-25-2020 11:08:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Done	Initial Entry

**5.c**

Date	Location	User	Value	Reason
Nov-25-2020 11:08:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Sponsor-Defined Identifier: Not Done Test:: Not Done	Initial Entry

090177e196d8902a\Final\Final On: 22-Apr-2021 02:13 (GMT)

Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF  
Nov/23/2020 Audit Trail History

Form Version: 15-Sep-2020 21:55

Form Status: Data Complete, Frozen, Verified

Site No: 1117

Site Name: (1117) Sundance Clinical Research

Subject No: 11171121

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 21-Apr-2021 18:02

			<b>Result::</b>	Not Done
			<b>Not Done::</b>	Not Done
			<b>Lab Normal Range:</b>	Not Done

5.c Sponsor ID:

Date	Location	User	Value	Reason
Nov-25-2020 11:08:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

5.c Test:

Date	Location	User	Value	Reason
Nov-25-2020 11:08:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

5.c Result:

Date	Location	User	Value	Reason
Nov-25-2020 11:08:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

5.c Not Done:

Date	Location	User	Value	Reason
Nov-25-2020 11:08:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

5.c LNMT

Date	Location	User	Value	Reason
Nov-25-2020 11:08:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

5.d

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Nov-25-2020 11:08:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sponsor-Defined Identifier:</b> Not Done <b>Test::</b> Not Done <b>Result::</b> Not Done <b>Not Done::</b> Not Done <b>Lab Normal Range:</b> Not Done	Initial Entry

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Nov/23/2020 Audit Trail History

Form Version: 15-Sep-2020 21:55

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5.e

Date	Location	User	Value	Reason
Nov-25-2020 11:08:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Sponsor-Defined Identifier: Not Done Test:: Not Done	Initial Entry

090177e196d8902a\Final\Final On: 22-Apr-2021 02:13 (GMT)

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Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF  
Nov/23/2020 Audit Trail History

Form Version: 15-Sep-2020 21:55

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			<b>Result::</b>	Not Done
			<b>Not Done::</b>	Not Done
			<b>Lab Normal Range:</b>	Not Done

5.e Sponsor ID:

Date	Location	User	Value	Reason
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090177e196d8902a\Final\Final On: 22-Apr-2021 02:13 (GMT)

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Nov/23/2020 Audit Trail History

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Nov/23/2020 Audit Trail History

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Generated Time (GMT): 21-Apr-2021 18:02

5.f Sponsor ID:

Date	Location	User	Value	Reason
Nov-25-2020 11:08:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Done	Initial Entry

5.f Test:

Date	Location	User	Value	Reason
Nov-25-2020 11:08:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Done	Initial Entry

5.f Result:

Date	Location	User	Value	Reason
Nov-25-2020 11:08:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Done	Initial Entry

5.f Not Done:

Date	Location	User	Value	Reason
Nov-25-2020 11:08:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Done	Initial Entry

5.f LNMT

Date	Location	User	Value	Reason
Nov-25-2020 11:08:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Done	Initial Entry

5.g

Date	Location	User	Value	Reason
Nov-25-2020 11:08:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Sponsor-Defined Identifier: Not Done Test:: Not Done	Initial Entry

090177e196d8902a\Final\Final On: 22-Apr-2021 02:13 (GMT)

Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF  
Nov/23/2020 Audit Trail History

Form Version: 15-Sep-2020 21:55

Form Status: Data Complete, Frozen, Verified

Site No: 1117

Site Name: (1117) Sundance Clinical Research

Subject No: 11171121

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 21-Apr-2021 18:02

			<b>Result::</b>	Not Done
			<b>Not Done::</b>	Not Done
			<b>Lab Normal Range:</b>	Not Done

5.g Sponsor ID:

Date	Location	User	Value	Reason
Nov-25-2020 11:08:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

5.g Test:

Date	Location	User	Value	Reason
Nov-25-2020 11:08:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

5.g Result:

Date	Location	User	Value	Reason
Nov-25-2020 11:08:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

5.g Not Done:

Date	Location	User	Value	Reason
Nov-25-2020 11:08:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

5.g LNMT

Date	Location	User	Value	Reason
Nov-25-2020 11:08:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

5.h

090177e196d8902a\Final\Final On: 22-Apr-2021 02:13 (GMT)



**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/23/2020 **Form:** LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

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

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

**Site No:** 1117

**Site Name:** (1117) Sundance Clinical Research

**Subject No:** 11171121

**Subject Initials:** ---

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

**Generated Time (GMT):** 21-Apr-2021 18:02

Date	Location	User	Value	Reason
Nov-25-2020 11:08:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sponsor-Defined Identifier:</b> Not Done <b>Test::</b> Not Done <b>Result::</b> Not Done <b>Not Done::</b> Not Done <b>Lab Normal Range:</b> Not Done	Initial Entry

Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF  
Nov/23/2020 Audit Trail History

Form Version: 15-Sep-2020 21:55

Form Status: Data Complete, Frozen, Verified

Site No: 1117

Site Name: (1117) Sundance Clinical Research

Subject No: 11171121

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 21-Apr-2021 18:02

**5.h Sponsor ID:**

Date	Location	User	Value	Reason
Nov-25-2020 11:08:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Done	Initial Entry

**5.h Test:**

Date	Location	User	Value	Reason
Nov-25-2020 11:08:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Done	Initial Entry

**5.h Result:**

Date	Location	User	Value	Reason
Nov-25-2020 11:08:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Done	Initial Entry

**5.h Not Done:**

Date	Location	User	Value	Reason
Nov-25-2020 11:08:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Done	Initial Entry

**5.h LNMT**

Date	Location	User	Value	Reason
Nov-25-2020 11:08:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Done	Initial Entry

**5.i**

Date	Location	User	Value	Reason
Nov-25-2020 11:08:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Sponsor-Defined Identifier: Not Done Test:: Not Done	Initial Entry

090177e196d8902a\Final\Final On: 22-Apr-2021 02:13 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/23/2020 **Form:** LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

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

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

**Site No:** 1117

**Site Name:** (1117) Sundance Clinical Research

**Subject No:** 11171121

**Subject Initials:** ---

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

**Generated Time (GMT):** 21-Apr-2021 18:02

			<b>Result::</b>	Not Done
				e
			<b>Not Done::</b>	Not Done
				e
			<b>Lab Normal Range:</b>	Not Done
				e

Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/23/2020 Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

Form Version: 15-Sep-2020 21:55

Form Status: Data Complete, Frozen, Verified

Site No: 1117

Site Name: (1117) Sundance Clinical Research

Subject No: 11171121

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 21-Apr-2021 18:02

[Back to Form](#)

**5.i Sponsor ID:**

Date	Location	User	Value	Reason
Nov-25-2020 11:08:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

**5.i Test:**

Date	Location	User	Value	Reason
Nov-25-2020 11:08:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

**5.i Result:**

Date	Location	User	Value	Reason
Nov-25-2020 11:08:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

**5.i Not Done:**

Date	Location	User	Value	Reason
Nov-25-2020 11:08:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

**5.i LNMT**

Date	Location	User	Value	Reason
Nov-25-2020 11:08:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

**5.j**

Date	Location	User	Value	Reason
Nov-25-2020 11:08:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sponsor-Defined Identifier: Not Done	Initial Entry

090177e196d8902a\Final\Final On: 22-Apr-2021 02:13 (GMT)

Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF  
Nov/23/2020 Audit Trail History

Form Version: 15-Sep-2020 21:55

Form Status: Data Complete, Frozen, Verified

Site No: 1117

Site Name: (1117) Sundance Clinical Research

Subject No: 11171121

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 21-Apr-2021 18:02

			Test::	Not Done
			Result::	Not Done
			Not Done::	Not Done
			Lab Normal Range:	Not Done

5.j Sponsor ID:

Date	Location	User	Value	Reason
Nov-25-2020 11:08:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Done	Initial Entry

5.j Test:

Date	Location	User	Value	Reason
Nov-25-2020 11:08:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Done	Initial Entry

5.j Result:

Date	Location	User	Value	Reason
Nov-25-2020 11:08:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Done	Initial Entry

5.j Not Done:

Date	Location	User	Value	Reason
Nov-25-2020 11:08:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Done	Initial Entry

5.j LNMT

Date	Location	User	Value	Reason
Nov-25-2020 11:08:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Done	Initial Entry

090177e196d8902a\Final\Final On: 22-Apr-2021 02:13 (GMT)

Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Form: VITAL SIGNS - COVID - eCRF Audit Trail History  
Nov/23/2020

Form Version: 15-Sep-2020 21:52

Form Status: Data Complete, Frozen, Verified

Site No: 1117

Site Name: (1117) Sundance Clinical Research

Subject No: 11171121

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 21-Apr-2021 18:02

[Back to Form](#)

**1. Date:**

Date	Location	User	Value	Reason
Nov-25-2020 11:09:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

**2.a**

Date	Location	User	Value	Reason
Nov-25-2020 11:09:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Record Identifier::</b> Not D one <b>Systolic::</b> Not D one <b>Diastolic::</b> Not D one <b>Respiratory Rate in respir</b> Not D <b>ations/minute:</b> one <b>Heart Rate in beats/minut</b> Not D <b>e:</b> one	Initial Entry

**2.a Record Identifier:**

Date	Location	User	Value	Reason
Nov-25-2020 11:09:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

**2.a Systolic:**

Date	Location	User	Value	Reason
Nov-25-2020 11:09:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

**2.a Diastolic:**

Date	Location	User	Value	Reason
Nov-25-2020 11:09:15 (UTC-06:00) Central Time	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

090177e196d8902a\Final\Final On: 22-Apr-2021 02:13 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on **Form:** VITAL SIGNS - COVID - eCRF Audit Trail History  
Nov/23/2020

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

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

**Site No:** 1117

**Site Name:** (1117) Sundance Clinical Research

**Subject No:** 11171121

**Subject Initials:** ---

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

**Generated Time (GMT):** 21-Apr-2021 18:02

(US & Canada)

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

**2.a Respiratory Rate in respirations/minute:**

Date	Location	User	Value	Reason
Nov-25-2020 11:09:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

**2.a Heart Rate in beats/minute:**

Date	Location	User	Value	Reason
Nov-25-2020 11:09:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

090177e196d8902a\Final\Final On: 22-Apr-2021 02:13 (GMT)

Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/23/2020 Form: VITAL SIGNS - PULSE OX ROOM AIR - eCRF Audit Trail History

Form Version: 15-Sep-2020 21:54

Form Status: Data Complete, Frozen, Verified

Site No: 1117

Site Name: (1117) Sundance Clinical Research

Subject No: 11171121

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 21-Apr-2021 18:02

[Back to Form](#)

**1. Date:**

Date	Location	User	Value	Reason
Nov-25-2020 11:09:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

**2.a**

Date	Location	User	Value	Reason
Nov-25-2020 11:09:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Record Identifier::</b> Not Done <b>Oxygen Saturation:</b> Not Done	Initial Entry

**2.a Record Identifier:**

Date	Location	User	Value	Reason
Nov-25-2020 11:09:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

**2.a SPO2 Pulse Oximetry %**

Date	Location	User	Value	Reason
Nov-25-2020 11:09:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

090177e196d8902a\Final\Final On: 22-Apr-2021 02:13 (GMT)



Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Form: OXYGENATION PARAMETERS - eCRF Audit Trail History  
Nov/23/2020

Form Version: 06-Jul-2020 21:52

Form Status: Data Complete, Frozen, Verified

Site No: 1117

Site Name: (1117) Sundance Clinical Research

Subject No: 11171121

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 21-Apr-2021 18:02

[Back to Form](#)

**1. Date Time of Assessment:**

Date	Location	User	Value	Reason
Nov-25-2020 11:09:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

**2. Arterial Blood Gases PaO2 (mmHg):**

Date	Location	User	Value	Reason
Nov-25-2020 11:09:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

**3. FiO2 (Fraction of Inhaled Oxygen):**

Date	Location	User	Value	Reason
Nov-25-2020 11:09:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

090177e196d8902a\Final\Final On: 22-Apr-2021 02:13 (GMT)

Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Form: CONCOMITANT MEDICATIONS - VASOPRESSORS - eCRF  
Nov/23/2020 Audit Trail History

Form Version: 06-Jul-2020 21:55

Form Status: Data Complete, Frozen, Verified

Site No: 1117

Site Name: (1117) Sundance Clinical Research

Subject No: 11171121

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 21-Apr-2021 18:02

[Back to Form](#)

**1. What is the medication identifier?**

Date	Location	User	Value	Reason
Nov-25-2020 11:10:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

**2. Category:**

Date	Location	User	Value	Reason
Nov-25-2020 11:10:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

**3. Concomitant Medications Pre-specified:**

Date	Location	User	Value	Reason
Nov-25-2020 11:10:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

**4. Medication:**

*Provide the complete generic drug name (including salt form, where applicable). Where generic name is unknown, enter the full trade or proprietary name. Include clarifying information in the Medication text (e.g., Ingredient(s), route, use, formulation).*

Date	Location	User	Value	Reason
Nov-25-2020 11:10:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

**5. Start Date:**

Date	Location	User	Value	Reason
Nov-25-2020 11:10:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

**6. Ongoing?**

Date	Location	User	Value	Reason
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090177e196d8902a\Final\Final On: 22-Apr-2021 02:13 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on **Form:** CONCOMITANT MEDICATIONS - VASOPRESSORS - eCRF  
Nov/23/2020 Audit Trail History

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

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

**Site No:** 1117

**Site Name:** (1117) Sundance Clinical Research

**Subject No:** 11171121

**Subject Initials:** ---

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

**Generated Time (GMT):** 21-Apr-2021 18:02

Nov-25-2020 11:10:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry
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Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Form: IMAGING - eCRF Audit Trail History  
Nov/23/2020

Form Version: 06-Jul-2020 21:53

Form Status: Data Complete, Frozen, Verified

Site No: 1117

Site Name: (1117) Sundance Clinical Research

Subject No: 11171121

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 21-Apr-2021 18:02

[Back to Form](#)

**1. Date of Assessment:**

Date	Location	User	Value	Reason
Nov-25-2020 11:10:19 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

**2. Location of Assessment:**

Date	Location	User	Value	Reason
Nov-25-2020 11:10:19 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

**3. Type of Imaging Exam:**

Date	Location	User	Value	Reason
Nov-25-2020 11:10:19 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

**4. Assessment:**

Date	Location	User	Value	Reason
Nov-25-2020 11:10:19 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

090177e196d8902a\Final\Final On: 22-Apr-2021 02:13 (GMT)

**Header Text:** c4591001

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

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

**Site No:** 1117

**Subject No:** 11171121

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

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

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

**Site Name:** (1117) Sundance Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 21-Apr-2021 18:02

[Back to Form](#)

**I. Date of Visit**

Date	Location	User	Value	Reason
Feb-23-2021 01:49:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Deleted	Rest of form marked as NA.
Feb-22-2021 10:14:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Candidate	Erroneous Visit is marked, but date of visit is entered. Please either untick the erroneous visit button if visit occurred, or mark any forms containing data within this visit as Not Done/Not Applicable at the form level.
Feb-22-2021 10:14:04 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Feb-22-2021 03:48:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	Erroneous Visit is marked, but date of visit is entered. Please either untick the erroneous visit button if visit occurred, or mark any forms containing data within this visit as Not Done/Not Applicable at the form level.
Feb-19-2021 10:46:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	Erroneous Visit is marked, but date of visit is entered. Please either untick the erroneous visit button if visit occurred, or mark any forms containing

090177e196d8902a\Final\Final On: 22-Apr-2021 02:13 (GMT)

Header Text: c4591001

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

Form: DATE OF VISIT - ILLNESS CONVALESCENT - eCRF Audit Trail  
History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Frozen, Verified

Site No: 1117

Site Name: (1117) Sundance Clinical Research

Subject No: 11171121

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 21-Apr-2021 18:02

				data within this visit as Not Done/Not Applicable at the form level.
Dec-28-2020 21:28:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Dec/22/2020	Initial Entry

**2. Erroneous Visit**

Date	Location	User	Value	Reason
Feb-22-2021 10:14:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> ERRONEOUS VISIT	Initial Entry
Feb-22-2021 10:14:04 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	Changed Information
Feb-19-2021 10:46:05 (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
Feb-19-2021 10:46:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry</b> : Not Applicable	Initial Entry
Feb-19-2021 10:46:23 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry</b> :	Changed Information
Jan-25-2021 15:21:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query

090177e196d8902a\Final\Final On: 22-Apr-2021 02:13 (GMT)

**Header Text:** c4591001

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

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

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

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

**Site No:** 1117

**Site Name:** (1117) Sundance Clinical Research

**Subject No:** 11171121

**Subject Initials:** ---

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

**Generated Time (GMT):** 21-Apr-2021 18:02

Jan-25-2021 11:39:06 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Ans wered	Original value is correct
Jan-25-2021 00:33:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (b) (4)	Query 1: Op ened	DMW6961670;COVID-19 Illness Visit ID in this convalescent visit is the same as another convalescent visit, however date of visit are different. Please review and update as appropriate.
Dec-28-2020 21:28:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry</b> : COVI D_A1	Initial Entry

090177e196d8902a\Final\Final On: 22-Apr-2021 02:13 (GMT)

Header Text: c4591001

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

Form Version: 22-Apr-2020 21:03

Site No: 1117

Subject No: 11171121

Generated By: (b) (4)

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

Form Status: Data Complete, Frozen, Verified

Site Name: (1117) Sundance Clinical Research

Subject Initials: ---

Generated Time (GMT): 21-Apr-2021 18:02

[Back to Form](#)

**1. Data Origin**

Date	Location	User	Value	Reason
Feb-19-2021 10:45:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> Not Applicable	Initial Entry
Feb-19-2021 10:45:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b>	Changed Information
Dec-29-2020 16:14:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SITE	Initial Entry

**2. Sample Type**

Date	Location	User	Value	Reason
Feb-19-2021 10:45:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> Not Applicable	Initial Entry
Feb-19-2021 10:45:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b>	Changed Information
Dec-29-2020 16:14:41 (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
Feb-19-2021 15:58:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Closed	Response satisfies query
Feb-19-2021 10:45:45 (UTC-06:00) Central Time	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entr y:</b> Not Appli cable	Initial Entry

090177e196d8902a\Final\Final On: 22-Apr-2021 02:13 (GMT)



Header Text: c4591001

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

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1117

Site Name: (1117) Sundance Clinical Research

Subject No: 11171121

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 21-Apr-2021 18:02

(US & Canada)				
Feb-19-2021 10:45:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 3: Deleted	Close Auto Query
Feb-19-2021 10:45:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	Changed Information
Feb-19-2021 10:45:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 3: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Feb-19-2021 10:42:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Answered	DATES LOOK CORRECT
Feb-18-2021 21:38:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (b) (4)	Query 2: Opened	DMW7314581;Date of Collection is not equal to Date of Visit. Please clarify or correct.
Dec-29-2020 16:14:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Dec-29-2020 16:14:41 (UTC-06:00) Central Time	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please

090177e196d8902a\Final\Final On: 22-Apr-2021 02:13 (GMT)

Header Text: c4591001

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

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1117

Site Name: (1117) Sundance Clinical Research

Subject No: 11171121

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 21-Apr-2021 18:02

(US & Canada)				review and correct as appropriate.
Dec-29-2020 16:14:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES Date of Collection:  Dec/22/2020	Initial Entry

4. If no sample was collected or sample was not collected according to protocol, please provide reason:

Date	Location	User	Value	Reason
Feb-19-2021 10:45:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

5.a

Date	Location	User	Value	Reason
Feb-19-2021 10:44:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample ID:</b>	Changed Information
Feb-19-2021 10:44:17 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample ID:</b> BM8Z2F	Changed Information
Feb-19-2021 10:44:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample ID:</b> <del>BM8Z2F</del>	Changed Information (DELETED)
Dec-29-2020 16:14:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample ID:</b> BM8Z2F	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Feb-19-2021 10:44:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	Changed Information

090177e196d8902a\Final\Final On: 22-Apr-2021 02:13 (GMT)

Header Text: c4591001

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

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1117

Site Name: (1117) Sundance Clinical Research

Subject No: 11171121

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 21-Apr-2021 18:02

Feb-19-2021 10:44:17 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BM8Z2F	Changed Information
Feb-19-2021 10:44:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <del>BM8Z2F</del>	Changed Information (DELETED)
Dec-29-2020 16:14:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BM8Z2F	Initial Entry

5.b

Date	Location	User	Value	Reason
Feb-19-2021 10:44:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample ID:</b>	Changed Information
Dec-29-2020 16:15:06 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample ID:</b> BM8Z2G	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Feb-19-2021 10:44:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	Changed Information
Dec-29-2020 16:15:06 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BM8Z2G	Initial Entry

5.c

Date	Location	User	Value	Reason
Feb-19-2021 10:44:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample ID:</b>	Changed Information
Dec-29-2020 16:15:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample ID:</b> BM8Z2H	Initial Entry

090177e196d8902a\Final\Final On: 22-Apr-2021 02:13 (GMT)

Header Text: c4591001

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

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1117

Site Name: (1117) Sundance Clinical Research

Subject No: 11171121

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 21-Apr-2021 18:02

5.c Sample ID

Date	Location	User	Value	Reason
Feb-19-2021 10:44:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	Changed Information
Dec-29-2020 16:15:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BM8Z2H	Initial Entry

5.d

Date	Location	User	Value	Reason
Feb-19-2021 10:45:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample ID:</b>	Changed Information
Dec-29-2020 16:15:24 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample ID:</b> BRSRF3	Initial Entry

5.d Sample ID

Date	Location	User	Value	Reason
Feb-19-2021 10:45:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	Changed Information
Dec-29-2020 16:15:24 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BRSRF3	Initial Entry

5.e

Date	Location	User	Value	Reason
Feb-19-2021 10:45:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample ID:</b>	Changed Information
Dec-29-2020 16:15:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample ID:</b> BRSRF4	Initial Entry

090177e196d8902a\Final\Final On: 22-Apr-2021 02:13 (GMT)

**Header Text:** c4591001

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

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

**Site No:** 1117

**Subject No:** 11171121

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

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

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

**Site Name:** (1117) Sundance Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 21-Apr-2021 18:02

**5.e Sample ID**

<b>Date</b>	<b>Location</b>	<b>User</b>	<b>Value</b>	<b>Reason</b>
Feb-19-2021 10:45:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	Changed Information
Dec-29-2020 16:15:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BRSRF4	Initial Entry

**Header Text:** c4591001

**Visit:** POT\_COVID\_CONVA 2 - Unscheduled Visit on Jan/21/2021

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

**Site No:** 1117

**Subject No:** 11171121

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

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

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

**Site Name:** (1117) Sundance Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 21-Apr-2021 18:02

[Back to Form](#)

**1. Date of Visit**

Date	Location	User	Value	Reason
Jan-22-2021 15:08:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Jan/21/2021	Initial Entry

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

Date	Location	User	Value	Reason
Feb-19-2021 12:48:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Closed	Response satisfies query
Feb-19-2021 10:47:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Answered	Changed data per query
Feb-19-2021 06:03:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Reissued: Opened	DM : COVID_A1 dated 22/DEC/2020 is unfrozen now. Please review and update the data as per previous query response. Thank you.
Feb-18-2021 16:48:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Answered	FOLLOW UP EVENT ON 22DEC2020 WILL NEED TO BE REMOVED. PLEASE SUBMIT REQUEST TO DM TO HAVE THE FORMS UNLOCKED FOR EDITING. SITE WILL SUBMIT SPECIMEN DESTRUCTION FORM FOR 22DEC2020 EVENT AND MARK AS

090177e196d8902a\Final\Final On: 22-Apr-2021 02:13 (GMT)

Header Text: c4591001

Visit: POT\_COVID\_CONVA 2 - Unscheduled Visit on Jan/21/2021

Form: DATE OF VISIT - ILLNESS CONVALESCENT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Frozen, Verified

Site No: 1117

Site Name: (1117) Sundance Clinical Research

Subject No: 11171121

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 21-Apr-2021 18:02

				ERRONEOUS.
Feb-08-2021 01:16:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Op ened	Thanks for response to previous query. Symptoms are resolved per SOD CRF. COVID-19 Illness Visit ID in this convalescent visit is the same as another convalescent visit, however date of visit are different. Please review and update as appropriate
Jan-27-2021 01:43:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Clo sed	Response satisfies query
Jan-26-2021 11:49:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Ans wered	PER COVID ILL, SOD FORM, LAST SYMPTOM RESOLVED 11JAN2020.
Jan-25-2021 00:33:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (b) (4)	Query 1: Op ened	DMW6961671;COVID-19 Illness Visit ID in this convalescent visit is the same as another convalescent visit, however date of visit are different. Please review and update as appropriate.
Jan-22-2021 15:08:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry</b> : COVI D_A1	Initial Entry

090177e196d8902a\Final\Final On: 22-Apr-2021 02:13 (GMT)

Header Text: c4591001

Visit: POT\_COVID\_CONVA 2 - Unscheduled  
Visit on Jan/21/2021

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1117

Site Name: (1117) Sundance Clinical Research

Subject No: 11171121

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 21-Apr-2021 18:02

[Back to Form](#)

**1. Data Origin**

Date	Location	User	Value	Reason
Jan-25-2021 12:49:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SITE	Initial Entry

**2. Sample Type**

Date	Location	User	Value	Reason
Jan-25-2021 12:49:09 (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
Feb-19-2021 14:53:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (b) (4)	Query 2: Closed	Auto closed by Validation Check: VC_BEETRK001_03
Feb-19-2021 10:47:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Answered	Original value is correct
Feb-18-2021 21:20:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (b) (4)	Query 2: Opened	DMW7314558;Date of Collection is not equal to Date of Visit. Please clarify or correct.
Jan-25-2021 12:49:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query

090177e196d8902a\Final\Final On: 22-Apr-2021 02:13 (GMT)



Header Text: c4591001

Visit: POT\_COVID\_CONVA 2 - Unscheduled  
Visit on Jan/21/2021

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1117

Site Name: (1117) Sundance Clinical Research

Subject No: 11171121

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 21-Apr-2021 18:02

Jan-25-2021 12:49:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Jan-25-2021 12:49:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES Date of Collection:  Jan/21 /2021	Initial Entry

5.a

Date	Location	User	Value	Reason
Jan-25-2021 12:49:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample ID:</b> BRSRJK	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Jan-25-2021 12:49:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BRSRJK	Initial Entry

5.b

Date	Location	User	Value	Reason
Jan-25-2021 12:49:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample ID:</b> BRSRJK	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Jan-25-2021 12:49:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BRSRJK	Initial Entry

090177e196d8902a\Final\Final On: 22-Apr-2021 02:13 (GMT)

Header Text: c4591001

Visit: POT\_COVID\_CONVA 2 - Unscheduled  
Visit on Jan/21/2021

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1117

Site Name: (1117) Sundance Clinical Research

Subject No: 11171121

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 21-Apr-2021 18:02

5.c

Date	Location	User	Value	Reason
Jan-25-2021 13:27:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample ID:</b> BP5907	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Jan-25-2021 13:27:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BP5907	Initial Entry

5.d

Date	Location	User	Value	Reason
Jan-25-2021 13:28:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample ID:</b> BP5908	Initial Entry

5.d Sample ID

Date	Location	User	Value	Reason
Jan-25-2021 13:28:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BP5908	Initial Entry

5.e

Date	Location	User	Value	Reason
Jan-25-2021 13:28:19 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample ID:</b> BP5909	Initial Entry

5.e Sample ID

Date	Location	User	Value	Reason
Jan-25-2021 13:28:19 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BP5909	Initial Entry

090177e196d8902a\Final\Final On: 22-Apr-2021 02:13 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1117

**Subject No:** 11171121

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

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

**Form Status:**

**Site Name:** (1117) Sundance Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 21-Apr-2021 18:02

[Back to Form](#)

Date	Location	User	Value	Reason
Nov-05-2020 18:30:34 (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: 1117

Subject No: 11171121

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen

Site Name: (1117) Sundance Clinical Research

Subject Initials: ---

Generated Time (GMT): 21-Apr-2021 18:02

[Back to Form](#)

**1. Category:**

Date	Location	User	Value	Reason
Nov-05-2020 18:30:34 (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
Nov-05-2020 18:30:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 1	Initial Entry

**3. Adverse Event:**

*(If possible specify diagnosis, not individual symptoms)*

Date	Location	User	Value	Reason
Nov-05-2020 18:30:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> ANGIOEDEMA	Initial Entry

**4. Start Date Time:**

Date	Location	User	Value	Reason
Nov-05-2020 18:30:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Oct/31/2020 08:00	Initial Entry

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

Date	Location	User	Value	Reason
Nov-05-2020 18:30:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO End Date Time: Nov/3/2020 UNK:UNK	Initial Entry

**6. Toxicity Grade:**

Date	Location	User	Value	Reason
Nov-05-2020 18:30:34 (UTC-06:00) Central Time	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 1	Initial Entry

090177e196d8902a\Final\Final On: 22-Apr-2021 02:13 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Locked, Frozen

Site No: 1117

Site Name: (1117) Sundance Clinical Research

Subject No: 11171121

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 21-Apr-2021 18:02

(US & Canada)		(b) (4), (b) (6)	
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7. Is the adverse event serious?

If Yes, NOTIFY PFIZER IMMEDIATELY.

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

Date	Location	User	Value	Reason
Nov-05-2020 18:30:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

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

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

Date	Location	User	Value	Reason
Nov-05-2020 18:30:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Nov-05-2020 18:30:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NOT RELATED If Not Related to study treatment(s), this event is due to:  OTHER  If Other, specify:  CONMED REACTION, LISI NOPRIL	Initial Entry

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Nov-05-2020 18:30:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NOT APPLICABLE	Initial Entry

11. Was a Concomitant Medication given?

090177e196d8902a\Final\Final On: 22-Apr-2021 02:13 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1117

Subject No: 11171121

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen

Site Name: (1117) Sundance Clinical Research

Subject Initials: ---

Generated Time (GMT): 21-Apr-2021 18:02

Date	Location	User	Value	Reason
Nov-05-2020 18:30:34 (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
Nov-05-2020 18:30:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

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

Date	Location	User	Value	Reason
Nov-05-2020 18:30:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> RECOVERED/RESOLVED	Initial Entry

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

Date	Location	User	Value	Reason
Nov-05-2020 18:30:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

090177e196d8902a\Final\Final On: 22-Apr-2021 02:13 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

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

**Form Status:**

**Site No:** 1117

**Site Name:** (1117) Sundance Clinical Research

**Subject No:** 11171121

**Subject Initials:** ---

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

**Generated Time (GMT):** 21-Apr-2021 18:02

[Back to Form](#)

Date	Location	User	Value	Reason
Nov-12-2020 13:05:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

Header Text: c4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - NON STUDY  
VACCINATIONS - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1117

Site Name: (1117) Sundance Clinical Research

Subject No: 11171121

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 21-Apr-2021 18:02

[Back to Form](#)

**1. What is the medication identifier?**

Date	Location	User	Value	Reason
Nov-12-2020 13:05:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 1	Initial Entry

**2. Category:**

Date	Location	User	Value	Reason
Nov-12-2020 13:05:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> VACCINATIONS	Initial Entry

**3. Concomitant Medications Pre-specified:**

Date	Location	User	Value	Reason
Nov-12-2020 13:05:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> NO	Initial Entry

**4. Medication:**

*Provide the complete generic drug name (including salt form, where applicable). Where generic name is unknown, enter the full trade or proprietary name. Include clarifying information in the Medication text (e.g., Ingredient(s), route, use, formulation).*

Date	Location	User	Value	Reason
Nov-12-2020 13:05:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> FLU VACCINE	Initial Entry

**5. Date:**

Date	Location	User	Value	Reason
Nov-12-2020 13:05:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sep/1/2020	Initial Entry

090177e196d8902a\Final\Final On: 22-Apr-2021 02:13 (GMT)



**Header Text:** c4591001

**Visit:** End of Treatment - Unscheduled

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

**Site No:** 1117

**Subject No:** 11171121

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

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

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

**Site Name:** (1117) Sundance Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 21-Apr-2021 18:02

[Back to Form](#)

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

Date	Location	User	Value	Reason
Nov-05-2020 18:28:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Nov/5/2020	Initial Entry

**2. Phase of Disposition:**

Date	Location	User	Value	Reason
Nov-05-2020 18:28:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> VACCINATION	Initial Entry

**3. Status:**

Date	Location	User	Value	Reason
Nov-05-2020 18:28:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> COMPLETED	Initial Entry

090177e196d8902a\Final\Final On: 22-Apr-2021 02:13 (GMT)

**Header Text:** c4591001

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

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

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

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

**Site No:** 1117

**Site Name:** (1117) Sundance Clinical Research

**Subject No:** 11171121

**Subject Initials:** ---

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

**Generated Time (GMT):** 21-Apr-2021 18:02

[Back to Form](#)

*1. Date of Visit*

Date	Location	User	Value	Reason
Feb-10-2021 10:04:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Feb-05-2021 16:38:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Changed Information
Feb-05-2021 16:38:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Jan/7/2021	Changed Information
Feb-03-2021 09:59:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	Please confirm, contact with subject to continue with unblinding was completed via email on 07Jan2021. If confirmed, please change data appropriately.
Jan-22-2021 15:12:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Jan/18/2021	Initial Entry

090177e196d8902a\Final\Final On: 22-Apr-2021 02:13 (GMT)

**Header Text:** c4591001

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

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

**Site No:** 1117

**Subject No:** 11171121

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

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

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

**Site Name:** (1117) Sundance Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 21-Apr-2021 18:02

[Back to Form](#)

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

Date	Location	User	Value	Reason
Jan-22-2021 15:12:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Participant is willing to return for Va ccination 3 Participant is:  eligible per local/national recom mendations and confirmed to hav e received only placebo at Vaccin ation 1/2	Initial Entry

**Header Text:** c4591001

**Visit:** Disposition - Unscheduled

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

**Site No:** 1117

**Subject No:** 11171121

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

**Form:** TREATMENT UNBLINDED - eCRF Audit Trail History

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

**Site Name:** (1117) Sundance Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 21-Apr-2021 18:02

[Back to Form](#)

**1. Date Treatment Unblinded :**

Date	Location	User	Value	Reason
Jan-22-2021 15:12:18 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Jan/11/2021	Initial Entry

**2. Primary Reason for Unblinding:**

Date	Location	User	Value	Reason
Jan-22-2021 15:12:18 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> ASSESS ELIGIBILITY FOR ADDI TIONAL VACCINATION	Initial Entry

**Header Text:** c4591001

**Visit:** V101\_VAX3

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

**Site No:** 1117

**Subject No:** 11171121

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

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

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

**Site Name:** (1117) Sundance Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 21-Apr-2021 18:02

[Back to Form](#)

*I. Date of Visit*

Date	Location	User	Value	Reason
Jan-26-2021 03:47:55 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Jan-25-2021 17:42:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Changed data per query
Jan-25-2021 04:02:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	DM: Kindly consider to update missing SWAB PFE and SAMP TRK forms or else clarify. Thank you.
Jan-22-2021 15:13:02 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Jan/18/2021	Initial Entry

090177e196d8902a\Final\Final On: 22-Apr-2021 02:13 (GMT)

**Header Text:** c4591001

**Visit:** V101\_VAX3

**Form:** INFORMED CONSENT - FURTHER VACCINATION - eCRF  
Audit Trail History

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

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

**Site No:** 1117

**Site Name:** (1117) Sundance Clinical Research

**Subject No:** 11171121

**Subject Initials:** ---

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

**Generated Time (GMT):** 21-Apr-2021 18:02

[Back to Form](#)

*I. Consent Was:*

<b>Date</b>	<b>Location</b>	<b>User</b>	<b>Value</b>	<b>Reason</b>
Jan-22-2021 15:13:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> OBTAINED Date Written Consent Obtained  Jan/18/2021	Initial Entry

Header Text: c4591001

Visit: V101\_VAX3

Form: DISPOSITION - SCREENING FOR FURTHER VACCINATION - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:31

Form Status: Data Complete, Frozen, Verified

Site No: 1117

Site Name: (1117) Sundance Clinical Research

Subject No: 11171121

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 21-Apr-2021 18:02

[Back to Form](#)

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

Date	Location	User	Value	Reason
Jan-22-2021 15:13:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Jan/18/2021	Initial Entry

**2. Phase of Disposition:**

Date	Location	User	Value	Reason
Jan-22-2021 15:13:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> REPEAT SCREENING 1	Initial Entry

**3. Status:**

Date	Location	User	Value	Reason
Jan-22-2021 15:13:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> COMPLETED	Initial Entry

090177e196d8902a\Final\Final On: 22-Apr-2021 02:13 (GMT)

Header Text: c4591001

Visit: V101\_VAX3

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

Form Version: 14-Jan-2021 02:21

Form Status: Data Complete, Frozen, Verified

Site No: 1117

Site Name: (1117) Sundance Clinical Research

Subject No: 11171121

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 21-Apr-2021 18:02

[Back to Form](#)

**1. Lab Panel:**

Date	Location	User	Value	Reason
Jan-22-2021 15:13:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> URINALYSIS	Initial Entry

**2. Lab Sub-Panel:**

Date	Location	User	Value	Reason
Jan-22-2021 15:13:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> PREGNANCY	Initial Entry

**3. Collection Date:**

Date	Location	User	Value	Reason
Jan-22-2021 15:13:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Jan/18/2021	Initial Entry

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

Date	Location	User	Value	Reason
Jan-22-2021 15:13:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> STUDY SITE	Initial Entry

**5. Specimen Type:**

Date	Location	User	Value	Reason
Jan-22-2021 15:13:59 (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
Jan-22-2021 15:13:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> Sponsor-Define 113 <b>d Identifier:</b>	Initial Entry

090177e196d8902a\Final\Final On: 22-Apr-2021 02:13 (GMT)



Header Text: c4591001

Visit: V101\_VAX3

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

Form Version: 14-Jan-2021 02:21

Form Status: Data Complete, Frozen, Verified

Site No: 1117

Site Name: (1117) Sundance Clinical Research

Subject No: 11171121

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 21-Apr-2021 18:02

			<b>Test::</b> Choriogonadotropin Beta_PX113 <b>Result::</b> NEGATIVE <b>Not Done::</b>
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**6.a Sponsor ID:**

Date	Location	User	Value	Reason
Jan-22-2021 15:13:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 113	Initial Entry

**6.a Test:**

Date	Location	User	Value	Reason
Jan-22-2021 15:13:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Choriogonadotropin Beta_PX113	Initial Entry

**6.a Result:**

Date	Location	User	Value	Reason
Jan-22-2021 15:13:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NEGATIVE	Initial Entry

090177e196d8902a\Final\Final On: 22-Apr-2021 02:13 (GMT)

Header Text: c4591001

Visit: V101\_VAX3

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1117

Site Name: (1117) Sundance Clinical Research

Subject No: 11171121

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 21-Apr-2021 18:02

[Back to Form](#)

**1. Data Origin**

Date	Location	User	Value	Reason
Jan-25-2021 13:00:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SITE	Initial Entry

**2. Sample Type**

Date	Location	User	Value	Reason
Jan-25-2021 13:00:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SERUM	Initial Entry

**3. Sample Collected?**

Date	Location	User	Value	Reason
Jan-25-2021 13:00:19 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Jan-25-2021 13:00:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Jan-25-2021 13:00:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES Date of Collection:  Jan/18/2021	Initial Entry

**5.a**

Date	Location	User	Value	Reason
Jan-25-2021 13:00:19 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample ID: BRSRH9</b>	Initial Entry

**5.a Sample ID**

090177e196d8902a\Final\Final On: 22-Apr-2021 02:13 (GMT)

Header Text: c4591001

Visit: V101\_VAX3

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1117

Site Name: (1117) Sundance Clinical Research

Subject No: 11171121

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 21-Apr-2021 18:02

Date	Location	User	Value	Reason
Jan-25-2021 13:00:19 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> BRSRH9	Initial Entry

5.b

Date	Location	User	Value	Reason
Jan-25-2021 13:00:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Sample ID: BRSRHB	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Jan-25-2021 13:00:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> BRSRHB	Initial Entry

5.c

Date	Location	User	Value	Reason
Jan-25-2021 14:46:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Sample ID: BRDFTS	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Jan-25-2021 14:46:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> BRDFTS	Initial Entry

5.d

Date	Location	User	Value	Reason
Jan-25-2021 14:46:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Sample ID: BRDFTT	Initial Entry

090177e196d8902a\Final\Final On: 22-Apr-2021 02:13 (GMT)

Header Text: c4591001

Visit: V101\_VAX3

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1117

Site Name: (1117) Sundance Clinical Research

Subject No: 11171121

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 21-Apr-2021 18:02

**5.d Sample ID**

Date	Location	User	Value	Reason
Jan-25-2021 14:46:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BRDFTT	Initial Entry

**5.e**

Date	Location	User	Value	Reason
Jan-25-2021 14:47:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample ID:</b> BRDFTV	Initial Entry

**5.e Sample ID**

Date	Location	User	Value	Reason
Jan-25-2021 14:47:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BRDFTV	Initial Entry

090177e196d8902a\Final\Final On: 22-Apr-2021 02:13 (GMT)

Header Text: c4591001

Visit: V101\_VAX3

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1117

Site Name: (1117) Sundance Clinical Research

Subject No: 11171121

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 21-Apr-2021 18:02

[Back to Form](#)

**1. Data Origin**

Date	Location	User	Value	Reason
Jan-25-2021 14:27:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SITE	Initial Entry

**2. Sample Type**

Date	Location	User	Value	Reason
Jan-25-2021 14:27:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> NASAL_SWAB	Initial Entry

**3. Sample Collected?**

Date	Location	User	Value	Reason
Jan-25-2021 14:27:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Jan-25-2021 14:27:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Jan-25-2021 14:27:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES Date of Collection:  Jan/18/2021	Initial Entry

**5.a**

Date	Location	User	Value	Reason
Jan-25-2021 14:27:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample ID: BP58ZT</b>	Initial Entry

**5.a Sample ID**

090177e196d8902a\Final\Final On: 22-Apr-2021 02:13 (GMT)

**Header Text:** c4591001

**Visit:** V101\_VAX3

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

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

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

**Site No:** 1117

**Site Name:** (1117) Sundance Clinical Research

**Subject No:** 11171121

**Subject Initials:** ---

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

**Generated Time (GMT):** 21-Apr-2021 18:02

Date	Location	User	Value	Reason
Jan-25-2021 14:27:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> BP58ZT	Initial Entry

Header Text: c4591001

Visit: V101\_VAX3

Form Version: 10-Dec-2020 02:26

Site No: 1117

Subject No: 11171121

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1117) Sundance Clinical Research

Subject Initials: ---

Generated Time (GMT): 21-Apr-2021 18:02

[Back to Form](#)

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

Date	Location	User	Value	Reason
Jan-22-2021 15:14:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**2. Treatment Name**

Date	Location	User	Value	Reason
Jan-22-2021 15:14:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> BNT162b2	Initial Entry

**3. Formulation:**

Date	Location	User	Value	Reason
Jan-22-2021 15:14:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> INJECTION	Initial Entry

**4. Dose Date Time:**

Date	Location	User	Value	Reason
Jan-22-2021 15:14:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Jan/18/2021 09:58	Initial Entry

**5. Anatomical Location:**

Date	Location	User	Value	Reason
Jan-22-2021 15:14:34 (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
Jan-22-2021 15:14:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> LEFT	Initial Entry

090177e196d8902a\Final\Final On: 22-Apr-2021 02:13 (GMT)

Header Text: c4591001

Visit: V101\_VAX3

Form: VACCINATION - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:26

Form Status: Data Complete, Frozen, Verified

Site No: 1117

Site Name: (1117) Sundance Clinical Research

Subject No: 11171121

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 21-Apr-2021 18:02

7. Route:

Date	Location	User	Value	Reason
Jan-22-2021 15:14:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> INTRAMUSCULAR	Initial Entry

8. Actual Dose:

Date	Location	User	Value	Reason
Jan-22-2021 15:14:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 30.0	Initial Entry

9. Unit:

Date	Location	User	Value	Reason
Jan-22-2021 15:14:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> ug	Initial Entry

10. Timeframe Subject Was Observed

Date	Location	User	Value	Reason
Jan-22-2021 15:14:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 30 MINUTES	Initial Entry

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

Date	Location	User	Value	Reason
Jan-22-2021 15:14:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

090177e196d8902a\Final\Final On: 22-Apr-2021 02:13 (GMT)



**Header Text:** c4591001

**Visit:** V102\_VAX4

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

**Site No:** 1117

**Subject No:** 11171121

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

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

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

**Site Name:** (1117) Sundance Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 21-Apr-2021 18:02

[Back to Form](#)

*I. Date of Visit*

<b>Date</b>	<b>Location</b>	<b>User</b>	<b>Value</b>	<b>Reason</b>
Feb-08-2021 17:28:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Feb/8/2021	Initial Entry

Header Text: c4591001

Visit: V102\_VAX4

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

Form Version: 14-Jan-2021 02:21

Form Status: Data Complete, Frozen, Verified

Site No: 1117

Site Name: (1117) Sundance Clinical Research

Subject No: 11171121

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 21-Apr-2021 18:02

[Back to Form](#)

**1. Lab Panel:**

Date	Location	User	Value	Reason
Feb-08-2021 17:28:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> URINALYSIS	Initial Entry

**2. Lab Sub-Panel:**

Date	Location	User	Value	Reason
Feb-08-2021 17:28:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> PREGNANCY	Initial Entry

**3. Collection Date:**

Date	Location	User	Value	Reason
Feb-08-2021 17:28:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Feb/8/2021	Initial Entry

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

Date	Location	User	Value	Reason
Feb-08-2021 17:28:25 (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
Feb-08-2021 17:28:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> URINE	Initial Entry

**6.a**

Date	Location	User	Value	Reason
Feb-08-2021 17:28:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> Sponsor-Define 113 <b>d Identifier:</b>	Initial Entry

090177e196d8902a\Final\Final On: 22-Apr-2021 02:13 (GMT)

Header Text: c4591001

Visit: V102\_VAX4

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

Form Version: 14-Jan-2021 02:21

Form Status: Data Complete, Frozen, Verified

Site No: 1117

Site Name: (1117) Sundance Clinical Research

Subject No: 11171121

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 21-Apr-2021 18:02

			<b>Test::</b> Choriogonadotropin Beta_PX113 <b>Result::</b> NEGATIVE <b>Not Done::</b>
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**6.a Sponsor ID:**

Date	Location	User	Value	Reason
Feb-08-2021 17:28:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 113	Initial Entry

**6.a Test:**

Date	Location	User	Value	Reason
Feb-08-2021 17:28:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Choriogonadotropin Beta_PX113	Initial Entry

**6.a Result:**

Date	Location	User	Value	Reason
Feb-08-2021 17:28:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NEGATIVE	Initial Entry

090177e196d8902a\Final\Final On: 22-Apr-2021 02:13 (GMT)

Header Text: c4591001

Visit: V102\_VAX4

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1117

Site Name: (1117) Sundance Clinical Research

Subject No: 11171121

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 21-Apr-2021 18:02

[Back to Form](#)

**1. Data Origin**

Date	Location	User	Value	Reason
Feb-11-2021 12:32:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SITE	Initial Entry

**2. Sample Type**

Date	Location	User	Value	Reason
Feb-11-2021 12:32:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> NASAL_SWAB	Initial Entry

**3. Sample Collected?**

Date	Location	User	Value	Reason
Feb-11-2021 12:32:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Feb-11-2021 12:32:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Feb-11-2021 12:32:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES Date of Collection:  Feb/8/2021	Initial Entry

**5.a**

Date	Location	User	Value	Reason
Feb-11-2021 12:32:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample ID: BR6RV0</b>	Initial Entry

**5.a Sample ID**

090177e196d8902a\Final\Final On: 22-Apr-2021 02:13 (GMT)

**Header Text:** c4591001

**Visit:** V102\_VAX4

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

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

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

**Site No:** 1117

**Site Name:** (1117) Sundance Clinical Research

**Subject No:** 11171121

**Subject Initials:** ---

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

**Generated Time (GMT):** 21-Apr-2021 18:02

Date	Location	User	Value	Reason
Feb-11-2021 12:32:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> BR6RV0	Initial Entry

Header Text: c4591001

Visit: V102\_VAX4

Form Version: 10-Dec-2020 02:26

Site No: 1117

Subject No: 11171121

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1117) Sundance Clinical Research

Subject Initials: ---

Generated Time (GMT): 21-Apr-2021 18:02

[Back to Form](#)

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

Date	Location	User	Value	Reason
Feb-08-2021 17:28:54 (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
Feb-08-2021 17:28:54 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> BNT162b2	Initial Entry

**3. Formulation:**

Date	Location	User	Value	Reason
Feb-08-2021 17:28:54 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> INJECTION	Initial Entry

**4. Dose Date Time:**

Date	Location	User	Value	Reason
Feb-08-2021 17:28:54 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Feb/8/2021 09:43	Initial Entry

**5. Anatomical Location:**

Date	Location	User	Value	Reason
Feb-08-2021 17:28:54 (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
Feb-08-2021 17:28:54 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> LEFT	Initial Entry

090177e196d8902a\Final\Final On: 22-Apr-2021 02:13 (GMT)

Header Text: c4591001

Visit: V102\_VAX4

Form: VACCINATION - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:26

Form Status: Data Complete, Frozen, Verified

Site No: 1117

Site Name: (1117) Sundance Clinical Research

Subject No: 11171121

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 21-Apr-2021 18:02

7. Route:

Date	Location	User	Value	Reason
Feb-08-2021 17:28:54 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> INTRAMUSCULAR	Initial Entry

8. Actual Dose:

Date	Location	User	Value	Reason
Feb-08-2021 17:28:54 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 30.0	Initial Entry

9. Unit:

Date	Location	User	Value	Reason
Feb-08-2021 17:28:54 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> ug	Initial Entry

10. Timeframe Subject Was Observed

Date	Location	User	Value	Reason
Feb-08-2021 17:28:54 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 30 MINUTES	Initial Entry

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

Date	Location	User	Value	Reason
Feb-08-2021 17:28:54 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

090177e196d8902a\Final\Final On: 22-Apr-2021 02:13 (GMT)

Header Text: c4591001

Visit: Subject Status - Unscheduled

Form: SUBJECT STATUS - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Verified

Site No: 1117

Site Name: (1117) Sundance Clinical Research

Subject No: 11171121

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 21-Apr-2021 18:02

[Back to Form](#)

**1. Subject Status**

Date	Location	User	Value	Reason
Nov-05-2020 18:28:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> FOLLOW-UP	Initial Entry
Sep-18-2020 13:14:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> ENROLLED/RANDOMIZED	Initial Entry
Sep-18-2020 12:54:42 (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
Dec-02-2020 13:03:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Emily Worobetz (b) (4)	Query 1: Closed	COVID illness visit entered
Dec-02-2020 12:52:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Changed data per query
Nov-25-2020 08:32:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	Illness ed diary: As per Illness ed diary records, subject reported "Yes" for the question "Have you experienced any of the following?" for the COVID-19 symptoms or diagnosis on 22NOV2020. But corresponding COVID Illness visit not reported. Please clarify.
Nov-05-2020 18:28:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> Nov/5/2020	Initial Entry

090177e196d8902a\Final\Final On: 22-Apr-2021 02:13 (GMT)



**Header Text:** c4591001

**Visit:** Subject Status - Unscheduled

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

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

**Form Status:** Data Complete, Verified

**Site No:** 1117

**Site Name:** (1117) Sundance Clinical Research

**Subject No:** 11171121

**Subject Initials:** ---

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

**Generated Time (GMT):** 21-Apr-2021 18:02

Sep-18-2020 13:14:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> Sep/15/2020	Initial Entry
Sep-18-2020 12:54:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> Sep/15/2020	Initial Entry

090177e196d8902a\Final\Final On: 22-Apr-2021 02:13 (GMT)

**Header Text:** c4591001

**Visit:** Investigator Signature - Unscheduled

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

**Site No:** 1117

**Subject No:** 11171121

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

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

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

**Site Name:** (1117) Sundance Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 21-Apr-2021 18:02

[Back to Form](#)

*I. Casebook Signature*

Date	Location	User	Value	Reason
Nov-09-2020 14:50:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Click Here to Enable	Initial Entry