

Header Text: c4591001

Visit: COHORT_SELECTION

Form Version: 30-Jul-2020 21:29

Site No: 1117

Subject No: 11171036

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): 29-Mar-2021 10:58

[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

090177e196ae3dcc\Final\Final On: 01-Apr-2021 04:41 (GMT)

Header Text: c4591001

Visit: COHORT_SELECTION

Form Version: 22-Apr-2020 21:02

Site No: 1117

Subject No: 11171036

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): 29-Mar-2021 10:58

[eCRF Audit Trail History](#)

Informed Consent

1.	Consent Was:	OBTAINED Date Written Consent Obtained Aug/20/2020
----	--------------	--

Header Text: c4591001

Visit: COHORT_SELECTION

Form: DEMOGRAPHY

Form Version: 06-Jul-2020 21:55

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1117

Site Name: (1117) Sundance Clinical Research

Subject No: 11171036

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

[eCRF Audit Trail History](#)

Demography

1.	Subject ID	[11171036]
2.	Birth Date:	(b) (6)/1974
3.	Sex:	MALE
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: 11171036

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): 29-Mar-2021 10:58

[eCRF Audit Trail History](#)

Date of Visit

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

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 30-Jul-2020 21:29

Site No: 1117

Subject No: 11171036

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): 29-Mar-2021 10:58

Form Comments

Inclusion Criteria Not Met

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

Exclusion Criteria Met

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

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1117

Subject No: 11171036

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): 29-Mar-2021 10:58

[eCRF Audit Trail History](#)

Disposition - Screening

1.	Date of Completion/Discontinuation /Death	Aug/20/2020
2.	Phase of Disposition:	SCREENING
3.	Status:	COMPLETED
4.	Specify Status:	[]

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1117

Subject No: 11171036

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY

Form Status: Data Complete, Frozen, Verified

Site Name: (1117) Sundance Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:58

[eCRF Audit Trail History](#)

Medical History Details

1.a	Line/MH Number:	[1]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[ALCOHOLISM]
	Start Date:	UNK/UNK/2005
	Ongoing:	NO End Date: UNK/UNK/2017
1.b	Line/MH Number:	[2]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[SCHIZOPHRENIA]
	Start Date:	UNK/UNK/2016
	Ongoing:	YES
1.c	Line/MH Number:	[3]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[ANXIETY]
	Start Date:	UNK/UNK/2017
	Ongoing:	YES
1.d	Line/MH Number:	[4]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[BIPOLAR DISORDER]
	Start Date:	UNK/UNK/2016
	Ongoing:	YES
1.e	Line/MH Number:	[5]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[INSOMNIA]
	Start Date:	UNK/UNK/2017
	Ongoing:	YES

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Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1117

Subject No: 11171036

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY

Form Status: Data Complete, Frozen, Verified

Site Name: (1117) Sundance Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:58

1.f	Line/MH Number:	[6]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[FISH ALLERGY]
	Start Date:	UNK/UNK/1979
	Ongoing:	YES
1.g	Line/MH Number:	[7]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[DIABETES MELLITUS TYPE II]
	Start Date:	UNK/UNK/2019
	Ongoing:	YES
1.h	Line/MH Number:	[8]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[HYPERTENSION]
	Start Date:	UNK/UNK/2016
	Ongoing:	YES
1.i	Line/MH Number:	[9]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[MAJOR DEPRESSIVE DISORDER]
	Start Date:	UNK/UNK/2016
	Ongoing:	YES
1.j	Line/MH Number:	[10]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[CONSTIPATION]
	Start Date:	UNK/UNK/2018
	Ongoing:	YES

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Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1117

Subject No: 11171036

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY

Form Status: Data Complete, Frozen, Verified

Site Name: (1117) Sundance Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:58

1.k	Line/MH Number:	[11]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Chronic Kidney Disease, Stage 2]
	Start Date:	Jan/UNK/2020
	Ongoing:	YES

090177e196ae3dcc\Final\Final On: 01-Apr-2021 04:41 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 21-Aug-2020 02:51

Site No: 1117

Subject No: 11171036

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): 29-Mar-2021 10:58

[eCRF Audit Trail History](#)

Vital Signs

1.	Date:	Aug/20/2020
2.	Weight:	[269.2]
3.	Unit:	LB
4.	Height:	[76.6]
5.	Unit:	in
6.	Body Mass Index:	[32.3]

Vital Signs Details

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

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Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1117

Subject No: 11171036

Generated By: (b) (4)

Form: RANDOMIZATION

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1117) Sundance Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:58

[eCRF Audit Trail History](#)

Disposition

1.	Randomization Date :	Aug/20/2020
2.	Randomization Number:	[57122]
3.	Randomization Group:	[]

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1117

Subject No: 11171036

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): 29-Mar-2021 10:58

[eCRF Audit Trail History](#)

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	SERUM
3.	Sample Collected?	YES Date of Collection: Aug/20/2020
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[]

Aliquot

Please enter barcode for each aliquot.

5.a	Sample ID	[BPRTY5]
5.b	Sample ID	[BPRTY6]
5.c	Sample ID	[BP58HH]
5.d	Sample ID	[BP58HJ]
5.e	Sample ID	[BP58HK]

090177e196ae3dcc\Final\Final On: 01-Apr-2021 04:41 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1117

Subject No: 11171036

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): 29-Mar-2021 10:58

[eCRF Audit Trail History](#)

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Aug/20/2020
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[]

Aliquot

Please enter barcode for each aliquot.

5.a	Sample ID	[BP58GR]
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090177e196ae3dcc\Final\Final On: 01-Apr-2021 04:41 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:04

Site No: 1117

Subject No: 11171036

Generated By: (b) (4)

Form: VACCINATION

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1117) Sundance Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:58

[eCRF Audit Trail History](#)

Vaccination

1.	Was there a temporary delay of vaccination?	NO
2.	Treatment Name	[BLINDED THERAPY]
3.	Formulation:	INJECTION
4.	Dose Date Time:	Aug/20/2020 16:02
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

090177e196ae3dcc\Final\Final On: 01-Apr-2021 04:41 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 06-Jul-2020 21:53

Site No: 1117

Subject No: 11171036

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): 29-Mar-2021 10:58

[eCRF Audit Trail History](#)

Reactogenicity Diary

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

090177e196ae3dcc\Final\Final On: 01-Apr-2021 04:41 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 1117

Subject No: 11171036

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): 29-Mar-2021 10:58

[eCRF Audit Trail History](#)

Date of Visit

1.	Date of Visit	Sep/10/2020	
2.	Erroneous Visit	Not Applicable	Comments

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 15-Sep-2020 21:54

Site No: 1117

Subject No: 11171036

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): 29-Mar-2021 10:58

[eCRF Audit Trail History](#)

Vital Signs

1.	Date:	Sep/10/2020
----	-------	-------------

Vital Signs Details

2.a	Record Identifier:	1
	Temperature:	[98.2]
	Unit:	F
	Temperature Location:	ORAL CAVITY

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:03

Site No: 1117

Subject No: 11171036

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): 29-Mar-2021 10:58

[eCRF Audit Trail History](#)

Electronic Sample Tracking

1.	Data Origin	SITE	
2.	Sample Type	NASAL_SWAB	
3.	Sample Collected?	YES Date of Collection: Sep/10/2020	
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	Not Applicable []	Comments

Aliquot

Please enter barcode for each aliquot.

5.a	Sample ID	[BM8YFW]
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Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1117

Subject No: 11171036

Generated By: (b) (4)

Form: VACCINATION

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1117) Sundance Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:58

[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/10/2020 13:12
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

090177e196ae3dcc\Final\Final On: 01-Apr-2021 04:41 (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: 11171036

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

[eCRF Audit Trail History](#)

Date of Visit

1.	Date of Visit	Oct/8/2020
2.	Erroneous Visit	

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1117

Site Name: (1117) Sundance Clinical Research

Subject No: 11171036

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

[eCRF Audit Trail History](#)

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	SERUM
3.	Sample Collected?	YES Date of Collection: Oct/8/2020
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	[BRJ8DP]
5.b	Sample ID	[BRJ8DR]
5.c	Sample ID	[BRJ8F6]
5.d	Sample ID	[BRSRLH]
5.e	Sample ID	[BRSRLJ]

090177e196ae3dcc\Final\Final On: 01-Apr-2021 04:41 (GMT)

Header Text: c4591001

Visit: V4_MONTH6_L

Form Version: 22-Apr-2020 21:02

Site No: 1117

Subject No: 11171036

Generated By: (b) (4)

Form: DATE OF VISIT

Form Status: Not Started

Site Name: (1117) Sundance Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:58

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

Header Text: c4591001

Visit: V4_MONTH6_L

Form Version: 22-Apr-2020 21:03

Site No: 1117

Subject No: 11171036

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Status: Not Started

Site Name: (1117) Sundance Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:58

Electronic Sample Tracking

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

Aliquot

Please enter barcode for each aliquot.

5.	Sample ID	[]
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Header Text: c4591001

Visit: V5_MONTH12_L

Form Version: 22-Apr-2020 21:02

Site No: 1117

Subject No: 11171036

Generated By: (b) (4)

Form: DATE OF VISIT

Form Status: Not Started

Site Name: (1117) Sundance Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:58

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

Header Text: c4591001

Visit: V5_MONTH12_L

Form Version: 22-Apr-2020 21:03

Site No: 1117

Subject No: 11171036

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Status: Not Started

Site Name: (1117) Sundance Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:58

Electronic Sample Tracking

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

Aliquot

Please enter barcode for each aliquot.

5.	Sample ID	[]
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090177e196ae3dcc\Final\Final On: 01-Apr-2021 04:41 (GMT)

Header Text: c4591001

Visit: V6_MONTH24_L

Form Version: 22-Apr-2020 21:02

Site No: 1117

Subject No: 11171036

Generated By: (b) (4)

Form: DATE OF VISIT

Form Status: Not Started

Site Name: (1117) Sundance Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:58

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

Header Text: c4591001

Visit: V6_MONTH24_L

Form Version: 22-Apr-2020 21:03

Site No: 1117

Subject No: 11171036

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Status: Not Started

Site Name: (1117) Sundance Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:58

Electronic Sample Tracking

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

Aliquot

Please enter barcode for each aliquot.

5.	Sample ID	[]
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Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on **Form:** DATE OF VISIT - ILLNESS ONSET
Oct/08/2020

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1117

Site Name: (1117) Sundance Clinical Research

Subject No: 11171036

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

[eCRF Audit Trail History](#)

Date of Visit

1.	Date of Visit	Oct/8/2020
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 Oct/08/2020 Form: SIGNS AND SYMPTOMS OF POTENTIAL COVID-19

Form Version: 15-Sep-2020 21:55

Form Status: Data Complete, Frozen, Not Complete

Site No: 1117

Site Name: (1117) Sundance Clinical Research

Subject No: 11171036

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

[eCRF Audit Trail History](#)

Signs and Symptoms

1.	Date of Assessment:	Oct/8/2020
2.	Date of First Symptom Started:	Sep/22/2020
3.	Symptoms Ongoing?	NO Date of Last Symptom Resolved: Dec/3/2020

Symptoms

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

Symptoms - Other

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

090177e196ae3dcc\Final\Final On: 01-Apr-2021 04:41 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/08/2020 **Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19

Form Version: 15-Sep-2020 21:55

Form Status: Data Complete, Frozen, Not Complete

Site No: 1117

Site Name: (1117) Sundance Clinical Research

Subject No: 11171036

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

5.b	Symptoms - Other Text:	[SINUS PRESSURE]
5.c	Symptoms - Other Text:	[LEFT ARM SORENESS]
5.d	Symptoms - Other Text:	[NECK STIFFNESS]

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: 11171036

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

#	Date of Collection	Specimen Type	Specimen Collection Location	Assay Code and Description	Device Type	Form Instance
1.	Not Done	Not Done	Not Done	Not Done	Not Done	Repeating Pages

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on **Form:** MICROBIOLOGY SPECIMEN
Oct/08/2020

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen, Verified

Site No: 1117

Site Name: (1117) Sundance Clinical Research

Subject No: 11171036

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

[Back to Form](#)

[Form Comments](#)

[eCRF Audit Trail History](#)

Microbiology Specimen

1.	Actual Date of Collection:	Not Done _____ //	Comments
2.	Specimen Type:	Not Done _____	Comments
3.	Specimen Collection Location:	Not Done _____	Comments
4.	Assay Code and Description:	Not Done _____	Comments
5.	Device Type:	Not Done _____	Comments
6.	Trade Name:	Not Done _____	Comments
7.	Test Result:	Not Done _____	Comments
8.	Comments/Findings/Details:	Not Done _____ []	Comments
9.	Trade Name Other, Specify:	Not Done _____ []	Comments

090177e196ae3dcc\Final\Final On: 01-Apr-2021 04:41 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/08/2020 **Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB SELF

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1117

Site Name: (1117) Sundance Clinical Research

Subject No: 11171036

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

[Form Comments](#)
[eCRF Audit Trail History](#)

Electronic Sample Tracking

1.	Data Origin	SITE	Comments
2.	Sample Type	NASAL_SWAB_SELF	Comments
3.	Sample Collected?	NO	Comments
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[SWAB PFE WAS COLLECTED BY CLINIC PERSONNEL]	Comments

Aliquot

Please enter barcode for each aliquot.

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

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/08/2020 **Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1117

Site Name: (1117) Sundance Clinical Research

Subject No: 11171036

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

[eCRF Audit Trail History](#)

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Oct/8/2020
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	[BRJ8DB]
-----	-----------	----------

090177e196ae3dcc\Final\Final On: 01-Apr-2021 04:41 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/08/2020 Form: HEALTH CARE UTILIZATION

Form Version: 10-Oct-2020 15:59

Form Status: Data Complete, Frozen, Verified

Site No: 1117

Site Name: (1117) Sundance Clinical Research

Subject No: 11171036

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

[eCRF Audit Trail History](#)

Health Care Utilization

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

090177e196ae3dcc\Final\Final On: 01-Apr-2021 04:41 (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: 11171036

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

#	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	Repeating Pages

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on **Form:** RESPIRATORY TREATMENT
Oct/08/2020

Form Version: 06-Jul-2020 21:53

Form Status: Data Complete, Frozen, Verified

Site No: 1117

Site Name: (1117) Sundance Clinical Research

Subject No: 11171036

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

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Respiratory Treatment

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

090177e196ae3dcc\Final\Final On: 01-Apr-2021 04:41 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/08/2020 **Form:** ILLNESS DETAILS

Form Version: 06-Jul-2020 21:52

Form Status: Data Complete, Frozen, Verified

Site No: 1117

Site Name: (1117) Sundance Clinical Research

Subject No: 11171036

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

[eCRF Audit Trail History](#)

Illness Details

1.	Category of Clinical Event:	POTENTIAL COVID-19 ILLNESS
2.	Was a diagnosis obtained for Potential COVID-19 Illness?	NO
3.	Toxicity Grade:	1

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: 11171036

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

#	Category of Clinical Event:	Subcategory of Clinical Event	Diagnosis Obtained	Toxicity Grade	Form Instance
1.	Not Done	Not Done	Not Done	Not Done	Repeating Pages

090177e196ae3dcc\Final\Final On: 01-Apr-2021 04:41 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/08/2020 **Form:** ILLNESS DETAILS - SEVERE

Form Version: 17-Jul-2020 21:55

Form Status: Data Complete, Frozen, Verified

Site No: 1117

Site Name: (1117) Sundance Clinical Research

Subject No: 11171036

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

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Illness Details

1.	Category of Clinical Event:	Not Done _____	Comments
2.	Subcategory of Clinical Event:	Not Done _____	Comments
3.	Was a diagnosis obtained?	Not Done _____	Comments
4.	Toxicity Grade:	Not Done _____	Comments

Header Text: c4591001

Visit: POT_COVID_ILL 1

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY

Form Version: 21-Aug-2020 02:49

Site No: 1117

Site Name: (1117) Sundance Clinical Research

Subject No: 11171036

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

#	Category for Lab Test	Vendor Name	Collection Date:	Specimen Type	Lab Result			Form Instance
1.	Not Done	Not Done	Not Done	Not Done	Sponsor-Defined Identifier	Test:	Result:	Repeating Pages
					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	

090177e196ae3dcc\Final\Final On: 01-Apr-2021 04:41 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/08/2020 **Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Frozen, Verified

Site No: 1117

Site Name: (1117) Sundance Clinical Research

Subject No: 11171036

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

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[eCRF Audit Trail History](#)

Lab Chemistry Details

1.	Lab Panel:	Not Done _____	Comments
2.	Laboratory Name and Address	Not Done _____ []	Comments
3.	Collection Date:	Not Done _____ //	Comments
4.	Specimen Type:	Not Done _____	Comments

Lab Result

5.a	Sponsor ID:	Not Done _____ []	Comments
	Test:	C Reactive Protein_PX329	
	Result:	Not Done _____ []	Comments
	Not Done:	Not Done _____	Comments
	LNMT	Not Done _____ Low [] High [] Unit	Comments

090177e196ae3dcc\Final\Final On: 01-Apr-2021 04:41 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on **Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY
Oct/08/2020

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Frozen, Verified

Site No: 1117

Site Name: (1117) Sundance Clinical Research

Subject No: 11171036

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

5.b	Sponsor ID:	Not Done _____	Comments
		[]	
	Test:	Alanine Aminotransferase_PX30	
	Result:	Not Done _____	Comments
		[]	
Not Done:	Not Done _____	Comments	
LNMT	Not Done _____	Comments	
	Low [] High [] Unit		

5.c	Sponsor ID:	Not Done _____	Comments
		[]	
	Test:	Aspartate Aminotransferase_PX28	
	Result:	Not Done _____	Comments
		[]	
Not Done:	Not Done _____	Comments	
LNMT	Not Done _____	Comments	
	Low [] High [] Unit		

090177e196ae3dcc\Final\Final On: 01-Apr-2021 04:41 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on **Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY
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Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Frozen, Verified

Site No: 1117

Site Name: (1117) Sundance Clinical Research

Subject No: 11171036

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

5.d	Sponsor ID:	Not Done _____	Comments
		[]	
	Test:	Alkaline Phosphatase_PX35	
	Result:	Not Done _____	Comments
		[]	
Not Done:	Not Done _____	Comments	
LNMT	Not Done _____	Comments	
	Low [] High [] Unit		

5.e	Sponsor ID:	Not Done _____	Comments
		[]	
	Test:	Bilirubin_PX21	
	Result:	Not Done _____	Comments
		[]	
Not Done:	Not Done _____	Comments	
LNMT	Not Done _____	Comments	
	Low [] High [] Unit		

090177e196ae3dcc\Final\Final On: 01-Apr-2021 04:41 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on **Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY
Oct/08/2020

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Frozen, Verified

Site No: 1117

Site Name: (1117) Sundance Clinical Research

Subject No: 11171036

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

5.f	Sponsor ID:	Not Done _____	Comments
		[]	
	Test:	Blood Urea Nitrogen_PX47	
	Result:	Not Done _____	Comments
		[]	
Not Done:	Not Done _____	Comments	
LNMT	Not Done _____	Comments	
	Low [] High [] Unit		

5.g	Sponsor ID:	Not Done _____	Comments
		[]	
	Test:	Creatinine_PX48	
	Result:	Not Done _____	Comments
		[]	
Not Done:	Not Done _____	Comments	
LNMT	Not Done _____	Comments	
	Low [] High [] Unit		

090177e196ae3dcc\Final\Final On: 01-Apr-2021 04:41 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1

Form: LOCAL LABORATORY DATA - REPEATING Hematology

Form Version: 21-Aug-2020 02:51

Site No: 1117

Site Name: (1117) Sundance Clinical Research

Subject No: 11171036

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

#	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	Sponsor-Defined Identifier	Test:	Result:	Repeating Pages
					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	

090177e196ae3dcc\Final\Final On: 01-Apr-2021 04:41 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/08/2020 **Form:** LOCAL LABORATORY DATA - REPEATING Hematology

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete, Frozen, Verified

Site No: 1117

Site Name: (1117) Sundance Clinical Research

Subject No: 11171036

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

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Laboratory Data Hematology

1.	Lab Panel:	Not Done _____	Comments
2.	Laboratory Name and Address	Not Done _____ []	Comments
3.	Collection Date:	Not Done _____ //	Comments
4.	Specimen Type:	Not Done _____	Comments

Lab Result

5.a	Sponsor ID:	Not Done _____ []	Comments
	Test:	Hemoglobin_PX1	
	Result:	Not Done _____ []	Comments
	Not Done:	Not Done _____	Comments
	LNMT	Not Done _____ Low [] High [] Unit	Comments

090177e196ae3dcc\Final\Final On: 01-Apr-2021 04:41 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on **Form:** LOCAL LABORATORY DATA - REPEATING Hematology
Oct/08/2020

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete, Frozen, Verified

Site No: 1117

Site Name: (1117) Sundance Clinical Research

Subject No: 11171036

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

5.b	Sponsor ID:	Not Done _____	Comments
		[]	
	Test:	Hematocrit_PX2	
	Result:	Not Done _____	Comments
		[]	
Not Done:	Not Done _____	Comments	
LNMT	Not Done _____	Comments	
	Low [] High [] Unit		

5.c	Sponsor ID:	Not Done _____	Comments
		[]	
	Test:	Erythrocytes_PX3	
	Result:	Not Done _____	Comments
		[]	
Not Done:	Not Done _____	Comments	
LNMT	Not Done _____	Comments	
	Low [] High [] Unit		

090177e196ae3dcc\Final\Final On: 01-Apr-2021 04:41 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on **Form:** LOCAL LABORATORY DATA - REPEATING Hematology
Oct/08/2020

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete, Frozen, Verified

Site No: 1117

Site Name: (1117) Sundance Clinical Research

Subject No: 11171036

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

5.d	Sponsor ID:	Not Done _____	Comments
		[]	
	Test:	Platelets_PX5	
	Result:	Not Done _____	Comments
		[]	
Not Done:	Not Done _____	Comments	
LNMT	Not Done _____	Comments	
	Low [] High [] Unit		
5.e	Sponsor ID:	Not Done _____	Comments
		[]	
	Test:	Leukocytes_PX7	
	Result:	Not Done _____	Comments
		[]	
Not Done:	Not Done _____	Comments	
LNMT	Not Done _____	Comments	
	Low [] High [] Unit		

090177e196ae3dcc\Final\Final On: 01-Apr-2021 04:41 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on **Form:** LOCAL LABORATORY DATA - REPEATING Hematology
Oct/08/2020

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete, Frozen, Verified

Site No: 1117

Site Name: (1117) Sundance Clinical Research

Subject No: 11171036

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

5.f	Sponsor ID:	Not Done _____	Comments
		[]	
	Test:	Neutrophils_PX608	
	Result:	Not Done _____	Comments
		[]	
Not Done:	Not Done _____	Comments	
LNMT	Not Done _____	Comments	
	Low [] High [] Unit		

5.g	Sponsor ID:	Not Done _____	Comments
		[]	
	Test:	Eosinophils_PX609	
	Result:	Not Done _____	Comments
		[]	
Not Done:	Not Done _____	Comments	
LNMT	Not Done _____	Comments	
	Low [] High [] Unit		

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Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on **Form:** LOCAL LABORATORY DATA - REPEATING Hematology
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Form Version: 21-Aug-2020 02:51

Form Status: Data Complete, Frozen, Verified

Site No: 1117

Site Name: (1117) Sundance Clinical Research

Subject No: 11171036

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

5.h	Sponsor ID:	Not Done _____	Comments
		[]	
	Test:	Monocytes_PX612	
	Result:	Not Done _____	Comments
		[]	
Not Done:	Not Done _____	Comments	
LNMT	Not Done _____	Comments	
	Low [] High [] Unit		
5.i	Sponsor ID:	Not Done _____	Comments
		[]	
	Test:	Basophils_PX610	
	Result:	Not Done _____	Comments
		[]	
Not Done:	Not Done _____	Comments	
LNMT	Not Done _____	Comments	
	Low [] High [] Unit		

090177e196ae3dcc\Final\Final On: 01-Apr-2021 04:41 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on **Form:** LOCAL LABORATORY DATA - REPEATING Hematology
Oct/08/2020

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete, Frozen, Verified

Site No: 1117

Site Name: (1117) Sundance Clinical Research

Subject No: 11171036

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

5.j	Sponsor ID:	Not Done _____ []	Comments
	Test:	Lymphocytes_PX611	
	Result:	Not Done _____ []	Comments
	Not Done:	Not Done _____	Comments
	LNMT	Not Done _____ Low [] High [] Unit	Comments

090177e196ae3dcc\Final\Final On: 01-Apr-2021 04:41 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1

Form: VITAL SIGNS - COVID

Form Version: 21-Aug-2020 02:50

Site No: 1117

Site Name: (1117) Sundance Clinical Research

Subject No: 11171036

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

#	Date:	Vital Signs Details			Form Instance
1.	Not Done	Record Identifier:	Systolic:	Diastolic:	Repeating Pages
		Not Done	Not Done	Not Done	

090177e196ae3dcc\Final\Final On: 01-Apr-2021 04:41 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on **Form:** VITAL SIGNS - COVID
Oct/08/2020

Form Version: 21-Aug-2020 02:50

Form Status: Data Complete, Frozen, Verified

Site No: 1117

Site Name: (1117) Sundance Clinical Research

Subject No: 11171036

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

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Vital Signs

1.	Date:	Not Done _____ //	Comments
----	-------	-------------------------	--------------------------

Vital Signs Details

2.a	Record Identifier:	Not Done _____ 1	
	Systolic:	Not Done _____ []	Comments
	Diastolic:	Not Done _____ []	Comments
	Respiratory Rate in respirations/minute:	Not Done _____ []	Comments
	Heart Rate in beats/minute:	Not Done _____ []	Comments

090177e196ae3dcc\Final\Final On: 01-Apr-2021 04:41 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1

Form: VITAL SIGNS - PULSE OX ROOM AIR

Form Version: 21-Aug-2020 02:51

Site No: 1117

Site Name: (1117) Sundance Clinical Research

Subject No: 11171036

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

#	Date:	Vital Signs Details		Form Instance
1.	Not Done	Record Identifier:	Oxygen Saturation	Repeating Pages
		Not Done	Not Done	

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/08/2020 **Form:** VITAL SIGNS - PULSE OX ROOM AIR

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete, Frozen, Verified

Site No: 1117

Site Name: (1117) Sundance Clinical Research

Subject No: 11171036

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

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Vital Signs

1.	Date:	Not Done _____ //	Comments
----	-------	-------------------------	--------------------------

Vital Signs Details

2.a	Record Identifier:	Not Done _____ 1	
	SPO2 Pulse Oximetry %	Not Done _____ []	Comments

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: 11171036

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

#	Date Time of Assessment	Arterial Blood Gases PaO2	FiO2 (Fraction of Inhaled Oxygen)	Form Instance
1.	Not Done	Not Done	Not Done	Repeating Pages

090177e196ae3dcc\Final\Final On: 01-Apr-2021 04:41 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on **Form:** OXYGENATION PARAMETERS
Oct/08/2020

Form Version: 06-Jul-2020 21:52

Form Status: Data Complete, Frozen, Verified

Site No: 1117

Site Name: (1117) Sundance Clinical Research

Subject No: 11171036

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

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[Form Comments](#)

[eCRF Audit Trail History](#)

Oxygenation Parameters

1.	Date Time of Assessment:	Not Done _____ //	Comments
2.	Arterial Blood Gases PaO2 (mmHg):	Not Done _____ []	Comments
3.	FiO2 (Fraction of Inhaled Oxygen):	Not Done _____ []	Comments

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: 11171036

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

#	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	Repeating Pages

090177e196ae3dcc\Final\Final On: 01-Apr-2021 04:41 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on **Form:** CONCOMITANT MEDICATIONS - VASOPRESSORS
Oct/08/2020

Form Version: 06-Jul-2020 21:55

Form Status: Data Complete, Frozen, Verified

Site No: 1117

Site Name: (1117) Sundance Clinical Research

Subject No: 11171036

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

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[eCRF Audit Trail History](#)

Concomitant Medications

1.	What is the medication identifier?	Not Done _____ []	Comments
2.	Category:	Not Done _____	Comments
3.	Concomitant Medications Pre-specified:	Not Done _____	Comments
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 _____ []	Comments
5.	Start Date:	Not Done _____ //	Comments
6.	Ongoing?	Not Done _____	Comments

090177e196ae3dcc\Final\Final On: 01-Apr-2021 04:41 (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: 11171036

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

#	Date of Assessment	Location of Assessment	Imaging Method	Overall Assessment	Form Instance
1.	Not Done	Not Done	Not Done	Not Done	Repeating Pages

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on **Form:** IMAGING
Oct/08/2020

Form Version: 06-Jul-2020 21:53

Form Status: Data Complete, Frozen, Verified

Site No: 1117

Site Name: (1117) Sundance Clinical Research

Subject No: 11171036

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

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[eCRF Audit Trail History](#)

Imaging

1.	Date of Assessment:	Not Done _____ //	Comments
2.	Location of Assessment:	Not Done _____	Comments
3.	Type of Imaging Exam:	Not Done _____	Comments
4.	Assessment:	Not Done _____	Comments

Header Text: c4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit on Dec/23/2020 **Form:** DATE OF VISIT - ILLNESS ONSET

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1117

Site Name: (1117) Sundance Clinical Research

Subject No: 11171036

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

[eCRF Audit Trail History](#)

Date of Visit

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

COVID-19 Illness Visit

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

Visit: POT_COVID_ILL 2 - Unscheduled Visit on Dec/23/2020 Form: SIGNS AND SYMPTOMS OF POTENTIAL COVID-19

Form Version: 10-Dec-2020 02:29

Form Status: Data Complete, Frozen, Verified

Site No: 1117

Site Name: (1117) Sundance Clinical Research

Subject No: 11171036

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

[Form Comments](#)
[eCRF Audit Trail History](#)

Signs and Symptoms

1.	Date of Assessment:	Not Applicable _____ //	Comments
2.	Date of First Symptom Started:	Not Applicable _____ //	Comments
3.	Symptoms Ongoing?	Not Applicable _____	Comments

Symptoms

4.a	Symptoms:	FEVER	
	Was symptom present?	Not Applicable _____	Comments
4.b	Symptoms:	NEW OR INCREASED COUGH	
	Was symptom present?	Not Applicable _____	Comments
4.c	Symptoms:	NEW OR INCREASED SHORTNESS OF BREATH	
	Was symptom present?	Not Applicable _____	Comments
4.d	Symptoms:	CHILLS	
	Was symptom present?	Not Applicable _____	Comments
4.e	Symptoms:	NEW OR INCREASED MUSCLE PAIN	
	Was symptom present?	Not Applicable _____	Comments
4.f	Symptoms:	NEW LOSS OF TASTE OR SMELL	
	Was symptom present?	Not Applicable _____	Comments
4.g	Symptoms:	NEW OR INCREASED SORE THROAT	
	Was symptom present?	Not Applicable _____	Comments

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Header Text: c4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit on Dec/23/2020 **Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19

Form Version: 10-Dec-2020 02:29

Form Status: Data Complete, Frozen, Verified

Site No: 1117

Site Name: (1117) Sundance Clinical Research

Subject No: 11171036

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

4.h	Symptoms:	DIARRHEA	
	Was symptom present?	Not Applicable _____	Comments
4.i	Symptoms:	VOMITING	
	Was symptom present?	Not Applicable _____	Comments
Symptoms - Other			
5.a	Symptoms - Other Text:	[]	
5.b	Symptoms - Other Text:	[]	
5.c	Symptoms - Other Text:	[]	

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Header Text: c4591001

Visit: POT_COVID_ILL 2

Form: MICROBIOLOGY SPECIMEN

Form Version: 06-Jul-2020 21:54

Site No: 1117

Site Name: (1117) Sundance Clinical Research

Subject No: 11171036

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

#	Date of Collection	Specimen Type	Specimen Collection Location	Assay Code and Description	Device Type	Form Instance
1.	Not Applicable	Not Applicable	Not Applicable	Not Applicable	Not Applicable	Repeating Pages

Header Text: c4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit on Dec/23/2020 **Form:** MICROBIOLOGY SPECIMEN

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen, Verified

Site No: 1117

Site Name: (1117) Sundance Clinical Research

Subject No: 11171036

Subject Initials: ---

Generated By: (b) (4)

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Microbiology Specimen

1.	Actual Date of Collection:	Not Applicable _____ //	Comments
2.	Specimen Type:	Not Applicable _____	Comments
3.	Specimen Collection Location:	Not Applicable _____	Comments
4.	Assay Code and Description:	Not Applicable _____	Comments
5.	Device Type:	Not Applicable _____	Comments
6.	Trade Name:	Not Applicable _____	Comments
7.	Test Result:	Not Applicable _____	Comments
8.	Comments/Findings/Details:	Not Applicable _____ []	Comments
9.	Trade Name Other, Specify:	Not Applicable _____ []	Comments

090177e196ae3dcc\Final\Final On: 01-Apr-2021 04:41 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit on Dec/23/2020 **Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB SELF

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1117

Site Name: (1117) Sundance Clinical Research

Subject No: 11171036

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

[Form Comments](#)
[eCRF Audit Trail History](#)

Electronic Sample Tracking

1.	Data Origin	SITE	Comments
2.	Sample Type	NASAL_SWAB_SELF	Comments
3.	Sample Collected?	YES Date of Collection: Dec/7/2020	Comments
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[SELF SWAB TAKEN WITHOUT ILLNESS]	Comments

Aliquot

Please enter barcode for each aliquot.

5.a	Sample ID	[CV60869]	Comments
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Header Text: c4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit on Dec/23/2020 **Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1117

Site Name: (1117) Sundance Clinical Research

Subject No: 11171036

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

[Form Comments](#)
[eCRF Audit Trail History](#)

Electronic Sample Tracking

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

Aliquot

Please enter barcode for each aliquot.

5.	Sample ID	Not Applicable _____ []
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090177e196ae3dcc\Final\Final On: 01-Apr-2021 04:41 (GMT)

Header Text: c4591001**Visit:** POT_COVID_ILL 2 - Unscheduled Visit on Dec/23/2020 **Form:** HEALTH CARE UTILIZATION**Form Version:** 10-Dec-2020 02:26**Form Status:** Data Complete, Frozen**Site No:** 1117**Site Name:** (1117) Sundance Clinical Research**Subject No:** 11171036**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 10:58**[Form Comments](#)**
[eCRF Audit Trail History](#)**Health Care Utilization**

1.a	Physician or Healthcare Professional:	SPECIALIST	
	Occurrence of Visits or Contacts:	Not Applicable	Comments
1.b	Physician or Healthcare Professional:	EMERGENCY ROOM	
	Occurrence of Visits or Contacts:	Not Applicable	Comments
1.c	Physician or Healthcare Professional:	PRIMARY CARE PHYSICIAN	
	Occurrence of Visits or Contacts:	Not Applicable	Comments
1.d	Physician or Healthcare Professional:	URGENT CARE	
	Occurrence of Visits or Contacts:	Not Applicable	Comments
1.e	Physician or Healthcare Professional:	TELEPHONE CONSULTATION	
	Occurrence of Visits or Contacts:	Not Applicable	Comments
1.f	Physician or Healthcare Professional:	OTHER	
	Occurrence of Visits or Contacts:	Not Applicable	Comments

Health Care Utilization Other

2.	Other Type of Practitioner Specify:	Not Applicable	Comments
		[]	

Health Care Utilization

3.	Has the subject been hospitalized due to potential COVID-19 illness?	Not Applicable	Comments
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Header Text: c4591001

Visit: POT_COVID_ILL 2

Form: RESPIRATORY TREATMENT

Form Version: 06-Jul-2020 21:53

Site No: 1117

Site Name: (1117) Sundance Clinical Research

Subject No: 11171036

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

#	Treatment Identifier	Con Non-Drug Treatments Pre-specified	Treatment	Treatment	Start Date	Form Instance
1.	Not Applicable	Not Applicable	Not Applicable	Not Applicable	Not Applicable	Repeating Pages

090177e196ae3dcc\Final\Final On: 01-Apr-2021 04:41 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit on Dec/23/2020 **Form:** RESPIRATORY TREATMENT

Form Version: 06-Jul-2020 21:53

Form Status: Data Complete, Frozen

Site No: 1117

Site Name: (1117) Sundance Clinical Research

Subject No: 11171036

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

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Respiratory Treatment

1.	What is the treatment Identifier?	Not Applicable _____ []	Comments
2.	Concomitant Non-drug Treatment Pre-specified:	Not Applicable _____	Comments
3.	Treatment:	Not Applicable _____	Comments
4.	Treatment:	Not Applicable _____ []	Comments
5.	Start Date:	Not Applicable _____ //	Comments
6.	Ongoing?	Not Applicable _____	Comments

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Header Text: c4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit on Dec/23/2020 **Form:** ILLNESS DETAILS

Form Version: 06-Jul-2020 21:52

Form Status: Data Complete, Frozen

Site No: 1117

Site Name: (1117) Sundance Clinical Research

Subject No: 11171036

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

[Form Comments](#)
[eCRF Audit Trail History](#)

Illness Details

1.	Category of Clinical Event:	Not Applicable _____	Comments
2.	Was a diagnosis obtained for Potential COVID-19 Illness?	Not Applicable _____	Comments
3.	Toxicity Grade:	Not Applicable _____	Comments

Header Text: c4591001

Visit: POT_COVID_ILL 2

Form: ILLNESS DETAILS - SEVERE

Form Version: 17-Jul-2020 21:55

Site No: 1117

Site Name: (1117) Sundance Clinical Research

Subject No: 11171036

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

#	Category of Clinical Event:	Subcategory of Clinical Event	Diagnosis Obtained	Toxicity Grade	Form Instance
1.	Not Applicable	Not Applicable	Not Applicable	Not Applicable	Repeating Pages

Header Text: c4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit on Dec/23/2020 **Form:** ILLNESS DETAILS - SEVERE

Form Version: 17-Jul-2020 21:55

Form Status: Data Complete, Frozen

Site No: 1117

Site Name: (1117) Sundance Clinical Research

Subject No: 11171036

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

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Illness Details

1.	Category of Clinical Event:	Not Applicable _____	Comments
2.	Subcategory of Clinical Event:	Not Applicable _____	Comments
3.	Was a diagnosis obtained?	Not Applicable _____	Comments
4.	Toxicity Grade:	Not Applicable _____	Comments

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Header Text: c4591001

Visit: POT_COVID_ILL 2

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY

Form Version: 21-Aug-2020 02:49

Site No: 1117

Site Name: (1117) Sundance Clinical Research

Subject No: 11171036

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

#	Category for Lab Test	Vendor Name	Collection Date:	Specimen Type	Lab Result			Form Instance
1.	Not Applicable	Not Applicable	Not Applicable	Not Applicable	Sponsor-Defined Identifier	Test:	Result:	Repeating Pages
					Not Applicable	Not Done	Not Applicable	
					Not Applicable	Not Done	Not Applicable	
					Not Applicable	Not Done	Not Applicable	
					Not Applicable	Not Done	Not Applicable	
					Not Applicable	Not Done	Not Applicable	
					Not Applicable	Not Done	Not Applicable	
					Not Applicable	Not Done	Not Applicable	

090177e196ae3dcc\Final\Final On: 01-Apr-2021 04:41 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit on Dec/23/2020 **Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Frozen

Site No: 1117

Site Name: (1117) Sundance Clinical Research

Subject No: 11171036

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

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[eCRF Audit Trail History](#)

Lab Chemistry Details

1.	Lab Panel:	Not Applicable _____	Comments
2.	Laboratory Name and Address	Not Applicable _____ []	Comments
3.	Collection Date:	Not Applicable _____ //	Comments
4.	Specimen Type:	Not Applicable _____	Comments

Lab Result

5.a	Sponsor ID:	Not Applicable _____ []	Comments
	Test:	C Reactive Protein_PX329	
	Result:	Not Applicable _____ []	Comments
	Not Done:	Not Applicable _____	Comments
	LNMT	Not Applicable _____ Low [] High [] Unit	Comments

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Header Text: c4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit on Dec/23/2020 Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Frozen

Site No: 1117

Site Name: (1117) Sundance Clinical Research

Subject No: 11171036

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

5.b	Sponsor ID:	Not Applicable _____	Comments
		[]	
	Test:	Alanine Aminotransferase_PX30	
	Result:	Not Applicable _____	Comments
		[]	
Not Done:	Not Applicable _____	Comments	
LNMT	Not Applicable _____	Comments	
	Low [] High [] Unit		

5.c	Sponsor ID:	Not Applicable _____	Comments
		[]	
	Test:	Aspartate Aminotransferase_PX28	
	Result:	Not Applicable _____	Comments
		[]	
Not Done:	Not Applicable _____	Comments	
LNMT	Not Applicable _____	Comments	
	Low [] High [] Unit		

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Header Text: c4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit on Dec/23/2020 Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Frozen

Site No: 1117

Site Name: (1117) Sundance Clinical Research

Subject No: 11171036

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

5.d	Sponsor ID:	Not Applicable _____	Comments
		[]	
	Test:	Alkaline Phosphatase_PX35	
	Result:	Not Applicable _____	Comments
		[]	
	Not Done:	Not Applicable _____	Comments
	LNMT	Not Applicable _____	Comments
		Low [] High [] Unit	
5.e	Sponsor ID:	Not Applicable _____	Comments
		[]	
	Test:	Bilirubin_PX21	
	Result:	Not Applicable _____	Comments
		[]	
	Not Done:	Not Applicable _____	Comments
	LNMT	Not Applicable _____	Comments
		Low [] High [] Unit	

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Header Text: c4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit on Dec/23/2020 Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Frozen

Site No: 1117

Site Name: (1117) Sundance Clinical Research

Subject No: 11171036

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

5.f	Sponsor ID:	Not Applicable _____	Comments
		[]	
	Test:	Blood Urea Nitrogen_PX47	
	Result:	Not Applicable _____	Comments
		[]	
Not Done:	Not Applicable _____	Comments	
LNMT	Not Applicable _____	Comments	
	Low [] High [] Unit		

5.g	Sponsor ID:	Not Applicable _____	Comments
		[]	
	Test:	Creatinine_PX48	
	Result:	Not Applicable _____	Comments
		[]	
Not Done:	Not Applicable _____	Comments	
LNMT	Not Applicable _____	Comments	
	Low [] High [] Unit		

090177e196ae3dcc\Final\Final On: 01-Apr-2021 04:41 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 2

Form: LOCAL LABORATORY DATA - REPEATING Hematology

Form Version: 21-Aug-2020 02:51

Site No: 1117

Site Name: (1117) Sundance Clinical Research

Subject No: 11171036

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

#	Category for Lab Test	Vendor Name (DE RIVED)	Collection Date:	Specimen Type	Lab Result			Form Instance
1.	Not Applicable	Not Applicable	Not Applicable	Not Applicable	Sponsor-Defined Identifier	Test:	Result:	Repeating Pages
					Not Applicable	Not Done	Not Applicable	
					Not Applicable	Not Done	Not Applicable	
					Not Applicable	Not Done	Not Applicable	
					Not Applicable	Not Done	Not Applicable	
					Not Applicable	Not Done	Not Applicable	
					Not Applicable	Not Done	Not Applicable	
					Not Applicable	Not Done	Not Applicable	
					Not Applicable	Not Done	Not Applicable	
					Not Applicable	Not Done	Not Applicable	
					Not Applicable	Not Done	Not Applicable	

090177e196ae3dcc\Final\Final On: 01-Apr-2021 04:41 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit on Dec/23/2020 **Form:** LOCAL LABORATORY DATA - REPEATING Hematology

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete, Frozen

Site No: 1117

Site Name: (1117) Sundance Clinical Research

Subject No: 11171036

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

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Laboratory Data Hematology

1.	Lab Panel:	Not Applicable _____	Comments
2.	Laboratory Name and Address	Not Applicable _____ []	Comments
3.	Collection Date:	Not Applicable _____ //	Comments
4.	Specimen Type:	Not Applicable _____	Comments

Lab Result

5.a	Sponsor ID:	Not Applicable _____ []	Comments
	Test:	Hemoglobin_PX1	
	Result:	Not Applicable _____ []	Comments
	Not Done:	Not Applicable _____	Comments
	LNMT	Not Applicable _____ Low [] High [] Unit	Comments

090177e196ae3dcc\Final\Final On: 01-Apr-2021 04:41 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit on Dec/23/2020 **Form:** LOCAL LABORATORY DATA - REPEATING Hematology

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete, Frozen

Site No: 1117

Site Name: (1117) Sundance Clinical Research

Subject No: 11171036

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

5.b	Sponsor ID:	Not Applicable _____	Comments
		[]	
	Test:	Hematocrit_PX2	
	Result:	Not Applicable _____	Comments
		[]	
Not Done:	Not Applicable _____	Comments	
LNMT	Not Applicable _____	Comments	
	Low []		
	High []		
	Unit		

5.c	Sponsor ID:	Not Applicable _____	Comments
		[]	
	Test:	Erythrocytes_PX3	
	Result:	Not Applicable _____	Comments
		[]	
Not Done:	Not Applicable _____	Comments	
LNMT	Not Applicable _____	Comments	
	Low []		
	High []		
	Unit		

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Header Text: c4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit on Dec/23/2020 **Form:** LOCAL LABORATORY DATA - REPEATING Hematology

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete, Frozen

Site No: 1117

Site Name: (1117) Sundance Clinical Research

Subject No: 11171036

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

5.d	Sponsor ID:	Not Applicable _____	Comments
		[]	
	Test:	Platelets_PX5	
	Result:	Not Applicable _____	Comments
		[]	
Not Done:	Not Applicable _____	Comments	
LNMT	Not Applicable _____	Comments	
	Low []		
	High []		
	Unit		
5.e	Sponsor ID:	Not Applicable _____	Comments
		[]	
	Test:	Leukocytes_PX7	
	Result:	Not Applicable _____	Comments
		[]	
Not Done:	Not Applicable _____	Comments	
LNMT	Not Applicable _____	Comments	
	Low []		
	High []		
	Unit		

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Header Text: c4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit on Dec/23/2020 Form: LOCAL LABORATORY DATA - REPEATING Hematology

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete, Frozen

Site No: 1117

Site Name: (1117) Sundance Clinical Research

Subject No: 11171036

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

5 f	Sponsor ID:	Not Applicable _____	Comments
		[]	
	Test:	Neutrophils_PX608	
	Result:	Not Applicable _____	Comments
		[]	
Not Done:	Not Applicable _____	Comments	
LNMT	Not Applicable _____	Comments	
	Low [] High [] Unit		

5.g	Sponsor ID:	Not Applicable _____	Comments
		[]	
	Test:	Eosinophils_PX609	
	Result:	Not Applicable _____	Comments
		[]	
Not Done:	Not Applicable _____	Comments	
LNMT	Not Applicable _____	Comments	
	Low [] High [] Unit		

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Header Text: c4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit on Dec/23/2020 **Form:** LOCAL LABORATORY DATA - REPEATING Hematology

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete, Frozen

Site No: 1117

Site Name: (1117) Sundance Clinical Research

Subject No: 11171036

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

5.h	Sponsor ID:	Not Applicable _____	Comments
		[]	
	Test:	Monocytes_PX612	
	Result:	Not Applicable _____	Comments
		[]	
Not Done:	Not Applicable _____	Comments	
LNMT	Not Applicable _____	Comments	
	Low []		
	High []		
	Unit		

5.i	Sponsor ID:	Not Applicable _____	Comments
		[]	
	Test:	Basophils_PX610	
	Result:	Not Applicable _____	Comments
		[]	
Not Done:	Not Applicable _____	Comments	
LNMT	Not Applicable _____	Comments	
	Low []		
	High []		
	Unit		

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Header Text: c4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit on **Form:** LOCAL LABORATORY DATA - REPEATING Hematology
Dec/23/2020

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete, Frozen

Site No: 1117

Site Name: (1117) Sundance Clinical Research

Subject No: 11171036

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

5.j	Sponsor ID:	Not Applicable _____ []	Comments
	Test:	Lymphocytes_PX611	
	Result:	Not Applicable _____ []	Comments
	Not Done:	Not Applicable _____	Comments
	LNMT	Not Applicable _____ Low [] High [] Unit	Comments

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Header Text: c4591001

Visit: POT_COVID_ILL 2

Form: VITAL SIGNS - COVID

Form Version: 21-Aug-2020 02:50

Site No: 1117

Site Name: (1117) Sundance Clinical Research

Subject No: 11171036

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

#	Date:	Vital Signs Details			Form Instance
1.	Not Applicable	Record Identifier:	Systolic:	Diastolic:	Repeating Pages
		Not Done	Not Applicable	Not Applicable	

Header Text: c4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit on **Form:** VITAL SIGNS - COVID
Dec/23/2020

Form Version: 21-Aug-2020 02:50

Form Status: Data Complete, Frozen

Site No: 1117

Site Name: (1117) Sundance Clinical Research

Subject No: 11171036

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

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Vital Signs

1.	Date:	Not Applicable _____ //	Comments
----	-------	-------------------------------	--------------------------

Vital Signs Details

2.a	Record Identifier:	Not Applicable _____ 1	
	Systolic:	Not Applicable _____ []	Comments
	Diastolic:	Not Applicable _____ []	Comments
	Respiratory Rate in respirations/minute:	Not Applicable _____ []	Comments
	Heart Rate in beats/minute:	Not Applicable _____ []	Comments

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Header Text: c4591001

Visit: POT_COVID_ILL 2

Form: VITAL SIGNS - PULSE OX ROOM AIR

Form Version: 21-Aug-2020 02:51

Site No: 1117

Site Name: (1117) Sundance Clinical Research

Subject No: 11171036

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

#	Date:	Vital Signs Details		Form Instance
1.	Not Applicable	Record Identifier:	Oxygen Saturation	Repeating Pages
		Not Done	Not Applicable	

Header Text: c4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit on Dec/23/2020 **Form:** VITAL SIGNS - PULSE OX ROOM AIR

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete, Frozen

Site No: 1117

Site Name: (1117) Sundance Clinical Research

Subject No: 11171036

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

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Vital Signs

1.	Date:	Not Applicable _____ //	Comments
----	-------	-------------------------------	--------------------------

Vital Signs Details

2.a	Record Identifier:	Not Applicable _____ 1	
	SPO2 Pulse Oximetry %	Not Applicable _____ []	Comments

Header Text: c4591001

Visit: POT_COVID_ILL 2

Form: OXYGENATION PARAMETERS

Form Version: 06-Jul-2020 21:52

Site No: 1117

Site Name: (1117) Sundance Clinical Research

Subject No: 11171036

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

#	Date Time of Assessment	Arterial Blood Gases PaO2	FiO2 (Fraction of Inhaled Oxygen)	Form Instance
1.	Not Applicable	Not Applicable	Not Applicable	Repeating Pages

Header Text: c4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit on Dec/23/2020 **Form:** OXYGENATION PARAMETERS

Form Version: 06-Jul-2020 21:52

Form Status: Data Complete, Frozen

Site No: 1117

Site Name: (1117) Sundance Clinical Research

Subject No: 11171036

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

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Oxygenation Parameters

1.	Date Time of Assessment:	Not Applicable _____ //	Comments
2.	Arterial Blood Gases PaO2 (mmHg):	Not Applicable _____ []	Comments
3.	FiO2 (Fraction of Inhaled Oxygen):	Not Applicable _____ []	Comments

Header Text: c4591001

Visit: POT_COVID_ILL 2

Form: CONCOMITANT MEDICATIONS - VASOPRESSORS

Form Version: 06-Jul-2020 21:55

Site No: 1117

Site Name: (1117) Sundance Clinical Research

Subject No: 11171036

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

#	Sponsor-Defined Identifier	Category for Medication	Concomitant Medications Pre-specified	Name of Medication	Start Date	Form Instance
1.	Not Applicable	Not Applicable	Not Applicable	Not Applicable	Not Applicable	Repeating Pages

Header Text: c4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit on Dec/23/2020 **Form:** CONCOMITANT MEDICATIONS - VASOPRESSORS

Form Version: 06-Jul-2020 21:55

Form Status: Data Complete, Frozen

Site No: 1117

Site Name: (1117) Sundance Clinical Research

Subject No: 11171036

Subject Initials: ---

Generated By: (b) (4)

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Concomitant Medications

1.	What is the medication identifier?	Not Applicable _____ []	Comments
2.	Category:	Not Applicable _____	Comments
3.	Concomitant Medications Pre-specified:	Not Applicable _____	Comments
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 Applicable _____ []	Comments
5.	Start Date:	Not Applicable _____ //	Comments
6.	Ongoing?	Not Applicable _____	Comments

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Header Text: c4591001

Visit: POT_COVID_ILL 2

Form: IMAGING

Form Version: 06-Jul-2020 21:53

Site No: 1117

Site Name: (1117) Sundance Clinical Research

Subject No: 11171036

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

#	Date of Assessment	Location of Assessment	Imaging Method	Overall Assessment	Form Instance
1.	Not Applicable	Not Applicable	Not Applicable	Not Applicable	Repeating Pages

Header Text: c4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit on **Form:** IMAGING
Dec/23/2020

Form Version: 06-Jul-2020 21:53

Form Status: Data Complete, Frozen

Site No: 1117

Site Name: (1117) Sundance Clinical Research

Subject No: 11171036

Subject Initials: ---

Generated By: (b) (4)

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Imaging

1.	Date of Assessment:	Not Applicable _____ //	Comments
2.	Location of Assessment:	Not Applicable _____	Comments
3.	Type of Imaging Exam:	Not Applicable _____	Comments
4.	Assessment:	Not Applicable _____	Comments

Header Text: c4591001

Visit: POT_COVID_CONVA 1 - Unscheduled Visit **Form:** DATE OF VISIT - ILLNESS CONVALESCENT
on Nov/05/2020

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Frozen, Verified

Site No: 1117

Site Name: (1117) Sundance Clinical Research

Subject No: 11171036

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

[eCRF Audit Trail History](#)

Date of Visit

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

COVID-19 Illness Visit

3.	COVID-19 Illness Visit:	Not Applicable	Comments
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Header Text: c4591001

Visit: POT_COVID_CONVA 1 - Unscheduled Visit **Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY
on Nov/05/2020

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1117

Site Name: (1117) Sundance Clinical Research

Subject No: 11171036

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

[Form Comments](#)
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Electronic Sample Tracking

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

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	[]

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Header Text: c4591001

Visit: POT_COVID_CONVA 2 - Unscheduled Visit **Form:** DATE OF VISIT - ILLNESS CONVALESCENT
on Dec/03/2020

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Frozen, Verified

Site No: 1117

Site Name: (1117) Sundance Clinical Research

Subject No: 11171036

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

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Date of Visit

1.	Date of Visit	Dec/3/2020	
2.	Erroneous Visit	ERRONEOUS VISIT	

COVID-19 Illness Visit

3.	COVID-19 Illness Visit:	Not Applicable	Comments
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Header Text: c4591001

Visit: POT_COVID_CONVA 2 - Unscheduled Visit **Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY on Dec/03/2020

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1117

Site Name: (1117) Sundance Clinical Research

Subject No: 11171036

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

[Form Comments](#)
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Electronic Sample Tracking

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

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	[]
5.f	Sample ID	[]
5.g	Sample ID	[]

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Header Text: c4591001

Visit: POT_COVID_CONVA 3 - Unscheduled Visit **Form:** DATE OF VISIT - ILLNESS CONVALESCENT
on Jan/07/2021

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Frozen, Verified

Site No: 1117

Site Name: (1117) Sundance Clinical Research

Subject No: 11171036

Subject Initials: ---

Generated By: (b) (4)

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Date of Visit

1.	Date of Visit	Jan/7/2021
2.	Erroneous Visit	

COVID-19 Illness Visit

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

Visit: POT_COVID_CONVA 3 - Unscheduled Visit **Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY
on Jan/07/2021

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1117

Site Name: (1117) Sundance Clinical Research

Subject No: 11171036

Subject Initials: ---

Generated By: (b) (4)

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[eCRF Audit Trail History](#)

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	SERUM
3.	Sample Collected?	YES Date of Collection: Jan/7/2021
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	[BRDFPG]
5.b	Sample ID	[BRDFPH]
5.c	Sample ID	[BRDFPJ]
5.d	Sample ID	[BSFB3F]
5.e	Sample ID	[BSFB3G]

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Header Text: c4591001

Visit: Unplanned - New Unscheduled Visit

Form: DATE OF VISIT

Form Version: 22-Apr-2020 21:02

Form Status: Not Started

Site No: 1117

Site Name: (1117) Sundance Clinical Research

Subject No: 11171036

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

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: 11171036

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

Unplanned Assessments

1.	Assessments	
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Header Text: c4591001

Visit: End of Treatment - Unscheduled

Form: DISPOSITION - TREATMENT

Form Version: 15-Sep-2020 21:55

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1117

Site Name: (1117) Sundance Clinical Research

Subject No: 11171036

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

[eCRF Audit Trail History](#)

Disposition - Treatment

1.	Date of Completion/Discontinuation /Death :	Oct/8/2020
2.	Phase of Disposition:	VACCINATION
3.	Status:	COMPLETED
4.	Specify Status:	[]

Header Text: c4591001

Visit: Follow-Up - Unscheduled

Form Version: 15-Sep-2020 21:53

Site No: 1117

Subject No: 11171036

Generated By: (b) (4)

Form: DISPOSITION - FOLLOW-UP

Form Status: Not Started

Site Name: (1117) Sundance Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:58

Disposition - Follow-Up

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

Header Text: c4591001

Visit: POT_COVID_REPEAT_SWAB 1 -
Unscheduled Visit on Dec/07/2020

Form: DATE OF VISIT - REPEAT SWAB

Form Version: 10-Oct-2020 15:57

Form Status: Data Complete, Frozen, Verified

Site No: 1117

Site Name: (1117) Sundance Clinical Research

Subject No: 11171036

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

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Date of Visit

1.	Date of Visit	Dec/7/2020	
2.	Erroneous Visit	ERRONEOUS VISIT	

COVID-19 Repeat Swab

3.	COVID-19 Repeat Swab:	Not Applicable	Comments
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Header Text: c4591001

Visit: POT_COVID_REPEAT_SWAB 1 -
Unscheduled Visit on Dec/07/2020

Form: ELECTRONIC SAMPLE TRACKING - REPEAT SWAB

Form Version: 10-Oct-2020 15:57

Form Status: Data Complete, Frozen, Verified

Site No: 1117

Site Name: (1117) Sundance Clinical Research

Subject No: 11171036

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

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Electronic Sample Tracking

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

Aliquot

Please enter barcode for each aliquot.

5.a	Sample ID	Not Applicable _____ []
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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: 11171036

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

#	Category	AE Identifier	Adverse Event	Start Date	Is the Adverse Event Still Ongoing	Form Instance
1.	ADVERSE EVENT	1	Syncopal Episode	Aug/26/2020 UNK:UNK	NO End Date Time: Aug/30/2020 UNK:UNK	Repeating Pages
2.	ADVERSE EVENT	2	Suicidal ideation	Aug/27/2020 UNK:UNK	NO End Date Time: Aug/30/2020 UNK:UNK	Repeating Pages
3.	ADVERSE EVENT	3	ACUTE KIDNEY INJURY	Aug/26/2020 UNK:UNK	NO End Date Time: Aug/30/2020 UNK:UNK	Repeating Pages
4.	ADVERSE EVENT	4	RHABDOMYOLYSIS	Aug/26/2020 UNK:UNK	NO End Date Time: Aug/30/2020 UNK:UNK	Repeating Pages
5.	ADVERSE EVENT	5	ARM SORENESS, LEFT	Sep/22/2020 08:00	NO End Date Time: Oct/2/2020 UNK:UNK	Repeating Pages
6.	ADVERSE EVENT	6	NECK STIFFNESS	Sep/21/2020 08:00	NO End Date Time: Oct/24/2020 UNK:UNK	Repeating Pages
7. DELETED	ADVERSE EVENT	7	SORE THROAT	Oct/8/2020 UNK:UNK	YES	Repeating Pages
8. DELETED	ADVERSE EVENT	8	SHORTNESS OF BREATH	Oct/8/2020 21:00	YES	Repeating Pages

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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: 11171036

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

#	Category	AE Identifier	Adverse Event	Start Date	Is the Adverse Event Still Ongoing	Form Instance
9. DELETED	ADVERSE EVENT	9	MYALGIA	Oct/9/2020 UNK:UNK	YES	Repeating Pages
10.	ADVERSE EVENT	10	SUICIDAL IDEATION	Nov/20/2020 UNK:UNK	NO End Date Time: Nov/25/2020 UNK:UNK	Repeating Pages
11.	ADVERSE EVENT	11	WORSENING DIABETES MELLITUS TYPE 2	Nov/10/2020 UNK:UNK	YES	Repeating Pages
12.	ADVERSE EVENT	12	SNORING	Sep/UNK/2020 UNK:UNK	YES	Repeating Pages
13.	ADVERSE EVENT	13	HYPOCALCEMIA	Sep/UNK/2020 UNK:UNK	YES	Repeating Pages
14.	ADVERSE EVENT	14	WORSENING INSOMNIA	Sep/UNK/2020 UNK:UNK	YES	Repeating Pages
15.	ADVERSE EVENT	15	WORSENING HYPERTENSION	Sep/UNK/2020 UNK:UNK	YES	Repeating Pages
16.	ADVERSE EVENT	16	CHRONIC KIDNEY DISEASE, STAGE 2, WORSENING	Dec/31/2020 UNK:UNK	YES	Repeating Pages
17.	ADVERSE EVENT	17	MODERATE EPISODE OF MAJOR DEPRESSIVE DISORDER W/ PSYCHOSIS	Dec/30/2020 UNK:UNK	NO End Date Time: Jan/1/2021 UNK:UNK	Repeating Pages

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Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1117

Subject No: 11171036

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1117) Sundance Clinical Research

Subject Initials: ---

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Adverse Event Report

1.	Category:	ADVERSE EVENT
2.	AE ID:	[1]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[Syncope Episode]
4.	Start Date Time:	Aug/26/2020 UNK:UNK
5.	Is the adverse event still ongoing?	NO End Date Time: Aug/30/2020 UNK:UNK
6.	Toxicity Grade:	4
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).	YES Is this serious event associated with congenital anomaly or birth defect? NO Did this serious event result in death? NO Did this serious event require or prolong hospitalization? YES Did this serious event result in persistent or significant disability/incapacity? NO Is this serious event life threatening? NO Other medically important serious event 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: [Due to heat, acute kidney injury, rhabdomyolysis]
10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE

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Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1117

Subject No: 11171036

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1117) Sundance Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:58

11.	Was a Concomitant Medication given?	NO
12.	Was a Non-Drug Treatment given?	NO
13.	What was the outcome of this adverse event?:	RECOVERED/RESOLVED
14.	Did the adverse event cause the subject to be discontinued from the study?	NO
15.	Serious Adverse Event Number: For Pfizer Use Only	[2020343046]

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Header Text: c4591001**Visit:** Logs - Unscheduled**Form Version:** 22-Apr-2020 21:02**Site No:** 1117**Subject No:** 11171036**Generated By:** (b) (4)**Form:** ADVERSE EVENT REPORT**Form Status:** Data Complete, Locked, Frozen, Verified**Site Name:** (1117) Sundance Clinical Research**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 10:58

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Adverse Event Report

1.	Category:	ADVERSE EVENT
2.	AE ID:	[2]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[Suicidal ideation]
4.	Start Date Time:	Aug/27/2020 UNK:UNK
5.	Is the adverse event still ongoing?	NO End Date Time: Aug/30/2020 UNK:UNK
6.	Toxicity Grade:	4
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).	YES Is this serious event associated with congenital anomaly or birth defect? NO Did this serious event result in death? NO Did this serious event require or prolong hospitalization? YES Did this serious event result in persistent or significant disability/incapacity? NO Is this serious event life threatening? NO Other medically important serious event 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: [Per participant: "due to being in the hospital"]

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1117

Subject No: 11171036

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1117) Sundance Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:58

10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE
11.	Was a Concomitant Medication given?	YES
12.	Was a Non-Drug Treatment given?	NO
13.	What was the outcome of this adverse event?:	RECOVERED/RESOLVED
14.	Did the adverse event cause the subject to be discontinued from the study?	NO
15.	Serious Adverse Event Number: For Pfizer Use Only	[2020343046]

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Header Text: c4591001

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Site No: 1117

Subject No: 11171036

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1117) Sundance Clinical Research

Subject Initials: ---

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Adverse Event Report

1.	Category:	ADVERSE EVENT
2.	AE ID:	[3]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[ACUTE KIDNEY INJURY]
4.	Start Date Time:	Aug/26/2020 UNK:UNK
5.	Is the adverse event still ongoing?	NO End Date Time: Aug/30/2020 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: [HEAT RELATED EVENT]
10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE
11.	Was a Concomitant Medication given?	YES
12.	Was a Non-Drug Treatment given?	NO

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Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1117

Subject No: 11171036

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1117) Sundance Clinical Research

Subject Initials: ---

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

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Site No: 1117

Subject No: 11171036

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Form: ADVERSE EVENT REPORT

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Site Name: (1117) Sundance Clinical Research

Subject Initials: ---

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Adverse Event Report

1.	Category:	ADVERSE EVENT
2.	AE ID:	[4]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[RHABDOMYOLYSIS]
4.	Start Date Time:	Aug/26/2020 UNK:UNK
5.	Is the adverse event still ongoing?	NO End Date Time: Aug/30/2020 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: [HEAT RELATED EVENT]
10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE
11.	Was a Concomitant Medication given?	YES
12.	Was a Non-Drug Treatment given?	NO

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

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Adverse Event Report

1.	Category:	ADVERSE EVENT
2.	AE ID:	[5]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[ARM SORENESS, LEFT]
4.	Start Date Time:	Sep/22/2020 08:00
5.	Is the adverse event still ongoing?	NO End Date Time: Oct/2/2020 UNK:UNK
6.	Toxicity Grade:	2
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: [ETIOLOGY NOT KNOWN PER INVESTIGATOR]
10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE
11.	Was a Concomitant Medication given?	NO
12.	Was a Non-Drug Treatment given?	NO

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

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Adverse Event Report

1.	Category:	ADVERSE EVENT
2.	AE ID:	[6]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[NECK STIFFNESS]
4.	Start Date Time:	Sep/21/2020 08:00
5.	Is the adverse event still ongoing?	NO End Date Time: Oct/24/2020 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: [ETIOLOGY UNKNOWN PER INVESTIGATOR]
10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE
11.	Was a Concomitant Medication given?	NO
12.	Was a Non-Drug Treatment given?	NO

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

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Adverse Event Report

1.	Category:	ADVERSE EVENT
2.	AE ID:	[7]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[SORE THROAT]
4.	Start Date Time:	Oct/8/2020 UNK:UNK
5.	Is the adverse event still ongoing?	YES
6.	Toxicity Grade:	4
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: [SUSPECT VIRAL ILLNESS]
10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE
11.	Was a Concomitant Medication given?	NO
12.	Was a Non-Drug Treatment given?	NO

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13.	What was the outcome of this adverse event?:	RECOVERING/RESOLVING
14.	Did the adverse event cause the subject to be discontinued from the study?	NO
15.	Serious Adverse Event Number: For Pfizer Use Only	[]

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Adverse Event Report

1.	Category:	ADVERSE EVENT
2.	AE ID:	[8]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[SHORTNESS OF BREATH]
4.	Start Date Time:	Oct/8/2020 21:00
5.	Is the adverse event still ongoing?	YES
6.	Toxicity Grade:	4
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: [SUSPECT VIRUS INFECTION]
10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE
11.	Was a Concomitant Medication given?	NO
12.	Was a Non-Drug Treatment given?	NO

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13.	What was the outcome of this adverse event?:	RECOVERING/RESOLVING
14.	Did the adverse event cause the subject to be discontinued from the study?	NO
15.	Serious Adverse Event Number: For Pfizer Use Only	[]

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Adverse Event Report

1.	Category:	ADVERSE EVENT
2.	AE ID:	[9]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[MYALGIA]
4.	Start Date Time:	Oct/9/2020 UNK:UNK
5.	Is the adverse event still ongoing?	YES
6.	Toxicity Grade:	4
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: [SUSPECT VIRAL ILLNESS]
10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE
11.	Was a Concomitant Medication given?	NO
12.	Was a Non-Drug Treatment given?	NO

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13.	What was the outcome of this adverse event?:	RECOVERING/RESOLVING
14.	Did the adverse event cause the subject to be discontinued from the study?	NO
15.	Serious Adverse Event Number: For Pfizer Use Only	[]

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Adverse Event Report

1.	Category:	ADVERSE EVENT
2.	AE ID:	[10]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[SUICIDAL IDEATION]
4.	Start Date Time:	Nov/20/2020 UNK:UNK
5.	Is the adverse event still ongoing?	NO End Date Time: Nov/25/2020 UNK:UNK
6.	Toxicity Grade:	4
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).	YES Is this serious event associated with congenital anomaly or birth defect? NO Did this serious event result in death? NO Did this serious event require or prolong hospitalization? YES Did this serious event result in persistent or significant disability/incapacity? NO Is this serious event life threatening? NO Other medically important serious event 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: [MENTAL HEALTH DISORDER]

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10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE
11.	Was a Concomitant Medication given?	YES
12.	Was a Non-Drug Treatment given?	YES
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	[2020479673]

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Adverse Event Report

1.	Category:	ADVERSE EVENT
2.	AE ID:	[11]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[WORSENING DIABETES MELLITUS TYPE 2]
4.	Start Date Time:	Nov/10/2020 UNK:UNK
5.	Is the adverse event still ongoing?	YES
6.	Toxicity Grade:	2
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: [DISEASE PROGRESSION]
10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE
11.	Was a Concomitant Medication given?	YES
12.	Was a Non-Drug Treatment given?	NO
13.	What was the outcome of this adverse event?:	RECOVERING/RESOLVING

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14.	Did the adverse event cause the subject to be discontinued from the study?	NO
15.	Serious Adverse Event Number: For Pfizer Use Only	[]

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Adverse Event Report

1.	Category:	ADVERSE EVENT
2.	AE ID:	[12]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[SNORING]
4.	Start Date Time:	Sep/UNK/2020 UNK:UNK
5.	Is the adverse event still ongoing?	YES
6.	Toxicity Grade:	2
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: [ETIOLOGY UNKNOWN]
10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE
11.	Was a Concomitant Medication given?	NO
12.	Was a Non-Drug Treatment given?	NO
13.	What was the outcome of this adverse event?:	NOT RECOVERED/NOT RESOLVED

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14.	Did the adverse event cause the subject to be discontinued from the study?	NO
15.	Serious Adverse Event Number: For Pfizer Use Only	[]

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Adverse Event Report

1.	Category:	ADVERSE EVENT
2.	AE ID:	[13]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[HYPOCALCEMIA]
4.	Start Date Time:	Sep/UNK/2020 UNK:UNK
5.	Is the adverse event still ongoing?	YES
6.	Toxicity Grade:	2
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: [ETIOLOGY UNKNOWN]
10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE
11.	Was a Concomitant Medication given?	YES
12.	Was a Non-Drug Treatment given?	NO
13.	What was the outcome of this adverse event?:	NOT RECOVERED/NOT RESOLVED

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14.	Did the adverse event cause the subject to be discontinued from the study?	NO
15.	Serious Adverse Event Number: For Pfizer Use Only	[]

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Adverse Event Report

1.	Category:	ADVERSE EVENT
2.	AE ID:	[14]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[WORSENING INSOMNIA]
4.	Start Date Time:	Sep/UNK/2020 UNK:UNK
5.	Is the adverse event still ongoing?	YES
6.	Toxicity Grade:	2
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: [ETIOLOGY UNKNOWN]
10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE
11.	Was a Concomitant Medication given?	NO
12.	Was a Non-Drug Treatment given?	NO
13.	What was the outcome of this adverse event?:	RECOVERING/RESOLVING

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Subject Initials: ---

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14.	Did the adverse event cause the subject to be discontinued from the study?	NO
15.	Serious Adverse Event Number: For Pfizer Use Only	[]

090177e196ae3dcc\Final\Final On: 01-Apr-2021 04:41 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1117

Subject No: 11171036

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete

Site Name: (1117) Sundance Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:58

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Adverse Event Report

1.	Category:	ADVERSE EVENT
2.	AE ID:	[15]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[WORSENING HYPERTENSION]
4.	Start Date Time:	Sep/UNK/2020 UNK:UNK
5.	Is the adverse event still ongoing?	YES
6.	Toxicity Grade:	2
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: [NON COMPLIANCE WITH PLAN OF CARE]
10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE
11.	Was a Concomitant Medication given?	YES
12.	Was a Non-Drug Treatment given?	NO
13.	What was the outcome of this adverse event?:	NOT RECOVERED/NOT RESOLVED

090177e196ae3dcc\Final\Final On: 01-Apr-2021 04:41 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1117

Subject No: 11171036

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete

Site Name: (1117) Sundance Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:58

14.	Did the adverse event cause the subject to be discontinued from the study?	NO
15.	Serious Adverse Event Number: For Pfizer Use Only	[]

090177e196ae3dcc\Final\Final On: 01-Apr-2021 04:41 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1117

Subject No: 11171036

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete

Site Name: (1117) Sundance Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:58

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Adverse Event Report

1.	Category:	ADVERSE EVENT
2.	AE ID:	[16]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[CHRONIC KIDNEY DISEASE, STAGE 2, WORSENING]
4.	Start Date Time:	Dec/31/2020 UNK:UNK
5.	Is the adverse event still ongoing?	YES
6.	Toxicity Grade:	2
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: [DIABETES MELLITUS II DISEASE PROGRESSION]
10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE
11.	Was a Concomitant Medication given?	NO
12.	Was a Non-Drug Treatment given?	NO
13.	What was the outcome of this adverse event?:	RECOVERING/RESOLVING

090177e196ae3dcc\Final\Final On: 01-Apr-2021 04:41 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1117

Subject No: 11171036

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete

Site Name: (1117) Sundance Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:58

14.	Did the adverse event cause the subject to be discontinued from the study?	NO
15.	Serious Adverse Event Number: For Pfizer Use Only	[]

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Header Text: c4591001

Visit: Logs - Unscheduled

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Site No: 1117

Subject No: 11171036

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Frozen

Site Name: (1117) Sundance Clinical Research

Subject Initials: ---

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Adverse Event Report

1.	Category:	ADVERSE EVENT
2.	AE ID:	[17]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[MODERATE EPISODE OF MAJOR DEPRESSIVE DISORDER W/ PSYCHOSIS]
4.	Start Date Time:	Dec/30/2020 UNK:UNK
5.	Is the adverse event still ongoing?	NO End Date Time: Jan/1/2021 UNK:UNK
6.	Toxicity Grade:	3
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).	YES Is this serious event associated with congenital anomaly or birth defect? NO Did this serious event result in death? NO Did this serious event require or prolong hospitalization? YES Did this serious event result in persistent or significant disability/incapacity? NO Is this serious event life threatening? NO Other medically important serious event 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: [BIPOLAR DISORDER]

090177e196ae3dcc\Final\Final On: 01-Apr-2021 04:41 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1117

Subject No: 11171036

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Frozen

Site Name: (1117) Sundance Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:58

10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE
11.	Was a Concomitant Medication given?	YES
12.	Was a Non-Drug Treatment given?	YES
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	[2021011278]

090177e196ae3dcc\Final\Final On: 01-Apr-2021 04:41 (GMT)

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: 11171036

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

#	Category	Medication Error	Start Date	Is the medication error Still Ongoing	Study Medication Errors Action	Form Instance
1.						Repeating Pages

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 17-Jul-2020 21:54

Site No: 1117

Subject No: 11171036

Generated By: (b) (4)

Form: MEDICATION ERROR

Form Status: Not Started

Site Name: (1117) Sundance Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:58

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Medication Error

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

090177e196ae3dcc\Final\Final On: 01-Apr-2021 04:41 (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: 11171036

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

#	Sponsor-Defined Identifier	Category for Medication	Concomitant Medications Pre-specified	Name of Medication	Start Date	Form Instance
1.	1	VACCINATIONS	NO	INFLUENZA VACCINE	Sep/14/2020	Repeating Pages

090177e196ae3dcc\Final\Final On: 01-Apr-2021 04:41 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1117

Subject No: 11171036

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): 29-Mar-2021 10:58

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Concomitant Medications

1.	What is the medication identifier?	[1]
2.	Category:	VACCINATIONS
3.	Concomitant Medications Pre-specified:	NO
4.	Medication: Provide the complete generic drug name (including salt form, where applicable). Where generic name is unknown, enter the full trade or proprietary name. Include clarifying information in the Medication text (e.g., Ingredient(s), route, use, formulation).	[INFLUENZA VACCINE]
5.	Date:	Sep/14/2020

090177e196ae3dcc\Final\Final On: 01-Apr-2021 04:41 (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: 11171036

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

#	Sponsor-Defined Identifier	Category for Medication	Concomitant Medications Pre-specified	Name of Medication	Dose Description	Form Instance
1.						Repeating Pages

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1117

Subject No: 11171036

Generated By: (b) (4)

Form: CONCOMITANT MEDICATIONS - PROHIBITED

Form Status: Not Started

Site Name: (1117) Sundance Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:58

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Concomitant Medications

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

090177e196ae3dcc\Final\Final On: 01-Apr-2021 04:41 (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: 11171036

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

#	Category	Treatment Identifier	Con Non-Drug Treatments Pre-specified	Treatment	Start Date	Form Instance
1.						Repeating Pages

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1117

Subject No: 11171036

Generated By: (b) (4)

Form: RADIATION TREATMENT

Form Status: Not Started

Site Name: (1117) Sundance Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:58

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Radiation Treatment

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

090177e196ae3dcc\Final\Final On: 01-Apr-2021 04:41 (GMT)

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: 11171036

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

#	Transfusion Type	Date of Transfusion	Form Instance
1.			Repeating Pages

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1117

Subject No: 11171036

Generated By: (b) (4)

Form: TRANSFUSIONS

Form Status: Not Started

Site Name: (1117) Sundance Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:58

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

Header Text: c4591001

Visit: Unplanned Vaccination - Unscheduled

Form: DATE OF VISIT

Form Version: 22-Apr-2020 21:02

Form Status: Not Started

Site No: 1117

Site Name: (1117) Sundance Clinical Research

Subject No: 11171036

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

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: 11171036

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

Vital Signs

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

Vital Signs Details

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

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: 11171036

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

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?	

090177e196ae3dcc\Final\Final On: 01-Apr-2021 04:41 (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: 11171036

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

Contact Outcome

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

090177e196ae3dcc\Final\Final On: 01-Apr-2021 04:41 (GMT)

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: 11171036 **Subject Initials:** ---
Generated By: (b) (4) **Generated Time (GMT):** 29-Mar-2021 10:58

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

Header Text: c4591001

Visit: V201_SURVEIL_CONSENT - Unscheduled **Form:** DATE OF VISIT

Form Version: 22-Apr-2020 21:02

Form Status: Not Started

Site No: 1117

Site Name: (1117) Sundance Clinical Research

Subject No: 11171036

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

Header Text: c4591001

Visit: V201_SURVEIL_CONSENT - Unscheduled **Form:** INFORMED CONSENT - ASYMPTOMATIC SURVEILLANCE

Form Version: 14-Jan-2021 02:29

Form Status: Not Started

Site No: 1117

Site Name: (1117) Sundance Clinical Research

Subject No: 11171036

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

Informed Consent - Asymptomatic Surveillance

1.	Consent Was:	
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090177e196ae3dcc\Final\Final On: 01-Apr-2021 04:41 (GMT)

Header Text: c4591001

Visit: V201_SURVEIL_CONSENT - Unscheduled **Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1117

Site Name: (1117) Sundance Clinical Research

Subject No: 11171036

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

Electronic Sample Tracking

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

Aliquot

Please enter barcode for each aliquot.

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

Header Text: c4591001

Visit: V201_SURVEIL_CONSENT - Unscheduled **Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1117

Site Name: (1117) Sundance Clinical Research

Subject No: 11171036

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

Electronic Sample Tracking

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

Aliquot

Please enter barcode for each aliquot.

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

Header Text: c4591001

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

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen, Verified

Site No: 1117

Site Name: (1117) Sundance Clinical Research

Subject No: 11171036

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

[eCRF Audit Trail History](#)

Date of Visit

1.	Date of Visit	Jan/28/2021
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: 11171036

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

[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: 11171036

Generated By: (b) (4)

Form: TREATMENT UNBLINDED

Form Status: Data Complete, Frozen, Verified

Site Name: (1117) Sundance Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:58

[eCRF Audit Trail History](#)

Treatment Unblinded

1.	Date Treatment Unblinded :	Jan/28/2021
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: 11171036

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

Withdrawal Of Consent

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

Header Text: c4591001

Visit: Disposition - Unscheduled

Form: DEATH DETAILS CODED

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1117

Site Name: (1117) Sundance Clinical Research

Subject No: 11171036

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

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: 11171036

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): 29-Mar-2021 10:58

[eCRF Audit Trail History](#)

Date of Visit

1.	Date of Visit	Jan/28/2021
2.	Erroneous Visit	

Header Text: c4591001

Visit: V101_VAX3

Form Version: 10-Dec-2020 02:31

Site No: 1117

Subject No: 11171036

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): 29-Mar-2021 10:58

[eCRF Audit Trail History](#)

Informed Consent - Further Vaccination

1.	Consent Was:	OBTAINED Date Written Consent Obtained Jan/28/2021
----	--------------	--

Header Text: c4591001

Visit: V101_VAX3

Form Version: 10-Dec-2020 02:30

Site No: 1117

Subject No: 11171036

Generated By: (b) (4)

Form: INCLUSION/EXCLUSION CRITERIA - FURTHER VACCINATION

Form Status: Data Complete, Frozen, Verified

Site Name: (1117) Sundance Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:58

[eCRF Audit Trail History](#)

Inclusion Criteria Not Met

1.a	Description of Inclusion Criterion Not Met	Healthy participants, determined by medical history, physical examination (if required), and clinical judgment of the investigator to be eligible for the study. Specific criteria apply for HIV/HCV/HBV
-----	--	--

Exclusion Criteria Met

2.a	Description of Exclusion Criterion Met	Other medical or psychiatric condition incl. recent (within past year) or active suicidal ideation/behavior/lab abnormality that may increase the risk of study participation
-----	--	---

Header Text: c4591001

Visit: V101_VAX3

Form Version: 10-Dec-2020 02:31

Site No: 1117

Subject No: 11171036

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): 29-Mar-2021 10:58

[eCRF Audit Trail History](#)

Disposition - Screening for Further Vaccination

1.	Date of Completion/Discontinuation /Death :	Jan/28/2021
2.	Phase of Disposition:	REPEAT SCREENING 1
3.	Status:	NO LONGER MEETS ELIGIBILITY CRITERIA
4.	Specify Status:	[INC 3, EXC 1]

Header Text: c4591001

Visit: Subject Status - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1117

Subject No: 11171036

Generated By: (b) (4)

Form: SUBJECT STATUS

Form Status: Data Complete, Verified

Site Name: (1117) Sundance Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:58

[eCRF Audit Trail History](#)

Subject Status

1.	Subject Status	FOLLOW-UP
2.	Subject Status Date	Oct/8/2020

Header Text: c4591001

Visit: Investigator Signature - Unscheduled

Form: CASEBOOK SIGNATURE FORM

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Signed, Verified

Site No: 1117

Site Name: (1117) Sundance Clinical Research

Subject No: 11171036

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

[eCRF Audit Trail History](#)

Casebook Signature Form

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

Header Text: c4591001

Visit: Investigator Signature - Unscheduled

Form Version: 22-Apr-2020 21:04

Site No: 1117

Subject No: 11171036

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): 29-Mar-2021 10:58

[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 16:28:53 (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.

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 30-Jul-2020 21:29

Site No: 1117

Subject No: 11171036

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): 29-Mar-2021 10:58

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Item	Date	User	Comment
Form	Aug-25-2020 10:01:45 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

090177e196ae3dcc\Final\Final On: 01-Apr-2021 04:41 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 1117

Subject No: 11171036

Generated By: (b) (4)

Form: DATE OF VISIT - Comments

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1117) Sundance Clinical Research

Subject Initials: ---

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Item	Date	User	Comment
2	Sep-16-2020 13:10:59 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:03

Site No: 1117

Subject No: 11171036

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB - Comments

Form Status: Data Complete, Locked, Frozen, Verified

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Subject Initials: ---

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Item	Date	User	Comment
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Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/08/2020 **Form:** MICROBIOLOGY SPECIMEN - Comments

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen, Verified

Site No: 1117

Site Name: (1117) Sundance Clinical Research

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Form Version: 06-Jul-2020 21:54

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Site No: 1117

Site Name: (1117) Sundance Clinical Research

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Site No: 1117

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6	Oct-15-2020 16:01:08 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Done

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7	Oct-15-2020 16:01:08 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Done

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Header Text: c4591001

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Site No: 1117

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8	Oct-15-2020 16:01:08 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Done

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Form Status: Data Complete, Frozen, Verified

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9	Oct-15-2020 16:01:08 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Done

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Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

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Form	Nov-06-2020 17:45:54 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	
Form	Oct-15-2020 16:06:51 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Done

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1	Oct-15-2020 16:06:51 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Done

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2	Oct-15-2020 16:06:51 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Done

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3	Oct-15-2020 16:06:51 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Done

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4	Oct-15-2020 16:06:51 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Done

Header Text: c4591001

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Form Version: 06-Jul-2020 21:53

Form Status: Data Complete, Frozen, Verified

Site No: 1117

Site Name: (1117) Sundance Clinical Research

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Generated By: (b) (4)

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Form	Nov-16-2020 15:16:27 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Done

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Header Text: c4591001

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Site No: 1117

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Item	Date	User	Comment
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Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/08/2020 **Form:** RESPIRATORY TREATMENT - Comments

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Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/08/2020 **Form:** ILLNESS DETAILS - SEVERE - Comments

Form Version: 17-Jul-2020 21:55

Form Status: Data Complete, Frozen, Verified

Site No: 1117

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Form	Nov-20-2020 10:41:40 (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 Oct/08/2020 **Form:** ILLNESS DETAILS - SEVERE - Comments

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Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/08/2020 **Form:** ILLNESS DETAILS - SEVERE - Comments

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Header Text: c4591001

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Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - Comments

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Frozen, Verified

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Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/08/2020

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Form Status: Data Complete, Frozen, Verified

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Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/08/2020

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Form Status: Data Complete, Frozen, Verified

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Header Text: c4591001

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Site No: 1117

Site Name: (1117) Sundance Clinical Research

Subject No: 11171036

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Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen, Verified

Site No: 1117

Site Name: (1117) Sundance Clinical Research

Subject No: 11171036

Subject Initials: ---

Generated By: (b) (4)

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Item	Date	User	Comment
8	Jan-21-2021 13:38:34 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Applicable
8	Dec-23-2020 15:30:13 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Done

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Header Text: c4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit on Dec/23/2020 **Form:** MICROBIOLOGY SPECIMEN - Comments

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Site No: 1117

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Item	Date	User	Comment
9	Jan-21-2021 13:38:34 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Applicable
9	Dec-23-2020 15:30:13 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Done

Header Text: c4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit on Dec/23/2020

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB SELF - Comments

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1117

Site Name: (1117) Sundance Clinical Research

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Item	Date	User	Comment
Form	Mar-04-2021 11:37:41 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	
Form	Jan-29-2021 16:30:16 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

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Header Text: c4591001

Visit: POT_COVID_ILL 2

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB SELF -
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Form Version: 22-Apr-2020 21:03

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Site No: 1117

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Item	Date	User	Comment
1	Mar-04-2021 11:37:41 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	
1	Jan-29-2021 16:30:16 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

Header Text: c4591001

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Item	Date	User	Comment
2	Mar-04-2021 11:37:41 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	
2	Jan-29-2021 16:30:16 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

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Item	Date	User	Comment
3	Mar-04-2021 11:37:41 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	
3	Jan-29-2021 16:30:16 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Applicable
3	Jan-26-2021 08:47:49 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

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Item	Date	User	Comment
4	Mar-04-2021 11:37:41 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	
4	Jan-29-2021 16:30:16 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Applicable
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Header Text: c4591001

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5.a	Mar-04-2021 11:40:03 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	
5.a	Jan-27-2021 13:38:16 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

Header Text: c4591001

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Form	Jan-26-2021 08:45:31 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

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Header Text: c4591001

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Item	Date	User	Comment
1	Jan-26-2021 08:45:31 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

Header Text: c4591001

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Item	Date	User	Comment
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3	Jan-26-2021 08:45:31 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

Header Text: c4591001

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Item	Date	User	Comment
4	Jan-26-2021 08:45:31 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

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Form Status: Data Complete, Frozen

Site No: 1117

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Subject Initials: ---

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Form	Jan-21-2021 13:38:12 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

Header Text: c4591001

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Form Version: 10-Dec-2020 02:26

Site No: 1117

Subject No: 11171036

Generated By: (b) (4)

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Item	Date	User	Comment
1.a	Jan-21-2021 13:38:12 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

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Header Text: c4591001

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Item	Date	User	Comment
1.b	Jan-21-2021 13:38:12 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

Header Text: c4591001

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Site No: 1117

Subject No: 11171036

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Item	Date	User	Comment
1.c	Jan-21-2021 13:38:12 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

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Header Text: c4591001

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Subject No: 11171036

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Site Name: (1117) Sundance Clinical Research

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Item	Date	User	Comment
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Header Text: c4591001

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Site No: 1117

Subject No: 11171036

Generated By: (b) (4)

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Item	Date	User	Comment
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Header Text: c4591001

Visit: POT_COVID_ILL 2

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Site No: 1117

Subject No: 11171036

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Item	Date	User	Comment
1.f	Jan-21-2021 13:38:12 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

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Site No: 1117

Subject No: 11171036

Generated By: (b) (4)

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Item	Date	User	Comment
2	Jan-21-2021 13:38:12 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

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Header Text: c4591001

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Item	Date	User	Comment
3	Jan-21-2021 13:38:12 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

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Item	Date	User	Comment
Form	Jan-21-2021 13:36:13 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Applicable
Form	Dec-23-2020 15:31:40 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Done

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Visit: POT_COVID_ILL 2 - Unscheduled Visit on Dec/23/2020 **Form:** RESPIRATORY TREATMENT - Comments

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Item	Date	User	Comment
1	Jan-21-2021 13:36:13 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Applicable
1	Dec-23-2020 15:31:40 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Done

Header Text: c4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit on Dec/23/2020 **Form:** RESPIRATORY TREATMENT - Comments

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Item	Date	User	Comment
2	Jan-21-2021 13:36:13 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Applicable
2	Dec-23-2020 15:31:40 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Done

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Item	Date	User	Comment
3	Jan-21-2021 13:36:13 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Applicable
3	Dec-23-2020 15:31:40 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Done

Header Text: c4591001

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4	Jan-21-2021 13:36:13 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Applicable
4	Dec-23-2020 15:31:40 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Done

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Item	Date	User	Comment
5	Jan-21-2021 13:36:13 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Applicable
5	Dec-23-2020 15:31:40 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Done

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Item	Date	User	Comment
6	Jan-21-2021 13:36:13 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Applicable
6	Dec-23-2020 15:31:40 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Done

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Form Status: Data Complete, Frozen

Site No: 1117

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Subject No: 11171036

Subject Initials: ---

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Form	Jan-21-2021 13:35:56 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

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Subject No: 11171036

Generated By: (b) (4)

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2	Jan-21-2021 13:35:56 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

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Site No: 1117

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Subject No: 11171036

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Form	Jan-21-2021 13:02:06 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Applicable
Form	Dec-23-2020 15:39:54 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Done

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1	Dec-23-2020 15:39:54 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Done

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2	Jan-21-2021 13:02:06 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Applicable
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Header Text: c4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit on Dec/23/2020 **Form:** ILLNESS DETAILS - SEVERE - Comments

Form Version: 17-Jul-2020 21:55

Form Status: Data Complete, Frozen

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Header Text: c4591001

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Form	Dec-23-2020 15:40:12 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Done

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5.f	Jan-21-2021 13:01:36 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Applicable
5.f	Dec-23-2020 15:40:29 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Done

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Form Status: Data Complete, Frozen

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Form	Jan-21-2021 13:00:44 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Applicable
Form	Dec-23-2020 15:41:43 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Done

Header Text: c4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit on Dec/23/2020 **Form:** CONCOMITANT MEDICATIONS - VASOPRESSORS - Comments

Form Version: 06-Jul-2020 21:55

Form Status: Data Complete, Frozen

Site No: 1117

Site Name: (1117) Sundance Clinical Research

Subject No: 11171036

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1	Jan-21-2021 13:00:44 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Applicable
1	Dec-23-2020 15:41:43 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Done

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Header Text: c4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit on Dec/23/2020 **Form:** CONCOMITANT MEDICATIONS - VASOPRESSORS - Comments

Form Version: 06-Jul-2020 21:55

Form Status: Data Complete, Frozen

Site No: 1117

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2	Dec-23-2020 15:41:43 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Done

Header Text: c4591001

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Item	Date	User	Comment
3	Jan-21-2021 13:00:44 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Applicable
3	Dec-23-2020 15:41:43 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Done

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Item	Date	User	Comment
4	Jan-21-2021 13:00:44 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Applicable
4	Dec-23-2020 15:41:43 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Done

Header Text: c4591001

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5	Jan-21-2021 13:00:44 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Applicable
5	Dec-23-2020 15:41:43 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Done

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Header Text: c4591001

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6	Jan-21-2021 13:00:44 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Applicable
6	Dec-23-2020 15:41:43 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Done

Header Text: c4591001

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Form	Jan-21-2021 13:00:29 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Applicable
Form	Dec-23-2020 15:41:59 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Done

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1	Jan-21-2021 13:00:29 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Applicable
1	Dec-23-2020 15:41:59 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Done

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2	Jan-21-2021 13:00:29 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Applicable
2	Dec-23-2020 15:41:59 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Done

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3	Dec-23-2020 15:41:59 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Done

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4	Dec-23-2020 15:41:59 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Done

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Generated By: (b) (4)

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3	Feb-15-2021 12:47:57 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

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Form	Feb-18-2021 17:20:13 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

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Form Version: 22-Apr-2020 21:03

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Item	Date	User	Comment
2	Feb-18-2021 17:20:13 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

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3	Feb-15-2021 12:50:09 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

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4	Feb-18-2021 17:20:13 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

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Generated By: (b) (4)

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3	Feb-15-2021 12:49:20 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

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4	Feb-18-2021 17:25:34 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

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3	Feb-25-2021 11:23:42 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

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Form Status: Data Complete, Frozen, Verified

Site No: 1117

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Form	Mar-05-2021 08:53:38 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Applicable
Form	Mar-04-2021 11:36:27 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	
Form	Feb-25-2021 11:22:33 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

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Item	Date	User	Comment
1	Mar-05-2021 08:53:38 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Applicable
1	Mar-04-2021 11:36:27 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	
1	Feb-25-2021 11:22:33 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

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2	Mar-05-2021 08:53:38 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Applicable
2	Mar-04-2021 11:36:27 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	
2	Feb-25-2021 11:22:33 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

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3	Mar-04-2021 11:36:27 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	
3	Feb-25-2021 11:22:33 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

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Item	Date	User	Comment
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4	Mar-04-2021 11:36:27 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	
4	Feb-25-2021 11:22:33 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

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Visit: Investigator Signature - Unscheduled

Form: CASEBOOK SIGNATURE FORM - Signature History

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Site No: 1117

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Generated By: (b) (4)

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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 16:28:53 (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	Nov-20-2020 10:41:40 (UTC-06:00) Central Time (US & Canada)		Edit - All signatures invalidated
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Affidavit:

N/A

(b) (6)	Approved	Nov-17-2020 17:52:48 (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-16-2020 15:13:28 (UTC-06:00) Central Time (US & Canada)		Edit - All signatures invalidated
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Affidavit:

N/A

Larkin Wadsworth	Approved	Nov-08-2020 20:17:49 (UTC-06:00) Central Time (US & Canada)	BOOK	Signed
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090177e196ae3dcc\Final\Final On: 01-Apr-2021 04:41 (GMT)

Header Text: c4591001

Visit: Investigator Signature - Unscheduled

Form: CASEBOOK SIGNATURE FORM - Signature History

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Form Status: Data Complete, Signed, Verified

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Subject No: 11171036

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

Affidavit:

By my dated signature below, I, LarkinWadsworth, 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-04-2020 14:52:45 (UTC-06:00) Central Time (US & Canada)		Edit - All signatures invalidated
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Affidavit:

N/A

(b) (6)	Approved	Oct-23-2020 08:36:58 (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	Oct-19-2020 14:40:30 (UTC-06:00) Central Time (US & Canada)		Edit - All signatures invalidated
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Affidavit:

N/A

(b) (6)	Approved	Oct-16-2020 15:38:23 (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.

090177e196ae3dcc\Final\Final On: 01-Apr-2021 04:41 (GMT)

Header Text: c4591001

Visit: COHORT_SELECTION

Form Version: 30-Jul-2020 21:29

Site No: 1117

Subject No: 11171036

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): 29-Mar-2021 10:58

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1. Select appropriate response - Protocol version

Date	Location	User	Value	Reason
Aug-21-2020 12:35:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 24 JUL 2020	Initial Entry

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

Date	Location	User	Value	Reason
Aug-21-2020 12:35:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: STAGE 3 COHORTS	Initial Entry

Header Text: c4591001

Visit: COHORT_SELECTION

Form Version: 22-Apr-2020 21:02

Site No: 1117

Subject No: 11171036

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): 29-Mar-2021 10:58

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I. Consent Was:

Date	Location	User	Value	Reason
Aug-21-2020 12:35:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: OBTAINED Date Written Consent Obtained Aug/20/2020	Initial Entry

090177e196ae3dcc\Final\Final On: 01-Apr-2021 04:41 (GMT)

Header Text: c4591001

Visit: COHORT_SELECTION

Form: DEMOGRAPHY - eCRF Audit Trail History

Form Version: 06-Jul-2020 21:55

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1117

Site Name: (1117) Sundance Clinical Research

Subject No: 11171036

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

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1. Subject ID

Date	Location	User	Value	Reason
Aug-21-2020 12:35:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 11171036	Item copied from previous form

2. Birth Date:

Date	Location	User	Value	Reason
Aug-21-2020 12:35:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: (b) (6)/1974	Enrollment Entry

3. Sex:

Date	Location	User	Value	Reason
Aug-21-2020 12:36:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: MALE	Initial Entry

4. Ethnicity:

Date	Location	User	Value	Reason
Aug-21-2020 12:36:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NOT HISPANIC OR LATINO(A) OR OF SPANISH ORIGIN	Initial Entry

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

Date	Location	User	Value	Reason
Aug-21-2020 12:36:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: WHITE	Initial Entry

090177e196ae3dcc\Final\Final On: 01-Apr-2021 04:41 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:02

Site No: 1117

Subject No: 11171036

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): 29-Mar-2021 10:58

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I. Date of Visit

Date	Location	User	Value	Reason
Aug-26-2020 05:38:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Aug-25-2020 10:16:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Changed data per query
Aug-25-2020 08:45:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	DM: Form INC EXC is missing. Kindly update.
Aug-21-2020 12:36:23 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Aug/20/2020	Initial Entry

090177e196ae3dcc\Final\Final On: 01-Apr-2021 04:41 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: DISPOSITION - SCREENING - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1117

Site Name: (1117) Sundance Clinical Research

Subject No: 11171036

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

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1. Date of Completion/Discontinuation/Death

Date	Location	User	Value	Reason
Aug-21-2020 12:36:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Aug/20/2020	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Aug-21-2020 12:36:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SCREENING	Initial Entry

3. Status:

Date	Location	User	Value	Reason
Aug-21-2020 12:36:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: COMPLETED	Initial Entry

090177e196ae3dcc\Final\Final On: 01-Apr-2021 04:41 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1117

Site Name: (1117) Sundance Clinical Research

Subject No: 11171036

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

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I.a

Date	Location	User	Value	Reason
Aug-21-2020 12:37:16 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 1 Medical History Term: ALCOHOLISM Start Date: UNK/UNK/2005 Ongoing: NO End Date: UNK/UNK/2017	Initial Entry

I.a Line/MH Number:

Date	Location	User	Value	Reason
Aug-21-2020 12:37:16 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 1	Initial Entry

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

Date	Location	User	Value	Reason
Oct-11-2020 21:08:17 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Oct-09-2020 14:41:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Changed data per query
Oct-07-2020 22:11:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	CLINICAL - SAE safety update included a past medical history of type 2 Diabetes mellitus (2019); based on renal issues during this event, please consider addition of DM to Med History CRF
Aug-21-2020 12:37:16 (UTC-06:00) Central Time	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: ALCOHOLISM	Initial Entry

090177e196ae3dcc\Final\Final On: 01-Apr-2021 04:41 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1117

Subject No: 11171036

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1117) Sundance Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:58

(US & Canada)

I.a Start Date:

Date	Location	User	Value	Reason
Aug-21-2020 12:37:16 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNK/UNK/2005	Initial Entry

I.a Ongoing:

Date	Location	User	Value	Reason
Aug-21-2020 12:37:16 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO End Date: UNK/UNK/2017	Initial Entry

I.b

Date	Location	User	Value	Reason
Aug-21-2020 12:37:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 2 Medical History Term: SCHIZOPHRENIA Start Date: UNK/UNK/2016 Ongoing: YES	Initial Entry

090177e196ae3dcc\Final\Final On: 01-Apr-2021 04:41 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1117

Site Name: (1117) Sundance Clinical Research

Subject No: 11171036

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

1.b Line/MH Number:

Date	Location	User	Value	Reason
Aug-21-2020 12:37:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 2	Initial Entry

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

Date	Location	User	Value	Reason
Aug-21-2020 12:37:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: SCHIZOPHRENIA	Initial Entry

1.b Start Date:

Date	Location	User	Value	Reason
Aug-21-2020 12:37:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNK/UNK/2016	Initial Entry

1.b Ongoing:

Date	Location	User	Value	Reason
Aug-21-2020 12:37:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

1.c

Date	Location	User	Value	Reason
Aug-21-2020 12:37:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 3 Medical History Term: ANXIETY Start Date: UNK/UNK/2017 Ongoing: YES	Initial Entry

090177e196ae3dcc\Final\Final On: 01-Apr-2021 04:41 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1117

Subject No: 11171036

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1117) Sundance Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:58

I.c Line/MH Number:

Date	Location	User	Value	Reason
Aug-21-2020 12:37:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 3	Initial Entry

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

Date	Location	User	Value	Reason
Aug-21-2020 12:37:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: ANXIETY	Initial Entry

I.c Start Date:

Date	Location	User	Value	Reason
Aug-21-2020 12:37:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNK/UNK/2017	Initial Entry

I.c Ongoing:

Date	Location	User	Value	Reason
Aug-21-2020 12:37:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

I.d

Date	Location	User	Value	Reason
Aug-23-2020 14:45:17 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Line/MH Number: 4 Medical History Term: BIPOLAR DISORDER Start Date: UNK/UNK/2016 Ongoing: YES	New Information
Aug-21-2020 12:38:06 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number 4 Medical History Term: BIPOLAR	Initial Entry

090177e196ae3dcc\Final\Final On: 01-Apr-2021 04:41 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1117

Subject No: 11171036

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1117) Sundance Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:58

			Start Date:	UNK/UNK/2 016	
			Ongoing:	YES	

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1117

Site Name: (1117) Sundance Clinical Research

Subject No: 11171036

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

1.d Line/MH Number:

Date	Location	User	Value	Reason
Aug-21-2020 12:38:06 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 4	Initial Entry

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

Date	Location	User	Value	Reason
Jan-25-2021 12:47:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Giselle Castillo (b) (4)	Query 2: Closed	Response satisfies query
Jan-21-2021 12:35:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Answered	PER INVESTIGATOR, AT TIME OF SCREENING, PARTICIPANT'S CONDITION WAS TREATED AND STABLE. INVESTIGATOR DETERMINED PARTICIPANT TO MEET INC#3 AND NOT TO MEET EXC#1 AT THAT TIME. PARTICIPANT IS BEING FOLLOWED FOR SAFETY.
Jan-12-2021 13:41:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Giselle Castillo (b) (4)	Query 2: Opened	Clinical_ Based on the MHx (schizophrenia and depression), please re-assess eligibility against Inclusion #3 and Exclusion #1. Thanks
Aug-23-2020 17:13:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	PFETMS Oracle (b) (4)	Query 1: Closed	Discrepancy has been closed.

090177e196ae3dcc\Final\Final On: 01-Apr-2021 04:41 (GMT)

Header Text: c4591001
Visit: V1_DAY1_VAX1_L
Form Version: 22-Apr-2020 21:03
Site No: 1117
Subject No: 11171036
Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History
Form Status: Data Complete, Frozen, Verified
Site Name: (1117) Sundance Clinical Research
Subject Initials: ---
Generated Time (GMT): 29-Mar-2021 10:58

Aug-23-2020 14:45:17 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	New Information
Aug-23-2020 14:45:17 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BIPOLAR DISORDER	New Information
Aug-22-2020 20:29:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	PFETMS Oracle (b) (4)	Query 1: Opened	Clarify BIPOLAR as follows...The term appears truncated. Are you reporting BIPOLAR DISORDER? BIPOLAR PACEMAKER INSERTION? If so, edit. Otherwise clarify. Thank you.
Aug-21-2020 12:38:06 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BIPOLAR	Initial Entry

1.d Start Date:

Date	Location	User	Value	Reason
Aug-21-2020 12:38:06 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNK/UNK/2016	Initial Entry

1.d Ongoing:

Date	Location	User	Value	Reason
Aug-21-2020 12:38:06 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

1.e

Date	Location	User	Value	Reason
Aug-21-2020 12:38:20	ACV0PFEINFP6000	auto calc	Data Entry:	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1117

Subject No: 11171036

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1117) Sundance Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:58

(UTC-06:00) Central Time (US & Canada)		(autocalc)	Line/MH Number: 5 Medical History Term: INSOMNIA Start Date: UNK/UNK/2017 Ongoing: YES	
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I.e Line/MH Number:

Date	Location	User	Value	Reason
Aug-21-2020 12:38:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 5	Initial Entry

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

Date	Location	User	Value	Reason
Aug-21-2020 12:38:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: INSOMNIA	Initial Entry

I.e Start Date:

Date	Location	User	Value	Reason
Aug-21-2020 12:38:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNK/UNK/2017	Initial Entry

I.e Ongoing:

Date	Location	User	Value	Reason
Aug-21-2020 12:38:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

I.f

Date	Location	User	Value	Reason
Aug-21-2020 12:38:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 6 Medical History Term: FISH ALLERGY Start Date: UNK/UNK/1979 Ongoing: YES	Initial Entry

090177e196ae3dcc\Final\Final On: 01-Apr-2021 04:41 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1117

Subject No: 11171036

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1117) Sundance Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:58

I.f Line/MH Number:

Date	Location	User	Value	Reason
Aug-21-2020 12:38:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> 6	Initial Entry

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

Date	Location	User	Value	Reason
Aug-21-2020 12:38:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> FISH ALLERGY	Initial Entry

I.f Start Date:

Date	Location	User	Value	Reason
Aug-21-2020 12:38:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> UNK/UNK/1979	Initial Entry

I.f Ongoing:

Date	Location	User	Value	Reason
Aug-21-2020 12:38:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> YES	Initial Entry

I.g

Date	Location	User	Value	Reason
Oct-09-2020 14:41:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> Line/MH Number: 7 Medical History Term: DIABETES MELLITUS TYPE II Start Date: UNK/UNK/2019 Ongoing: YES	Initial Entry

090177e196ae3dcc\Final\Final On: 01-Apr-2021 04:41 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1117

Subject No: 11171036

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1117) Sundance Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:58

I.g Line/MH Number:

Date	Location	User	Value	Reason
Oct-09-2020 14:41:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> 7	Initial Entry

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

Date	Location	User	Value	Reason
Oct-09-2020 14:41:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> DIABETES MELLITUS TYPE II	Initial Entry

I.g Start Date:

Date	Location	User	Value	Reason
Oct-09-2020 14:41:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> UNK/UNK/2019	Initial Entry

I.g Ongoing:

Date	Location	User	Value	Reason
Oct-09-2020 14:41:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> YES	Initial Entry

I.h

Date	Location	User	Value	Reason
Oct-09-2020 14:42:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> Line/MH Number: 8 Medical History Term: HYPERTENSION Start Date: UNK/UNK/2016 Ongoing: YES	Initial Entry

090177e196ae3dcc\Final\Final On: 01-Apr-2021 04:41 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1117

Subject No: 11171036

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1117) Sundance Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:58

1.h Line/MH Number:

Date	Location	User	Value	Reason
Oct-09-2020 14:42:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 8	Initial Entry

1.h Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:

Date	Location	User	Value	Reason
Oct-09-2020 14:42:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: HYPERTENSION	Initial Entry

1.h Start Date:

Date	Location	User	Value	Reason
Oct-09-2020 14:42:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNK/UNK/2016	Initial Entry

090177e196ae3dcc\Final\Final On: 01-Apr-2021 04:41 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1117

Subject No: 11171036

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1117) Sundance Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:58

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I.h Ongoing:

Date	Location	User	Value	Reason
Oct-09-2020 14:42:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

I.i

Date	Location	User	Value	Reason
Mar-04-2021 12:43:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Line/MH Number: 9 Medical History Term: MAJOR DEPRESSIVE DISORDER Start Date: UNK/UNK/2016 Ongoing: YES	Changed Information
Oct-09-2020 14:42:17 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 9 Medical History Term: DEPRESSION Start Date: UNK/UNK/2016 Ongoing: YES	Initial Entry

090177e196ae3dcc\Final\Final On: 01-Apr-2021 04:41 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1117

Subject No: 11171036

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1117) Sundance Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:58

I.i Line/MH Number:

Date	Location	User	Value	Reason
Oct-09-2020 14:42:17 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 9	Initial Entry

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

Date	Location	User	Value	Reason
Mar-04-2021 12:43:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: MAJOR DEPRESSIVE DISORDER	Changed Information
Oct-09-2020 14:42:17 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: DEPRESSION	Initial Entry

I.i Start Date:

Date	Location	User	Value	Reason
Oct-09-2020 14:42:17 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNK/UNK/2016	Initial Entry

I.i Ongoing:

Date	Location	User	Value	Reason
Oct-09-2020 14:42:17 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

I.j

Date	Location	User	Value	Reason
Oct-09-2020 14:42:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 10 Medical History Term: CONSTIPATIO N Start Date: UNK/UNK/2018 Ongoing: YES	Initial Entry

090177e196ae3dcc\Final\Final On: 01-Apr-2021 04:41 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1117

Subject No: 11171036

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1117) Sundance Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:58

1.j Line/MH Number:

Date	Location	User	Value	Reason
Oct-09-2020 14:42:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 10	Initial Entry

1.j Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:

Date	Location	User	Value	Reason
Feb-02-2021 18:48:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Giselle Castillo (b) (4)	Query 1: Closed	Response satisfies query
Jan-29-2021 12:00:16 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Changed data per query
Jan-27-2021 12:31:02 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Giselle Castillo (b) (4)	Query 1: Reissued:Opened	Thank you for your response. However, In the safety report submitted (AER#2021011278), reflects that subject has a "Med History of chronic kidney disease stage 2". If this is wrong, please submit a FU form updating the information for the Safety report.
Jan-26-2021 09:26:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	PLEASE TAG QUERIES TO APPROPRIATE/APPLICABLE FIELDS. WE CAN CONFIRM THAT THIS IS THE FIRST TIME CKD STAGE 2 APPEARS IN THE MEDICAL RECORD.
Jan-25-2021 12:44:55 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Giselle Castillo (b) (4)	Query 1: Reissued:Opened	pls advise if refers to "chronic kidney disease stage 2" a prior underlying condition and update MedHx as appropriate.
Jan-21-2021 12:56:46 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	REPORTED AS AE#16
Jan-12-2021 13:39:55 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Giselle Castillo (b) (4)	Query 1: Opened	Clinical_ Per report the subject has "History of chronic kidney disease stage 2", however this additional information is missing on CRF. Please revise and update form accordingly.

090177e196ae3dcc\Final\Final On: 01-Apr-2021 04:41 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1117

Site Name: (1117) Sundance Clinical Research

Subject No: 11171036

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

				Thanks
Oct-09-2020 14:42:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: CONSTIPATION	Initial Entry

I.j Start Date:

Date	Location	User	Value	Reason
Oct-09-2020 14:42:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNK/UNK/2018	Initial Entry

I.j Ongoing:

Date	Location	User	Value	Reason
Oct-09-2020 14:42:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

I.k

Date	Location	User	Value	Reason
Feb-11-2021 17:31:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Line/MH Number: 11 Medical History Term: Chronic Kidney Disease, Stage 2 Start Date: Jan/UNK/2020 Ongoing: YES	Changed Information
Jan-29-2021 12:00:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 11 Medical History Term: Chronic Kidney Disease, Stage 2 Start Date: UNK/UNK/2020 Ongoing: YES	Initial Entry

090177e196ae3dcc\Final\Final On: 01-Apr-2021 04:41 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1117

Site Name: (1117) Sundance Clinical Research

Subject No: 11171036

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

I.k Line/MH Number:

Date	Location	User	Value	Reason
Jan-29-2021 12:00:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 11	Initial Entry

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

Date	Location	User	Value	Reason
Jan-29-2021 12:00:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Chronic Kidney Disease, Stage 2	Initial Entry

I.k Start Date:

Date	Location	User	Value	Reason
Feb-12-2021 09:31:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Feb-11-2021 17:31:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Answer Auto Query
Feb-11-2021 17:31:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Jan/UNK/2020	Changed Information
Feb-01-2021 04:38:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued:Opened	Please confirm if date occurred before/ or after the first vaccination date 20Aug2020?
Jan-29-2021 12:01:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	SUBJECT IS UNAWARE OF DIAGNOSIS, UNABLE TO DETERMINE CORRECT DATE.
Jan-29-2021 12:00:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	Start Date is after or equal to the first vaccination date 20/Aug/2020. Please review and update as appropriate.
Jan-29-2021 12:00:01	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Initial Entry

090177e196ae3dcc\Final\Final On: 01-Apr-2021 04:41 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1117

Subject No: 11171036

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1117) Sundance Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:58

(UTC-06:00) Central Time (US & Canada)		(b) (4), (b) (6)	UNK/UNK/2020	
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1.k Ongoing:

Date	Location	User	Value	Reason
Jan-29-2021 12:00:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: VITAL SIGNS - BASELINE - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1117

Site Name: (1117) Sundance Clinical Research

Subject No: 11171036

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

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1. Date:

Date	Location	User	Value	Reason
Aug-21-2020 12:39:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Aug/20/2020	Initial Entry

2. Weight:

Date	Location	User	Value	Reason
Aug-21-2020 12:39:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 269.2	Initial Entry

3. Unit:

Date	Location	User	Value	Reason
Aug-21-2020 12:39:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: LB	Initial Entry

4. Height:

Date	Location	User	Value	Reason
Aug-21-2020 12:39:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 76.6	Initial Entry

5. Unit:

Date	Location	User	Value	Reason
Aug-21-2020 12:39:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: in	Initial Entry

6. Body Mass Index:

Date	Location	User	Value	Reason
Aug-21-2020 12:39:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 32.3	Initial Entry

7.a

090177e196ae3dcc\Final\Final On: 01-Apr-2021 04:41 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: VITAL SIGNS - BASELINE - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1117

Site Name: (1117) Sundance Clinical Research

Subject No: 11171036

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

Date	Location	User	Value	Reason
Aug-21-2020 12:39:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Record Identifier:: 1 Temperature: 97.9 Temperature Unit: F Temperature Location:: ORAL CAVITY	Initial Entry

7.a Record Identifier:

Date	Location	User	Value	Reason
Aug-21-2020 12:39:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 1	Initial Entry

7.a Temperature:

Date	Location	User	Value	Reason
Aug-21-2020 12:39:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 97.9	Initial Entry

7.a Unit:

Date	Location	User	Value	Reason
Aug-21-2020 12:39:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: F	Initial Entry

7.a Temperature Location:

Date	Location	User	Value	Reason
Aug-21-2020 12:39:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: ORAL CAVITY	Initial Entry

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Header Text: c4591001

Visit: V1_DAY1_VAX1_L

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Site No: 1117

Subject No: 11171036

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): 29-Mar-2021 10:58

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1. Randomization Date :

Date	Location	User	Value	Reason
Aug-21-2020 12:39:24 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Aug/20/2020	Initial Entry

2. Randomization Number:

Date	Location	User	Value	Reason
Aug-21-2020 12:39:24 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 57122	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: 11171036

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

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1. Data Origin

Date	Location	User	Value	Reason
Aug-21-2020 12:39:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Aug-21-2020 12:39:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> SERUM	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Aug-21-2020 12:39:55 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Aug-21-2020 12:39:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Aug-21-2020 12:39:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> YES Date of Collection: Aug/20/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Aug-21-2020 12:39:55 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Sample ID: BPRTY5	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Aug-21-2020 12:39:55	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u>	Initial Entry

090177e196ae3dcc\Final\Final On: 01-Apr-2021 04:41 (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: 11171036

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

(UTC-06:00) Central Time (US & Canada)		(b) (4), (b) (6)	BPRTY5	
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5.b

Date	Location	User	Value	Reason
Aug-21-2020 12:40:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BPRTY6	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Aug-21-2020 12:40:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BPRTY6	Initial Entry

5.c

Date	Location	User	Value	Reason
Aug-21-2020 12:40:18 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BP58HH	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Aug-21-2020 12:40:18 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BP58HH	Initial Entry

5.d

Date	Location	User	Value	Reason
Aug-21-2020 12:40:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BP58HJ	Initial Entry

5.d Sample ID

Date	Location	User	Value	Reason
Aug-21-2020 12:40:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BP58HJ	Initial Entry

090177e196ae3dcc\Final\Final On: 01-Apr-2021 04:41 (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: 11171036

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

5.e

Date	Location	User	Value	Reason
Aug-21-2020 12:40:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BP58HK	Initial Entry

5.e Sample ID

Date	Location	User	Value	Reason
Aug-21-2020 12:40:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BP58HK	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1117

Site Name: (1117) Sundance Clinical Research

Subject No: 11171036

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

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1. Data Origin

Date	Location	User	Value	Reason
Aug-21-2020 12:40:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Aug-21-2020 12:40:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> NASAL_SWAB	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Aug-21-2020 12:40:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Aug-21-2020 12:40:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Aug-21-2020 12:40:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> YES Date of Collection: Aug/20/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Aug-21-2020 12:40:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Sample ID: BP58GR	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Aug-21-2020 12:40:57	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u>	Initial Entry

090177e196ae3dcc\Final\Final On: 01-Apr-2021 04:41 (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: 11171036

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

(UTC-06:00) Central Time
(US & Canada)

(b) (4), (b)
(6)

BP58GR

090177e196ae3dcc\Final\Final On: 01-Apr-2021 04:41 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:04

Site No: 1117

Subject No: 11171036

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): 29-Mar-2021 10:58

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1. Was there a temporary delay of vaccination?

Date	Location	User	Value	Reason
Aug-21-2020 12:41:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2. Treatment Name

Date	Location	User	Value	Reason
Aug-21-2020 12:41:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: BLINDED THERAPY	Initial Entry

3. Formulation:

Date	Location	User	Value	Reason
Aug-21-2020 12:41:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INJECTION	Initial Entry

4. Dose Date Time:

Date	Location	User	Value	Reason
Aug-21-2020 12:41:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Aug/20/2020 16:02	Initial Entry

5. Anatomical Location:

Date	Location	User	Value	Reason
Aug-21-2020 12:41:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: DELTOID MUSCLE	Initial Entry

6. Body Side:

Date	Location	User	Value	Reason
Aug-21-2020 12:41:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: RIGHT	Initial Entry

7. Route:

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090177e196ae3dcc\Final\Final On: 01-Apr-2021 04:41 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:04

Site No: 1117

Subject No: 11171036

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): 29-Mar-2021 10:58

Date	Location	User	Value	Reason
Aug-21-2020 12:41:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INTRAMUSCULAR	Initial Entry

10. Timeframe Subject Was Observed

Date	Location	User	Value	Reason
Aug-21-2020 12:41:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: THE PROTOCOL SPECIFIED OBSE RVATION PERIOD	Initial Entry

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

Date	Location	User	Value	Reason
Aug-21-2020 12:41:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

090177e196ae3dcc\Final\Final On: 01-Apr-2021 04:41 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 06-Jul-2020 21:53

Site No: 1117

Subject No: 11171036

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): 29-Mar-2021 10:58

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1. Select appropriate response - Reactogenicity diary collection

Date	Location	User	Value	Reason
Aug-21-2020 12:41:46 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 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: 11171036

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): 29-Mar-2021 10:58

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1. Date of Visit

Date	Location	User	Value	Reason
Sep-16-2020 13:10:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sep/10/2020	Initial Entry

2. Erroneous Visit

Date	Location	User	Value	Reason
Sep-16-2020 13:10:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 15-Sep-2020 21:54

Site No: 1117

Subject No: 11171036

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): 29-Mar-2021 10:58

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1. Date:

Date	Location	User	Value	Reason
Sep-16-2020 13:11:24 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sep/10/2020	Initial Entry

2.a

Date	Location	User	Value	Reason
Sep-16-2020 13:11:24 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Record Identifier:: 1 Temperature: 98.2 Temperature Unit: F Temperature Location: ORAL CAVITY	Initial Entry

2.a Record Identifier:

Date	Location	User	Value	Reason
Sep-16-2020 13:11:24 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 1	Initial Entry

2.a Temperature:

Date	Location	User	Value	Reason
Sep-16-2020 13:11:24 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 98.2	Initial Entry

2.a Unit:

Date	Location	User	Value	Reason
Sep-16-2020 13:11:24 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: F	Initial Entry

2.a Temperature Location:

Date	Location	User	Value	Reason
Sep-16-2020 13:11:24 (UTC-06:00) Central Time	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: ORAL CAVITY	Initial Entry

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Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 15-Sep-2020 21:54

Site No: 1117

Subject No: 11171036

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): 29-Mar-2021 10:58

(US & Canada)

(b) (4), (b) (6)

090177e196ae3dcc\Final\Final On: 01-Apr-2021 04:41 (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: 11171036

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

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1. Data Origin

Date	Location	User	Value	Reason
Sep-22-2020 13:21:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Sep-22-2020 13:21:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: NASAL_SWAB	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Sep-23-2020 06:25:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Sep-22-2020 16:21:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Deleted	Close Auto Query
Sep-22-2020 13:21:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Sep-22-2020 13:21:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Initial Entry
Sep-22-2020 13:21:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Collection: Sep/10/2020	Initial Entry
Sep-17-2020 16:34:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	Nasal Swab barcode BM8YFW has been received by the lab for Visit 2. Please

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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: 11171036

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

				review and update or submit SCF.
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4. If no sample was collected or sample was not collected according to protocol, please provide reason:

Date	Location	User	Value	Reason
Sep-22-2020 16:21:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.a

Date	Location	User	Value	Reason
Sep-22-2020 16:21:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BM8YFW	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Sep-22-2020 16:21:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BM8YFW	Initial Entry

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Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1117

Subject No: 11171036

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): 29-Mar-2021 10:58

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1. Was there a temporary delay of vaccination?

Date	Location	User	Value	Reason
Sep-16-2020 13:12:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2. Treatment Name

Date	Location	User	Value	Reason
Sep-16-2020 13:12:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: BLINDED THERAPY	Initial Entry

3. Formulation:

Date	Location	User	Value	Reason
Sep-16-2020 13:12:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INJECTION	Initial Entry

4. Dose Date Time:

Date	Location	User	Value	Reason
Sep-16-2020 13:12:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sep/10/2020 13:12	Initial Entry

5. Anatomical Location:

Date	Location	User	Value	Reason
Sep-16-2020 13:12:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: DELTOID MUSCLE	Initial Entry

6. Body Side:

Date	Location	User	Value	Reason
Sep-16-2020 13:12:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: RIGHT	Initial Entry

7. Route:

090177e196ae3dcc\Final\Final On: 01-Apr-2021 04:41 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1117

Subject No: 11171036

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): 29-Mar-2021 10:58

Date	Location	User	Value	Reason
Sep-16-2020 13:12:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INTRAMUSCULAR	Initial Entry

10. Timeframe Subject Was Observed

Date	Location	User	Value	Reason
Sep-16-2020 13:12:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: THE PROTOCOL SPECIFIED OBSE RVATION PERIOD	Initial Entry

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

Date	Location	User	Value	Reason
Sep-16-2020 13:12:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

090177e196ae3dcc\Final\Final On: 01-Apr-2021 04:41 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 1117

Subject No: 11171036

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): 29-Mar-2021 10:58

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I. Date of Visit

Date	Location	User	Value	Reason
Oct-15-2020 13:19:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Clo sed	Response satisfies query
Oct-14-2020 14:47:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Ans wered	Original value is correct
Oct-12-2020 05:06:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (b) (4)	Query 1: Ope ned	DMW4940157;The Date of Visit at Visit V3_MONTH1_POSTVAX2_L is the same as the other Date of Visit at Visit COVID_APlease review for duplication and update as appropriate.
Oct-09-2020 14:30:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry : Oct/8/ 2020	Initial Entry

090177e196ae3dcc\Final\Final On: 01-Apr-2021 04:41 (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: 11171036

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

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1. Data Origin

Date	Location	User	Value	Reason
Oct-22-2020 11:06:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Deleted	Form updated by Site
Oct-21-2020 09:51:23 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Candidate	Please leave candidate query until site updates and then delete query.
Oct-14-2020 14:46:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Oct-14-2020 14:46:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SERUM	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Oct-14-2020 14:47:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Oct-14-2020 14:46:44 (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-14-2020 14:46:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Collection: Oct/8/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
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090177e196ae3dcc\Final\Final On: 01-Apr-2021 04:41 (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: 11171036

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Generated By: (b) (4)

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Oct-14-2020 14:47:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BRJ8DP	Initial Entry
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5.a Sample ID

Date	Location	User	Value	Reason
Oct-14-2020 14:47:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BRJ8DP	Initial Entry

5.b

Date	Location	User	Value	Reason
Oct-14-2020 14:47:18 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BRJ8DR	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Oct-14-2020 14:47:18 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BRJ8DR	Initial Entry

5.c

Date	Location	User	Value	Reason
Oct-14-2020 14:47:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BRJ8F6	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Oct-14-2020 14:47:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BRJ8F6	Initial Entry

5.d

Date	Location	User	Value	Reason
Oct-21-2020 13:17:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BRSRLH	Initial Entry

090177e196ae3dccc\Final\Final On: 01-Apr-2021 04:41 (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: 11171036

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

5.d Sample ID

Date	Location	User	Value	Reason
Oct-21-2020 13:17:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BRSRLH	Initial Entry

5.e

Date	Location	User	Value	Reason
Oct-21-2020 13:17:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BRSRLJ	Initial Entry

5.e Sample ID

Date	Location	User	Value	Reason
Oct-21-2020 13:17:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BRSRLJ	Initial Entry

090177e196ae3dcc\Final\Final On: 01-Apr-2021 04:41 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/08/2020 Form: DATE OF VISIT - ILLNESS ONSET - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1117

Site Name: (1117) Sundance Clinical Research

Subject No: 11171036

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

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I. Date of Visit

Date	Location	User	Value	Reason
Oct-16-2020 03:17:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 4: Clo sed	Response satisfies query
Oct-16-2020 03:17:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Clo sed	Response satisfies query
Oct-15-2020 16:43:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 4: Ans wered	Changed data per query
Oct-15-2020 16:04:16 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Ans wered	PER INVESTIGATOR, PARTICIPANT WAS ONSITE FOR V3 AND CONDUCTED AN ILLNESS VISIT PER ASSESSMENT.
Oct-15-2020 07:35:24 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Rei ssued: Opene d	DM: The Date of Visit at Visit COVID_A is the same as the other Date of Visit at Visit V3_MONTH1_POSTVAX2_L. Please review for duplication and update as appropriate.
Oct-14-2020 13:54:27 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Ans wered	Original value is correct
Oct-14-2020 13:53:31 (UTC-06:00)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Clo sed	Close Auto Query

090177e196ae3dcc\Final\Final On: 01-Apr-2021 04:41 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/08/2020 **Form:** DATE OF VISIT - ILLNESS ONSET - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1117

Site Name: (1117) Sundance Clinical Research

Subject No: 11171036

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

Central Time (US & Canada)				
Oct-14-2020 02:25:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 4: Opened	DM: Kindly review and complete 'Health Care Utilization, Microbiology Specimen form' at this visit. Thank you.
Oct-12-2020 05:06:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (b) (4)	Query 3: Opened	DMW4940156;The Date of Visit at Visit COVID_A is the same as the other Date of Visit at Visit V3_MONTH1_POSTVAX2_L. Please review for duplication and update as appropriate.
Oct-10-2020 06:03:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	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.
Oct-09-2020 14:29:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Deleted	Close Auto Query
Oct-09-2020 14:28:03 (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.
Oct-09-2020 14:28:03 (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.
Oct-09-2020 14:28:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry i Oct/8/2020	Initial Entry

090177e196ae3dcc\Final\Final On: 01-Apr-2021 04:41 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/08/2020 **Form:** DATE OF VISIT - ILLNESS ONSET - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1117

Site Name: (1117) Sundance Clinical Research

Subject No: 11171036

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

Canada)

3. COVID-19 Illness Visit:

Date	Location	User	Value	Reason
Oct-09-2020 14:28:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: COVID_A	Initial Entry

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/08/2020

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

Form Version: 15-Sep-2020 21:55

Form Status: Data Complete, Frozen, Not Complete

Site No: 1117

Site Name: (1117) Sundance Clinical Research

Subject No: 11171036

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

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1. Date of Assessment:

Date	Location	User	Value	Reason
Oct-09-2020 14:29:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Oct/8/2020	Initial Entry

2. Date of First Symptom Started:

Date	Location	User	Value	Reason
Oct-09-2020 14:29:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sep/22/2020	Initial Entry

3. Symptoms Ongoing?

Date	Location	User	Value	Reason
Jan-22-2021 07:30:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Closed	Response satisfies query
Jan-21-2021 13:42:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Answered	Changed Information
Jan-21-2021 13:42:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO Date of Last Symptom Resolved: Dec/3/2020	Changed Information
Dec-24-2020 12:32:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Reissued:Opened	Clin: This date overlaps with COVID_B symptom dates of 09Oct2020 to 03Dec2020.
Dec-23-2020 15:27:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Answered	New Information
Dec-23-2020 15:27:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO Date of Last Symptom Resolved:	New Information

090177e196ae3dcc\Final\Final On: 01-Apr-2021 04:41 (GMT)

Header Text: c4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit on Oct/08/2020**Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF Audit Trail History**Form Version:** 15-Sep-2020 21:55**Form Status:** Data Complete, Frozen, Not Complete**Site No:** 1117**Site Name:** (1117) Sundance Clinical Research**Subject No:** 11171036**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 10:58

			Oct/24/2020	
Dec-09-2020 11:58:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Opened	Clinical Query: Symptoms in this visit are still ongoing, however COVID_B visit is conducted. Please clarify whether the symptoms are still ongoing or end date is available.
Nov-16-2020 15:26:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Nov-16-2020 15:16:16 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	AE STILL ONGOING PER LAST ONSITE VISIT ON 24OCT2020. PER INVESTIGATOR NOTES, SEVERAL SYMPTOMS WERE REPORTED TO ADD TO COVID VISIT. ADDED SHORTNESS OF BREATH.
Nov-14-2020 18:29:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	Illness onset source has No for symptoms ongoing. Please confirm and update accordingly.
Nov-07-2020 21:38:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Changed Information
Oct-09-2020 14:29:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO Date of Last Symptom Resolved: Sep/28/2020	Initial Entry

4.a

Date	Location	User	Value	Reason
Oct-09-2020 14:29:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptoms: FEVER	Initial Entry

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/08/2020

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

Form Version: 15-Sep-2020 21:55

Form Status: Data Complete, Frozen, Not Complete

Site No: 1117

Site Name: (1117) Sundance Clinical Research

Subject No: 11171036

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

			Symptom Present: NO	
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4.a Symptoms:

Date	Location	User	Value	Reason
Oct-09-2020 14:29:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: FEVER	Initial Entry

4.a Was symptom present?

Date	Location	User	Value	Reason
Oct-09-2020 14:29:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

4.b

Date	Location	User	Value	Reason
Oct-09-2020 14:29:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptoms: NEW OR INCREASED COUGH Symptom Present: NO	Initial Entry

4.b Symptoms:

Date	Location	User	Value	Reason
Oct-09-2020 14:29:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NEW OR INCREASED COUGH	Initial Entry

4.b Was symptom present?

Date	Location	User	Value	Reason
Oct-09-2020 14:29:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

4.c

Date	Location	User	Value	Reason
Nov-16-2020 15:13:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptoms: NEW OR INCREASED SHORTNESS OF BREATH	WRITTEN IN PROGRESS NOTE TO ADD TO VISIT

090177e196ae3dcc\Final\Final On: 01-Apr-2021 04:41 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/08/2020

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

Form Version: 15-Sep-2020 21:55

Form Status: Data Complete, Frozen, Not Complete

Site No: 1117

Site Name: (1117) Sundance Clinical Research

Subject No: 11171036

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

			TH Symptom YES Present:	PER INVESTIGATOR
Oct-09-2020 14:29:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom NEW OR INCREASED s: SHORTNESS OF BREA TH Symptom NO Present:	Initial Entry

4.c Symptoms:

Date	Location	User	Value	Reason
Oct-09-2020 14:29:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NEW OR INCREASED SHORTNES S OF BREATH	Initial Entry

4.c Was symptom present?

Date	Location	User	Value	Reason
Nov-16-2020 15:13:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	WRITTEN IN PROGRESS NOTE TO ADD TO VISIT PER INVESTIGATOR
Nov-14-2020 18:33:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Duplicate query already on AE log CRF.
Nov-14-2020 18:28:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	AE log has shortness of breath with start date 08Oct2020 and AE was removed from EDC. This is also noted on illness onset source. Please confirm if it should be captured here.
Oct-09-2020 14:29:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

4.d

Date	Location	User	Value	Reason
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090177e196ae3dcc\Final\Final On: 01-Apr-2021 04:41 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/08/2020

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

Form Version: 15-Sep-2020 21:55

Form Status: Data Complete, Frozen, Not Complete

Site No: 1117

Site Name: (1117) Sundance Clinical Research

Subject No: 11171036

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

Oct-09-2020 14:29:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptoms: CHILLS Symptom Present: YES	Initial Entry
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4.d Symptoms:

Date	Location	User	Value	Reason
Oct-09-2020 14:29:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: CHILLS	Initial Entry

4.d Was symptom present?

Date	Location	User	Value	Reason
Oct-09-2020 14:29:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

4.e

Date	Location	User	Value	Reason
Nov-07-2020 21:36:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptoms: NEW OR INCREASED MUSCLE PAIN Symptom Present: YES	Changed Information
Oct-09-2020 14:29:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptoms: NEW OR INCREASED MUSCLE PAIN Symptom Present: NO	Initial Entry

090177e196ae3dcc\Final\Final On: 01-Apr-2021 04:41 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/08/2020

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

Form Version: 15-Sep-2020 21:55

Form Status: Data Complete, Frozen, Not Complete

Site No: 1117

Site Name: (1117) Sundance Clinical Research

Subject No: 11171036

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

4.e Symptoms:

Date	Location	User	Value	Reason
Oct-09-2020 14:29:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NEW OR INCREASED MUSCLE PA IN	Initial Entry

4.e Was symptom present?

Date	Location	User	Value	Reason
Nov-07-2020 21:36:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Changed Information
Oct-09-2020 14:29:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

4.f

Date	Location	User	Value	Reason
Jan-21-2021 13:47:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptoms: NEW LOSS OF TAST E OR SMELL Symptom P YES resent:	New Information
Oct-09-2020 14:29:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptoms: NEW LOSS OF TAST E OR SMELL Symptom P NO resent:	Initial Entry

090177e196ae3dcc\Final\Final On: 01-Apr-2021 04:41 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/08/2020

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

Form Version: 15-Sep-2020 21:55

Form Status: Data Complete, Frozen, Not Complete

Site No: 1117

Site Name: (1117) Sundance Clinical Research

Subject No: 11171036

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

4.f Symptoms:

Date	Location	User	Value	Reason
Oct-09-2020 14:29:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NEW LOSS OF TASTE OR SMELL	Initial Entry

4.f Was symptom present?

Date	Location	User	Value	Reason
Jan-21-2021 13:47:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	New Information
Oct-09-2020 14:29:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

4.g

Date	Location	User	Value	Reason
Nov-07-2020 21:37:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptoms: NEW OR INCREASED SORE THROAT Symptom Present: YES	Changed Information
Oct-09-2020 14:29:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptoms: NEW OR INCREASED SORE THROAT Symptom Present: NO	Initial Entry

090177e196ae3dcc\Final\Final On: 01-Apr-2021 04:41 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/08/2020

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

Form Version: 15-Sep-2020 21:55

Form Status: Data Complete, Frozen, Not Complete

Site No: 1117

Site Name: (1117) Sundance Clinical Research

Subject No: 11171036

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

4.g Symptoms:

Date	Location	User	Value	Reason
Oct-09-2020 14:29:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NEW OR INCREASED SORE THRO AT	Initial Entry

4.g Was symptom present?

Date	Location	User	Value	Reason
Nov-07-2020 21:37:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Changed Information
Oct-09-2020 14:29:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

4.h

Date	Location	User	Value	Reason
Oct-09-2020 14:29:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptoms: DIARRHEA Symptom Present: NO	Initial Entry

4.h Symptoms:

Date	Location	User	Value	Reason
Oct-09-2020 14:29:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: DIARRHEA	Initial Entry

4.h Was symptom present?

Date	Location	User	Value	Reason
Oct-09-2020 14:29:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

4.i

Date	Location	User	Value	Reason
Oct-09-2020 14:29:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptoms: VOMITING Symptom Present: NO	Initial Entry

090177e196ae3dcc\Final\Final On: 01-Apr-2021 04:41 (GMT)

Header Text: c4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit on Oct/08/2020**Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF Audit Trail History**Form Version:** 15-Sep-2020 21:55**Form Status:** Data Complete, Frozen, Not Complete**Site No:** 1117**Site Name:** (1117) Sundance Clinical Research**Subject No:** 11171036**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 10:58**4.i Symptoms:**

Date	Location	User	Value	Reason
Oct-09-2020 14:29:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: VOMITING	Initial Entry

4.i Was symptom present?

Date	Location	User	Value	Reason
Oct-09-2020 14:29:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

5.a

Date	Location	User	Value	Reason
Jan-21-2021 13:47:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptoms - Other: HEADACHE	Initial Entry

5.a Symptoms - Other Text:

Date	Location	User	Value	Reason
Jan-21-2021 13:47:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: HEADACHE	Initial Entry

5.b

Date	Location	User	Value	Reason
Jan-21-2021 13:47:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptoms - Other: SINUS PRESSURE	Initial Entry

5.b Symptoms - Other Text:

Date	Location	User	Value	Reason
Jan-21-2021 13:47:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: SINUS PRESSURE	Initial Entry

5.c

Date	Location	User	Value	Reason
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Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/08/2020

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

Form Version: 15-Sep-2020 21:55

Form Status: Data Complete, Frozen, Not Complete

Site No: 1117

Site Name: (1117) Sundance Clinical Research

Subject No: 11171036

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

Jan-21-2021 13:50:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptoms - Other: LEFT ARM SORENESS	Initial Entry
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5.c Symptoms - Other Text:

Date	Location	User	Value	Reason
Jan-21-2021 13:50:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: LEFT ARM SORENESS	Initial Entry

5.d

Date	Location	User	Value	Reason
Jan-21-2021 13:50:24 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptoms - Other: NECK STIFFNESS	Initial Entry

5.d Symptoms - Other Text:

Date	Location	User	Value	Reason
Jan-21-2021 13:50:24 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NECK STIFFNESS	Initial Entry

090177e196ae3dcc\Final\Final On: 01-Apr-2021 04:41 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/08/2020 Form: MICROBIOLOGY SPECIMEN - eCRF Audit Trail History

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen, Verified

Site No: 1117

Site Name: (1117) Sundance Clinical Research

Subject No: 11171036

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

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1. Actual Date of Collection:

Date	Location	User	Value	Reason
Oct-15-2020 16:01:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

2. Specimen Type:

Date	Location	User	Value	Reason
Oct-15-2020 16:01:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

3. Specimen Collection Location:

Date	Location	User	Value	Reason
Oct-15-2020 16:01:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

4. Assay Code and Description:

Date	Location	User	Value	Reason
Oct-15-2020 16:01:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

5. Device Type:

Date	Location	User	Value	Reason
Oct-15-2020 16:01:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

6. Trade Name:

Date	Location	User	Value	Reason
Oct-15-2020 16:01:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

7. Test Result:

090177e196ae3dcc\Final\Final On: 01-Apr-2021 04:41 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/08/2020 **Form:** MICROBIOLOGY SPECIMEN - eCRF Audit Trail History

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen, Verified

Site No: 1117

Site Name: (1117) Sundance Clinical Research

Subject No: 11171036

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

Date	Location	User	Value	Reason
Oct-15-2020 16:01:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

8. Comments/Findings/Details:

Date	Location	User	Value	Reason
Oct-15-2020 16:01:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

9. Trade Name Other, Specify:

Date	Location	User	Value	Reason
Oct-15-2020 16:01:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

090177e196ae3dcc\Final\Final On: 01-Apr-2021 04:41 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/08/2020

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: 11171036

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

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1. Data Origin

Date	Location	User	Value	Reason
Nov-06-2020 17:46:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry
Nov-06-2020 17:45:54 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Initial Entry
Oct-15-2020 16:06:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Nov-06-2020 17:46:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: NASAL_SWAB_SELF	Initial Entry
Nov-06-2020 17:45:54 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Initial Entry
Oct-15-2020 16:06:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Nov-07-2020 09:54:24 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Closed	Response satisfies query
Nov-06-2020 17:46:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Answered	Initial Entry
Nov-06-2020 17:46:30	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: :	Initial Entry

090177e196ae3dcc\Final\Final On: 01-Apr-2021 04:41 (GMT)

Header Text: c4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit on Oct/08/2020**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:** 11171036**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 10:58

(UTC-06:00) Central Time (US & Canada)			NO	
Nov-06-2020 17:45:54 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry i	Initial Entry
Nov-06-2020 01:07:16 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: O pened	If no sample was collected or sample was not collected according to protocol, select "No" and provide reason why sample was not collected at protocol- specified timepoint in the space provided
Nov-06-2020 00:28:04 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: D eleted	Query is invalid or does not apply
Nov-05-2020 08:42:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (b) (4)	Query 1: C andidate	DMW5244283;Sample Collected is not expected to be Not Done. Please review and update appropriately or clarify
Oct-15-2020 16:06:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry i Not Done	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-06-2020 17:46:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: SWAB PFE WAS COLLECTED BY CLINIC PERSONNEL	Initial Entry
Nov-06-2020 17:45:54 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Initial Entry

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on
Oct/08/2020

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB SELF - eCRF
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Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1117

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Subject Initials: ---

Generated By: (b) (4)

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Oct-15-2020 16:06:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry
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Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/08/2020

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: 11171036

Subject Initials: ---

Generated By: (b) (4)

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1. Data Origin

Date	Location	User	Value	Reason
Oct-14-2020 13:53:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Oct-14-2020 13:53:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: NASAL_SWAB	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Nov-04-2020 23:23:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Closed	As per site confirmation - updated PD tracker
Nov-04-2020 14:50:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Answered	DATES ARE CORRECT. PARTICIPANT REVEALED COVID ILLNESS SYMPTOMS AT VISIT 3 (08OCT2020) WHEN SOLICITED FOR POSSIBLE ADVERSE EVENTS. COVID ILLNESS VISIT PROCEDURES CONDUCTED IN TANDEM WITH V3 STUDY PROCEDURES.
Oct-30-2020 08:17:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Opened	PDQ: Date of Collection is more than 4 days after Date of Last Symptom Resolved on the Signs and Symptoms form in the same visit. Please review and update as

090177e196ae3dcc\Final\Final On: 01-Apr-2021 04:41 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/08/2020

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: 11171036

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

				appropriate.
Oct-21-2020 10:12:16 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	As per site response
Oct-19-2020 16:57:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	PER SOURCE DOCUMENT, DATE OF ASSESSMENT IS 08OCT2020. PARTICIPANT WAS ONSITE FOR V3, INVESTIGATOR ALSO DID COVID ILLNESS VISIT AT SAME TIME.
Oct-18-2020 08:59:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued:Opened	DM: Thank you for the response. However, Date of Collection is more than 4 days after Date of Last Symptom Resolved on the Signs and Symptoms form in the same visit. Please confirm and update as appropriate. Else clarify.
Oct-15-2020 16:02:18 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Original value is correct
Oct-14-2020 13:53:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Deleted	Close Auto Query
Oct-14-2020 13:53:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Oct-14-2020 13:53:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	Date of Collection is more than 4 days after Date of Last Symptom Resolved on the Signs and Symptoms form in the same visit. Please review and update as appropriate.

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Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/08/2020

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

Form Version: 22-Apr-2020 21:03

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Subject Initials: ---

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Oct-14-2020 13:53:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Collection: Oct/8/2020	Initial Entry
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5.a

Date	Location	User	Value	Reason
Oct-14-2020 13:53:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BRJ8DB	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Oct-14-2020 13:53:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BRJ8DB	Initial Entry

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Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/08/2020 Form: HEALTH CARE UTILIZATION - eCRF Audit Trail History

Form Version: 10-Oct-2020 15:59

Form Status: Data Complete, Frozen, Verified

Site No: 1117

Site Name: (1117) Sundance Clinical Research

Subject No: 11171036

Subject Initials: ---

Generated By: (b) (4)

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I.a

Date	Location	User	Value	Reason
Oct-15-2020 16:06:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Type of Practitioner: SPECIALIST Occurrence of Visits or Contacts: NO	Initial Entry

I.a Physician or Healthcare Professional:

Date	Location	User	Value	Reason
Oct-15-2020 16:06:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: SPECIALIST	Initial Entry

I.a Occurrence of Visits or Contacts:

Date	Location	User	Value	Reason
Oct-15-2020 16:06:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

I.b

Date	Location	User	Value	Reason
Oct-15-2020 16:06:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Type of Practitioner : EMERGENCY ROOM Occurrence of Visits or Contacts: NO	Initial Entry

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Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/08/2020 **Form:** HEALTH CARE UTILIZATION - eCRF Audit Trail History

Form Version: 10-Oct-2020 15:59

Form Status: Data Complete, Frozen, Verified

Site No: 1117

Site Name: (1117) Sundance Clinical Research

Subject No: 11171036

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

1.b Physician or Healthcare Professional:

Date	Location	User	Value	Reason
Oct-15-2020 16:06:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: EMERGENCY ROOM	Initial Entry

1.b Occurrence of Visits or Contacts:

Date	Location	User	Value	Reason
Oct-15-2020 16:06:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

1.c

Date	Location	User	Value	Reason
Oct-15-2020 16:06:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Type of Practitioner: PRIMARY CARE PHYSICIAN Occurrence of Visits or Contacts: NO	Initial Entry

1.c Physician or Healthcare Professional:

Date	Location	User	Value	Reason
Oct-15-2020 16:06:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: PRIMARY CARE PHYSICIAN	Initial Entry

1.c Occurrence of Visits or Contacts:

Date	Location	User	Value	Reason
Oct-15-2020 16:06:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

1.d

Date	Location	User	Value	Reason
Oct-15-2020 16:06:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Type of Practitioner: URGENT CARE Occurrence of Visits or Contacts: NO	Initial Entry

Header Text: c4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit on Oct/08/2020 **Form:** HEALTH CARE UTILIZATION - eCRF Audit Trail History**Form Version:** 10-Oct-2020 15:59**Form Status:** Data Complete, Frozen, Verified**Site No:** 1117**Site Name:** (1117) Sundance Clinical Research**Subject No:** 11171036**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 10:58***I.d Physician or Healthcare Professional:***

Date	Location	User	Value	Reason
Oct-15-2020 16:06:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: URGENT CARE	Initial Entry

I.d Occurrence of Visits or Contacts:

Date	Location	User	Value	Reason
Oct-15-2020 16:06:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

I.e

Date	Location	User	Value	Reason
Oct-15-2020 16:06:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Type of Practitioner: TELEPHONE CONSULTATION Occurrence of Visits or Contacts: YES <i>Number of Visits or Contacts:</i> 1	Initial Entry

I.e Physician or Healthcare Professional:

Date	Location	User	Value	Reason
Oct-15-2020 16:06:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: TELEPHONE CONSULTATION	Initial Entry

I.e Occurrence of Visits or Contacts:

Date	Location	User	Value	Reason
Oct-15-2020 16:06:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES <i>Number of Visits or Contacts:</i> 1	Initial Entry

I.f

Date	Location	User	Value	Reason
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Header Text: c4591001
Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/08/2020 **Form:** HEALTH CARE UTILIZATION - eCRF Audit Trail History
Form Version: 10-Oct-2020 15:59 **Form Status:** Data Complete, Frozen, Verified
Site No: 1117 **Site Name:** (1117) Sundance Clinical Research
Subject No: 11171036 **Subject Initials:** ---
Generated By: (b) (4) **Generated Time (GMT):** 29-Mar-2021 10:58

Oct-19-2020 14:40:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Type of Practitioner: OTHER Occurrence of Visits or Contacts: NO	Changed Information
Oct-15-2020 16:06:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Type of Practitioner: OTHER Occurrence of Visits or Contacts: YES <i>Number of Visits or Contacts:</i> 1	Initial Entry

1.f Physician or Healthcare Professional:

Date	Location	User	Value	Reason
Oct-15-2020 16:06:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: OTHER	Initial Entry

1.f Occurrence of Visits or Contacts:

Date	Location	User	Value	Reason
Oct-19-2020 14:40:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Oct-19-2020 14:40:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Changed Information
Oct-19-2020 14:40:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	“Other” is selected , however other specific item is blank. Please review and update as appropriate.
Oct-15-2020 16:06:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES <i>Number of Visits or Contacts:</i> 1	Initial Entry

2. Other Type of Practitioner Specify:

Date	Location	User	Value	Reason
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Header Text: c4591001
Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/08/2020 **Form:** HEALTH CARE UTILIZATION - eCRF Audit Trail History
Form Version: 10-Oct-2020 15:59 **Form Status:** Data Complete, Frozen, Verified
Site No: 1117 **Site Name:** (1117) Sundance Clinical Research
Subject No: 11171036 **Subject Initials:** ---
Generated By: (b) (4) **Generated Time (GMT):** 29-Mar-2021 10:58

Oct-19-2020 18:23:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Oct-19-2020 14:40:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Changed Information
Oct-19-2020 14:40:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Changed Information
Oct-16-2020 11:55:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued:Opened	Clinical Query: To clarify, as visit with study investigator is specified to be performed per protocol, it should not be recorded as an Other Type of Practitioner on this CRF.
Oct-16-2020 11:51:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	SCHEDULED PROTOCOL VISIT, INVESTIGATOR DEEMED NECESSARY FOR COVID ILLNESS VISIT. CONTACTED CRA WHOM REPORTED THAT ALL STUDY PROCEDURES SHOULD BE COMPLETED AND REPORTED.
Oct-16-2020 10:34:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	Clinical Query: Protocol-specified visits should not be recorded on this CRF.
Oct-15-2020 16:06:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: STUDY INVESTIGATOR	Initial Entry

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

Date	Location	User	Value	Reason
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Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/08/2020 **Form:** HEALTH CARE UTILIZATION - eCRF Audit Trail History

Form Version: 10-Oct-2020 15:59

Form Status: Data Complete, Frozen, Verified

Site No: 1117

Site Name: (1117) Sundance Clinical Research

Subject No: 11171036

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Generated By: (b) (4)

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Oct-15-2020 16:06:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry
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Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/08/2020 Form: RESPIRATORY TREATMENT - eCRF Audit Trail History

Form Version: 06-Jul-2020 21:53

Form Status: Data Complete, Frozen, Verified

Site No: 1117

Site Name: (1117) Sundance Clinical Research

Subject No: 11171036

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

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1. What is the treatment Identifier?

Date	Location	User	Value	Reason
Nov-16-2020 15:16:27 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Done	Initial Entry

2. Concomitant Non-drug Treatment Pre-specified:

Date	Location	User	Value	Reason
Nov-16-2020 15:16:27 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Done	Initial Entry

3. Treatment:

Date	Location	User	Value	Reason
Nov-16-2020 15:16:27 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Done	Initial Entry

4. Treatment:

Date	Location	User	Value	Reason
Nov-16-2020 15:16:27 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Done	Initial Entry

5. Start Date:

Date	Location	User	Value	Reason
Nov-16-2020 15:16:27 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Done	Initial Entry

6. Ongoing?

Date	Location	User	Value	Reason
Nov-16-2020 15:16:27 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Done	Initial Entry

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Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/08/2020 **Form:** ILLNESS DETAILS - eCRF Audit Trail History

Form Version: 06-Jul-2020 21:52

Form Status: Data Complete, Frozen, Verified

Site No: 1117

Site Name: (1117) Sundance Clinical Research

Subject No: 11171036

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

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1. Category of Clinical Event:

Date	Location	User	Value	Reason
Oct-09-2020 14:30:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: POTENTIAL COVID-19 ILLNESS	Initial Entry

2. Was a diagnosis obtained for Potential COVID-19 Illness?

Date	Location	User	Value	Reason
Oct-09-2020 14:30:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

3. Toxicity Grade:

Date	Location	User	Value	Reason
Oct-09-2020 14:30:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 1	Initial Entry

090177e196ae3dcc\Final\Final On: 01-Apr-2021 04:41 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on **Form:** ILLNESS DETAILS - SEVERE - eCRF Audit Trail History
Oct/08/2020

Form Version: 17-Jul-2020 21:55

Form Status: Data Complete, Frozen, Verified

Site No: 1117

Site Name: (1117) Sundance Clinical Research

Subject No: 11171036

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

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1. Category of Clinical Event:

Date	Location	User	Value	Reason
Nov-20-2020 10:41:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

2. Subcategory of Clinical Event:

Date	Location	User	Value	Reason
Nov-20-2020 10:41:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

3. Was a diagnosis obtained?

Date	Location	User	Value	Reason
Nov-20-2020 10:41:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

4. Toxicity Grade:

Date	Location	User	Value	Reason
Nov-20-2020 10:41:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

090177e196ae3dcc\Final\Final On: 01-Apr-2021 04:41 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/08/2020

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Frozen, Verified

Site No: 1117

Site Name: (1117) Sundance Clinical Research

Subject No: 11171036

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

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1. Lab Panel:

Date	Location	User	Value	Reason
Nov-20-2020 10:41:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

2. Laboratory Name and Address

Date	Location	User	Value	Reason
Nov-20-2020 10:41:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

3. Collection Date:

Date	Location	User	Value	Reason
Nov-20-2020 10:41:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

4. Specimen Type:

Date	Location	User	Value	Reason
Nov-20-2020 10:41:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

5.a

Date	Location	User	Value	Reason
Nov-20-2020 10:41:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sponsor-Defined Identifier: Not Done Test:: Not Done Result:: Not Done Not Done:: Not Done Lab Normal Range: Not Done	Initial Entry

090177e196ae3dcc\Final\Final On: 01-Apr-2021 04:41 (GMT)

Header Text: c4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit on Oct/08/2020**Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History**Form Version:** 21-Aug-2020 02:49**Form Status:** Data Complete, Frozen, Verified**Site No:** 1117**Site Name:** (1117) Sundance Clinical Research**Subject No:** 11171036**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 10:58**5.a Sponsor ID:**

Date	Location	User	Value	Reason
Nov-20-2020 10:41:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

5.a Test:

Date	Location	User	Value	Reason
Nov-20-2020 10:41:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

5.a Result:

Date	Location	User	Value	Reason
Nov-20-2020 10:41:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

5.a Not Done:

Date	Location	User	Value	Reason
Nov-20-2020 10:41:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

5.a LNMT

Date	Location	User	Value	Reason
Nov-20-2020 10:41:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

5.b

Date	Location	User	Value	Reason
Nov-20-2020 10:41:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sponsor-Defined Identifier: Not Done Test:: Not Done Result:: Not Done	Initial Entry

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/08/2020

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Frozen, Verified

Site No: 1117

Site Name: (1117) Sundance Clinical Research

Subject No: 11171036

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

			Not Done::	Not Done
			Lab Normal Range:	Not Done

5.b Sponsor ID:

Date	Location	User	Value	Reason
Nov-20-2020 10:41:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

5.b Test:

Date	Location	User	Value	Reason
Nov-20-2020 10:41:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

5.b Result:

Date	Location	User	Value	Reason
Nov-20-2020 10:41:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

5.b Not Done:

Date	Location	User	Value	Reason
Nov-20-2020 10:41:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

5.b LNMT

Date	Location	User	Value	Reason
Nov-20-2020 10:41:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

5.c

Date	Location	User	Value	Reason
Nov-20-2020 10:41:56 (UTC-06:00) Central Time	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sponsor-Defined Identifie Not Don	Initial Entry

090177e196ae3dcc\Final\Final On: 01-Apr-2021 04:41 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/08/2020

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History

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Site No: 1117

Site Name: (1117) Sundance Clinical Research

Subject No: 11171036

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

(US & Canada)	(b) (4), (b) (6)	r:	e
		Test::	Not Done
		Result::	Not Done
		Not Done::	Not Done
		Lab Normal Range:	Not Done

5.c Sponsor ID:

Date	Location	User	Value	Reason
Nov-20-2020 10:41:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

5.c Test:

Date	Location	User	Value	Reason
Nov-20-2020 10:41:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

5.c Result:

Date	Location	User	Value	Reason
Nov-20-2020 10:41:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

5.c Not Done:

Date	Location	User	Value	Reason
Nov-20-2020 10:41:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

5.c LNMT

Date	Location	User	Value	Reason
Nov-20-2020 10:41:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

090177e196ae3dcc\Final\Final On: 01-Apr-2021 04:41 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/08/2020

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Frozen, Verified

Site No: 1117

Site Name: (1117) Sundance Clinical Research

Subject No: 11171036

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

5.d

Date	Location	User	Value	Reason
Nov-20-2020 10:41:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sponsor-Defined Identifier: Not Done Test:: Not Done Result:: Not Done Not Done:: Not Done Lab Normal Range: Not Done	Initial Entry

Header Text: c4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit on Oct/08/2020**Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History**Form Version:** 21-Aug-2020 02:49**Form Status:** Data Complete, Frozen, Verified**Site No:** 1117**Site Name:** (1117) Sundance Clinical Research**Subject No:** 11171036**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 10:58**5.d Sponsor ID:**

Date	Location	User	Value	Reason
Nov-20-2020 10:41:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

5.d Test:

Date	Location	User	Value	Reason
Nov-20-2020 10:41:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

5.d Result:

Date	Location	User	Value	Reason
Nov-20-2020 10:41:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

5.d Not Done:

Date	Location	User	Value	Reason
Nov-20-2020 10:41:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

5.d LNMT

Date	Location	User	Value	Reason
Nov-20-2020 10:41:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

5.e

Date	Location	User	Value	Reason
Nov-20-2020 10:41:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sponsor-Defined Identifier: Not Done Test:: Not Done Result:: Not Done	Initial Entry

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/08/2020

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Frozen, Verified

Site No: 1117

Site Name: (1117) Sundance Clinical Research

Subject No: 11171036

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

			Not Done::	Not Done
			Lab Normal Range:	Not Done

5.e Sponsor ID:

Date	Location	User	Value	Reason
Nov-20-2020 10:41:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

5.e Test:

Date	Location	User	Value	Reason
Nov-20-2020 10:41:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

5.e Result:

Date	Location	User	Value	Reason
Nov-20-2020 10:41:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

5.e Not Done:

Date	Location	User	Value	Reason
Nov-20-2020 10:41:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

5.e LNMT

Date	Location	User	Value	Reason
Nov-20-2020 10:41:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

5.f

Date	Location	User	Value	Reason
Nov-20-2020 10:41:56 (UTC-06:00) Central Time	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sponsor-Defined Identify Not Done	Initial Entry

090177e196ae3dcc\Final\Final On: 01-Apr-2021 04:41 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/08/2020

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Frozen, Verified

Site No: 1117

Site Name: (1117) Sundance Clinical Research

Subject No: 11171036

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

(US & Canada)		(b) (4), (b) (6)	r:	e	
			Test::	Not Done	
			Result::	Not Done	
			Not Done::	Not Done	
			Lab Normal Range:	Not Done	

5.f Sponsor ID:

Date	Location	User	Value	Reason
Nov-20-2020 10:41:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

5.f Test:

Date	Location	User	Value	Reason
Nov-20-2020 10:41:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

5.f Result:

Date	Location	User	Value	Reason
Nov-20-2020 10:41:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

5.f Not Done:

Date	Location	User	Value	Reason
Nov-20-2020 10:41:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

5.f LNMT

Date	Location	User	Value	Reason
Nov-20-2020 10:41:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

090177e196ae3dcc\Final\Final On: 01-Apr-2021 04:41 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/08/2020

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Frozen, Verified

Site No: 1117

Site Name: (1117) Sundance Clinical Research

Subject No: 11171036

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

5.g

Date	Location	User	Value	Reason
Nov-20-2020 10:41:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sponsor-Defined Identifier: Not Done Test:: Not Done Result:: Not Done Not Done:: Not Done Lab Normal Range: Not Done	Initial Entry

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/08/2020

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Frozen, Verified

Site No: 1117

Site Name: (1117) Sundance Clinical Research

Subject No: 11171036

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

5.g Sponsor ID:

Date	Location	User	Value	Reason
Nov-20-2020 10:41:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Done	Initial Entry

5.g Test:

Date	Location	User	Value	Reason
Nov-20-2020 10:41:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Done	Initial Entry

5.g Result:

Date	Location	User	Value	Reason
Nov-20-2020 10:41:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Done	Initial Entry

5.g Not Done:

Date	Location	User	Value	Reason
Nov-20-2020 10:41:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Done	Initial Entry

5.g LNMT

Date	Location	User	Value	Reason
Nov-20-2020 10:41:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Done	Initial Entry

090177e196ae3dcc\Final\Final On: 01-Apr-2021 04:41 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/08/2020

Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete, Frozen, Verified

Site No: 1117

Site Name: (1117) Sundance Clinical Research

Subject No: 11171036

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

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1. Lab Panel:

Date	Location	User	Value	Reason
Nov-20-2020 10:42:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

2. Laboratory Name and Address

Date	Location	User	Value	Reason
Nov-20-2020 10:42:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

3. Collection Date:

Date	Location	User	Value	Reason
Nov-20-2020 10:42:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

4. Specimen Type:

Date	Location	User	Value	Reason
Nov-20-2020 10:42:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

5.a

Date	Location	User	Value	Reason
Nov-20-2020 10:42:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sponsor-Defined Identifier: Not Done Test:: Not Done Result:: Not Done Not Done:: Not Done Lab Normal Range: Not Done	Initial Entry

090177e196ae3dcc\Final\Final On: 01-Apr-2021 04:41 (GMT)

090177e196ae3dcc\Final\Final On: 01-Apr-2021 04:41 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/08/2020

Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete, Frozen, Verified

Site No: 1117

Site Name: (1117) Sundance Clinical Research

Subject No: 11171036

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

5.a Sponsor ID:

Date	Location	User	Value	Reason
Nov-20-2020 10:42:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

5.a Test:

Date	Location	User	Value	Reason
Nov-20-2020 10:42:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

5.a Result:

Date	Location	User	Value	Reason
Nov-20-2020 10:42:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

5.a Not Done:

Date	Location	User	Value	Reason
Nov-20-2020 10:42:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

5.a LNMT

Date	Location	User	Value	Reason
Nov-20-2020 10:42:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

5.b

Date	Location	User	Value	Reason
Nov-20-2020 10:42:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sponsor-Defined Identifier: Not Done Test:: Not Done Result:: Not Done	Initial Entry

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/08/2020

Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete, Frozen, Verified

Site No: 1117

Site Name: (1117) Sundance Clinical Research

Subject No: 11171036

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Generated Time (GMT): 29-Mar-2021 10:58

			Not Done::	Not Done
			Lab Normal Range:	Not Done

5.b Sponsor ID:

Date	Location	User	Value	Reason
Nov-20-2020 10:42:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

5.b Test:

Date	Location	User	Value	Reason
Nov-20-2020 10:42:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

5.b Result:

Date	Location	User	Value	Reason
Nov-20-2020 10:42:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

5.b Not Done:

Date	Location	User	Value	Reason
Nov-20-2020 10:42:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

5.b LNMT

Date	Location	User	Value	Reason
Nov-20-2020 10:42:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

5.c

Date	Location	User	Value	Reason
Nov-20-2020 10:42:11 (UTC-06:00) Central Time	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sponsor-Defined Identify Not Done	Initial Entry

090177e196ae3dcc\Final\Final On: 01-Apr-2021 04:41 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/08/2020

Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete, Frozen, Verified

Site No: 1117

Site Name: (1117) Sundance Clinical Research

Subject No: 11171036

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

(US & Canada)		(b) (4), (b) (6)	r:	e	
			Test::	Not Done	
			Result::	Not Done	
			Not Done::	Not Done	
			Lab Normal Range:	Not Done	

5.c Sponsor ID:

Date	Location	User	Value	Reason
Nov-20-2020 10:42:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Done	Initial Entry

5.c Test:

Date	Location	User	Value	Reason
Nov-20-2020 10:42:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Done	Initial Entry

5.c Result:

Date	Location	User	Value	Reason
Nov-20-2020 10:42:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Done	Initial Entry

5.c Not Done:

Date	Location	User	Value	Reason
Nov-20-2020 10:42:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Done	Initial Entry

5.c LNMT

Date	Location	User	Value	Reason
Nov-20-2020 10:42:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Done	Initial Entry

090177e196ae3dcc\Final\Final On: 01-Apr-2021 04:41 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/08/2020

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Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

5.d

Date	Location	User	Value	Reason
Nov-20-2020 10:42:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sponsor-Defined Identifier: Not Done Test:: Not Done Result:: Not Done Not Done:: Not Done Lab Normal Range: Not Done	Initial Entry

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/08/2020

Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete, Frozen, Verified

Site No: 1117

Site Name: (1117) Sundance Clinical Research

Subject No: 11171036

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

5.d Sponsor ID:

Date	Location	User	Value	Reason
Nov-20-2020 10:42:11 (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-20-2020 10:42:11 (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-20-2020 10:42:11 (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-20-2020 10:42:11 (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-20-2020 10:42:11 (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-20-2020 10:42:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Sponsor-Defined Identifier: Not Done Test:: Not Done Result:: Not Done	Initial Entry

090177e196ae3dcc\Final\Final On: 01-Apr-2021 04:41 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/08/2020

Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete, Frozen, Verified

Site No: 1117

Site Name: (1117) Sundance Clinical Research

Subject No: 11171036

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

			Not Done::	Not Done
			Lab Normal Range:	Not Done

5.e Sponsor ID:

Date	Location	User	Value	Reason
Nov-20-2020 10:42:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

5.e Test:

Date	Location	User	Value	Reason
Nov-20-2020 10:42:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

5.e Result:

Date	Location	User	Value	Reason
Nov-20-2020 10:42:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

5.e Not Done:

Date	Location	User	Value	Reason
Nov-20-2020 10:42:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

5.e LNMT

Date	Location	User	Value	Reason
Nov-20-2020 10:42:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

5.f

Date	Location	User	Value	Reason
Nov-20-2020 10:42:11 (UTC-06:00) Central Time	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sponsor-Defined Identify Not Done	Initial Entry

090177e196ae3dcc\Final\Final On: 01-Apr-2021 04:41 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/08/2020

Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete, Frozen, Verified

Site No: 1117

Site Name: (1117) Sundance Clinical Research

Subject No: 11171036

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

(US & Canada)		(b) (4), (b) (6)	r:	e	
			Test::	Not Done	
			Result::	Not Done	
			Not Done::	Not Done	
			Lab Normal Range:	Not Done	

5.f Sponsor ID:

Date	Location	User	Value	Reason
Nov-20-2020 10:42:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

5.f Test:

Date	Location	User	Value	Reason
Nov-20-2020 10:42:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

5.f Result:

Date	Location	User	Value	Reason
Nov-20-2020 10:42:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

5.f Not Done:

Date	Location	User	Value	Reason
Nov-20-2020 10:42:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

5.f LNMT

Date	Location	User	Value	Reason
Nov-20-2020 10:42:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

090177e196ae3dcc\Final\Final On: 01-Apr-2021 04:41 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/08/2020

Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete, Frozen, Verified

Site No: 1117

Site Name: (1117) Sundance Clinical Research

Subject No: 11171036

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

5.g

Date	Location	User	Value	Reason
Nov-20-2020 10:42:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sponsor-Defined Identifier: Not Done Test:: Not Done Result:: Not Done Not Done:: Not Done Lab Normal Range: Not Done	Initial Entry

Header Text: c4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit on Oct/08/2020**Form:** LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History**Form Version:** 21-Aug-2020 02:51**Form Status:** Data Complete, Frozen, Verified**Site No:** 1117**Site Name:** (1117) Sundance Clinical Research**Subject No:** 11171036**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 10:58**5.g Sponsor ID:**

Date	Location	User	Value	Reason
Nov-20-2020 10:42:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

5.g Test:

Date	Location	User	Value	Reason
Nov-20-2020 10:42:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

5.g Result:

Date	Location	User	Value	Reason
Nov-20-2020 10:42:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

5.g Not Done:

Date	Location	User	Value	Reason
Nov-20-2020 10:42:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

5.g LNMT

Date	Location	User	Value	Reason
Nov-20-2020 10:42:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

5.h

Date	Location	User	Value	Reason
Nov-20-2020 10:42:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sponsor-Defined Identifier: Not Done Test:: Not Done Result:: Not Done	Initial Entry

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/08/2020

Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete, Frozen, Verified

Site No: 1117

Site Name: (1117) Sundance Clinical Research

Subject No: 11171036

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

			Not Done::	Not Done
			Lab Normal Range:	Not Done

5.h Sponsor ID:

Date	Location	User	Value	Reason
Nov-20-2020 10:42:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

5.h Test:

Date	Location	User	Value	Reason
Nov-20-2020 10:42:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

5.h Result:

Date	Location	User	Value	Reason
Nov-20-2020 10:42:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

5.h Not Done:

Date	Location	User	Value	Reason
Nov-20-2020 10:42:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

5.h LNMT

Date	Location	User	Value	Reason
Nov-20-2020 10:42:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

5.i

Date	Location	User	Value	Reason
Nov-20-2020 10:42:11 (UTC-06:00) Central Time	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sponsor-Defined Identify Not Done	Initial Entry

090177e196ae3dcc\Final\Final On: 01-Apr-2021 04:41 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/08/2020

Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete, Frozen, Verified

Site No: 1117

Site Name: (1117) Sundance Clinical Research

Subject No: 11171036

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

(US & Canada)		(b) (4), (b) (6)	r:	e	
			Test::	Not Don	
				e	
			Result::	Not Don	
				e	
			Not Done::	Not Don	
				e	
			Lab Normal Range:	Not Don	
				e	

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/08/2020

Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete, Frozen, Verified

Site No: 1117

Site Name: (1117) Sundance Clinical Research

Subject No: 11171036

Subject Initials: ---

Generated By: (b) (4)

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5.i Sponsor ID:

Date	Location	User	Value	Reason
Nov-20-2020 10:42:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

5.i Test:

Date	Location	User	Value	Reason
Nov-20-2020 10:42:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

5.i Result:

Date	Location	User	Value	Reason
Nov-20-2020 10:42:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

5.i Not Done:

Date	Location	User	Value	Reason
Nov-20-2020 10:42:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

5.i LNMT

Date	Location	User	Value	Reason
Nov-20-2020 10:42:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

5.j

Date	Location	User	Value	Reason
Nov-20-2020 10:42:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sponsor-Defined Identifier: Not Done Test: Not Done	Initial Entry

090177e196ae3dcc\Final\Final On: 01-Apr-2021 04:41 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/08/2020

Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete, Frozen, Verified

Site No: 1117

Site Name: (1117) Sundance Clinical Research

Subject No: 11171036

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

			Result::	Not Done
				e
			Not Done::	Not Done
				e
			Lab Normal Range:	Not Done
				e

5.j Sponsor ID:

Date	Location	User	Value	Reason
Nov-20-2020 10:42:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

5.j Test:

Date	Location	User	Value	Reason
Nov-20-2020 10:42:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

5.j Result:

Date	Location	User	Value	Reason
Nov-20-2020 10:42:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

5.j Not Done:

Date	Location	User	Value	Reason
Nov-20-2020 10:42:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

5.j LNMT

Date	Location	User	Value	Reason
Nov-20-2020 10:42:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

090177e196ae3dcc\Final\Final On: 01-Apr-2021 04:41 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/08/2020 Form: VITAL SIGNS - COVID - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:50

Form Status: Data Complete, Frozen, Verified

Site No: 1117

Site Name: (1117) Sundance Clinical Research

Subject No: 11171036

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

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1. Date:

Date	Location	User	Value	Reason
Nov-20-2020 10:43:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

2.a

Date	Location	User	Value	Reason
Nov-20-2020 10:43:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Record Identifier:: Not Done Systolic:: Not Done Diastolic:: Not Done Respiratory Rate in respirations/minute: Not Done Heart Rate in beats/minute: Not Done	Initial Entry

2.a Record Identifier:

Date	Location	User	Value	Reason
Nov-20-2020 10:43:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

2.a Systolic:

Date	Location	User	Value	Reason
Nov-20-2020 10:43:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

2.a Diastolic:

Date	Location	User	Value	Reason
Nov-20-2020 10:43:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

090177e196ae3dcc\Final\Final On: 01-Apr-2021 04:41 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/08/2020 **Form:** VITAL SIGNS - COVID - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:50

Form Status: Data Complete, Frozen, Verified

Site No: 1117

Site Name: (1117) Sundance Clinical Research

Subject No: 11171036

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

2.a Respiratory Rate in respirations/minute:

Date	Location	User	Value	Reason
Nov-20-2020 10:43:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

2.a Heart Rate in beats/minute:

Date	Location	User	Value	Reason
Nov-20-2020 10:43:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/08/2020 Form: VITAL SIGNS - PULSE OX ROOM AIR - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete, Frozen, Verified

Site No: 1117

Site Name: (1117) Sundance Clinical Research

Subject No: 11171036

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

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1. Date:

Date	Location	User	Value	Reason
Nov-20-2020 10:43:55 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

2.a

Date	Location	User	Value	Reason
Nov-20-2020 10:43:55 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Record Identifier:: Not Done Oxygen Saturation: Not Done	Initial Entry

2.a Record Identifier:

Date	Location	User	Value	Reason
Nov-20-2020 10:43:55 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

2.a SPO2 Pulse Oximetry %

Date	Location	User	Value	Reason
Nov-20-2020 10:43:55 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

090177e196ae3dcc\Final\Final On: 01-Apr-2021 04:41 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/08/2020 **Form:** OXYGENATION PARAMETERS - eCRF Audit Trail History

Form Version: 06-Jul-2020 21:52

Form Status: Data Complete, Frozen, Verified

Site No: 1117

Site Name: (1117) Sundance Clinical Research

Subject No: 11171036

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

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1. Date Time of Assessment:

Date	Location	User	Value	Reason
Nov-20-2020 10:44:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

2. Arterial Blood Gases PaO2 (mmHg):

Date	Location	User	Value	Reason
Nov-20-2020 10:44:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

3. FiO2 (Fraction of Inhaled Oxygen):

Date	Location	User	Value	Reason
Nov-20-2020 10:44:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

090177e196ae3dcc\Final\Final On: 01-Apr-2021 04:41 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/08/2020

Form: CONCOMITANT MEDICATIONS - VASOPRESSORS - eCRF 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: 11171036

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

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1. What is the medication identifier?

Date	Location	User	Value	Reason
Nov-20-2020 10:44:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Done	Initial Entry

2. Category:

Date	Location	User	Value	Reason
Nov-20-2020 10:44:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Done	Initial Entry

3. Concomitant Medications Pre-specified:

Date	Location	User	Value	Reason
Nov-20-2020 10:44:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> 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-20-2020 10:44:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Done	Initial Entry

5. Start Date:

Date	Location	User	Value	Reason
Nov-20-2020 10:44:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Done	Initial Entry

6. Ongoing?

Date	Location	User	Value	Reason
Nov-20-2020 10:44:21 (UTC-06:00) Central Time	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Done	Initial Entry

090177e196ae3dcc\Final\Final On: 01-Apr-2021 04:41 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/08/2020

Form: CONCOMITANT MEDICATIONS - VASOPRESSORS - eCRF 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: 11171036

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

(US & Canada)

(b) (4), (b) (6)

090177e196ae3dcc\Final\Final On: 01-Apr-2021 04:41 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/08/2020 Form: IMAGING - eCRF Audit Trail History

Form Version: 06-Jul-2020 21:53

Form Status: Data Complete, Frozen, Verified

Site No: 1117

Site Name: (1117) Sundance Clinical Research

Subject No: 11171036

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

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1. Date of Assessment:

Date	Location	User	Value	Reason
Nov-20-2020 10:44:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Done	Initial Entry

2. Location of Assessment:

Date	Location	User	Value	Reason
Nov-20-2020 10:44:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Done	Initial Entry

3. Type of Imaging Exam:

Date	Location	User	Value	Reason
Nov-20-2020 10:44:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Done	Initial Entry

4. Assessment:

Date	Location	User	Value	Reason
Nov-20-2020 10:44:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Done	Initial Entry

090177e196ae3dcc\Final\Final On: 01-Apr-2021 04:41 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit on Dec/23/2020 Form: DATE OF VISIT - ILLNESS ONSET - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1117

Site Name: (1117) Sundance Clinical Research

Subject No: 11171036

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

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I. Date of Visit

Date	Location	User	Value	Reason
Feb-01-2021 01:20:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 8: Closed	Response satisfies query
Jan-29-2021 16:30:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 8: Answered	Changed data per query
Jan-29-2021 04:36:37 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 7: Deleted	Query is invalid or does not apply
Jan-28-2021 01:30:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 8: Opened	DM: Erroneous visit is marked. However, form level comment is not present on SELF SWAB form of this visit. Kindly review and add form level comment by selecting Not Done or Not Applicable option on SELF SWAB form or else clarify.
Jan-27-2021 13:40:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 6: Closed	Response satisfies query
Jan-27-2021 13:38:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 6: Answered	Changed data per query
Jan-26-2021 23:30:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 6: Opened	DM: Erroneous visit is marked. However, deleted data is present on SELF SWAB form. Kindly erase data by undeleting logline and then add form level comment by selecting Not Done or Not Applicable option on SELF SWAB form or

090177e196ae3dcc\Final\Final On: 01-Apr-2021 04:41 (GMT)

Header Text: c4591001**Visit:** POT_COVID_ILL 2 - Unscheduled Visit on Dec/23/2020**Form:** DATE OF VISIT - ILLNESS ONSET - eCRF Audit Trail History**Form Version:** 22-Apr-2020 21:03**Form Status:** Data Complete, Frozen, Verified**Site No:** 1117**Site Name:** (1117) Sundance Clinical Research**Subject No:** 11171036**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 10:58

				else clarify.
Jan-26-2021 08:52:04 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 5: Closed	Response satisfies query
Jan-26-2021 08:46:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 7: 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.
Jan-26-2021 08:46:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 6: 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.
Jan-25-2021 19:02:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 5: Answered	UPON REVIEW OF MEDICAL RECORDS AND PARTICIPANT INTERVIEW, COVID_A SHOULD NEVER HAVE BEEN CLOSED OUT. PER INVESTIGATOR AND MONITOR, THIS IS ALL COVID_A. REQUEST TO UNLOCK FORMS HAS BEEN SENT TO MAKE FINAL ADJUSTMENTS.
Jan-25-2021 10:03:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 5: Opened	Date of Visit is completed but Date of Assessment in the Signs and Symptoms form is missing. Please review and update as

Header Text: c4591001**Visit:** POT_COVID_ILL 2 - Unscheduled Visit on Dec/23/2020**Form:** DATE OF VISIT - ILLNESS ONSET - eCRF Audit Trail History**Form Version:** 22-Apr-2020 21:03**Form Status:** Data Complete, Frozen, Verified**Site No:** 1117**Site Name:** (1117) Sundance Clinical Research**Subject No:** 11171036**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 10:58

				appropriate.
Jan-21-2021 13:41:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 5: Candidate	Date of Visit is completed but Date of Assessment in the Signs and Symptoms form is missing. Please review and update as appropriate.
Dec-24-2020 02:31:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Closed	Closed as data entered.
Dec-24-2020 00:07:23 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 4: Closed	Response satisfies query
Dec-23-2020 15:29:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Closed	Close Auto Query
Dec-23-2020 15:28:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 4: Answered	Changed Information
Dec-23-2020 15:28:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 3: Answered	Changed Information
Dec-23-2020 15:28:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Dec/23/2020	Changed Information
Dec-09-2020 11:08:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 4: Opened	DM: Kindly review and complete 'Microbiology Specimen form' at this visit. Thank you.
Dec-09-2020 05:08:46 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Opened	DM: Date of Visit is completed but Nasal Swab (SWAB PFE) CRF is not initiated. Please review and update the data as appropriate. Thanks
Dec-09-2020 03:35:24 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Opened	Date of Visit is completed but Date of Assessment in the Signs and Symptoms

Header Text: c4591001
Visit: POT_COVID_ILL 2 - Unscheduled Visit on Dec/23/2020 **Form:** DATE OF VISIT - ILLNESS ONSET - eCRF Audit Trail History
Form Version: 22-Apr-2020 21:03 **Form Status:** Data Complete, Frozen, Verified
Site No: 1117 **Site Name:** (1117) Sundance Clinical Research
Subject No: 11171036 **Subject Initials:** ---
Generated By: (b) (4) **Generated Time (GMT):** 29-Mar-2021 10:58

				form is missing. Please review and update as appropriate.
Dec-08-2020 13:19:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Dec-08-2020 13:19:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Candidate	Date of Visit is completed but Date of Assessment in the Signs and Symptoms form is missing. Please review and update as appropriate.
Dec-08-2020 13:19:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	Date of Visit is completed but Date of Collection in both Nasal Swab Self and Nasal Swab are missing. Please review and update as appropriate.
Dec-08-2020 13:19:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Dec/7/2020	Initial Entry

2. Erroneous Visit

Date	Location	User	Value	Reason
Mar-05-2021 04:01:37 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Mar-04-2021 13:25:37 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Changed Information
Mar-04-2021 13:25:37 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Changed Information
Mar-04-2021 12:11:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	Since we need the swab data; we need the Erroneous Visit data unchecked. We understand that Illness visit was performed in error.

Header Text: c4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit on Dec/23/2020 **Form:** DATE OF VISIT - ILLNESS ONSET - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1117

Site Name: (1117) Sundance Clinical Research

Subject No: 11171036

Subject Initials: ---

Generated By: (b) (4)

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				This is a data workaround so that we can pull in the swab data per CCGs
Jan-26-2021 08:46:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: ERRONEOUS VISIT	Initial Entry

3. COVID-19 Illness Visit:

Date	Location	User	Value	Reason
Dec-08-2020 13:19:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: COVID_B	Initial Entry

Header Text: c4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit on Dec/23/2020

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

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Form Status: Data Complete, Frozen, Verified

Site No: 1117

Site Name: (1117) Sundance Clinical Research

Subject No: 11171036

Subject Initials: ---

Generated By: (b) (4)

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1. Date of Assessment:

Date	Location	User	Value	Reason
Jan-21-2021 13:41:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry
Jan-21-2021 13:41:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Changed Information
Dec-23-2020 15:29:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Dec/23/2020	Initial Entry

2. Date of First Symptom Started:

Date	Location	User	Value	Reason
Jan-21-2021 13:41:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry
Jan-21-2021 13:41:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Changed Information
Dec-23-2020 15:29:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Oct/9/2020	Initial Entry

3. Symptoms Ongoing?

Date	Location	User	Value	Reason
Jan-21-2021 13:41:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry
Jan-21-2021 13:41:19 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Changed Information
Dec-23-2020 15:29:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO Date of Last Symptom Resolved: Dec/3/2020	Initial Entry

090177e196ae3dcc\Final\Final On: 01-Apr-2021 04:41 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit on Dec/23/2020

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

Form Version: 10-Dec-2020 02:29

Form Status: Data Complete, Frozen, Verified

Site No: 1117

Site Name: (1117) Sundance Clinical Research

Subject No: 11171036

Subject Initials: ---

Generated By: (b) (4)

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4.a

Date	Location	User	Value	Reason
Jan-21-2021 13:41:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptoms: FEVER Symptom Present: Not Applicable	Initial Entry
Jan-21-2021 13:41:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptoms: FEVER Symptom Present:	Changed Information
Dec-23-2020 15:29:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptoms: FEVER Symptom Present: NO	Initial Entry

4.a Symptoms:

Date	Location	User	Value	Reason
Dec-23-2020 15:29:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: FEVER	Initial Entry

4.a Was symptom present?

Date	Location	User	Value	Reason
Jan-21-2021 13:41:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry
Jan-21-2021 13:41:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Changed Information
Dec-23-2020 15:29:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

4.b

Date	Location	User	Value	Reason
Jan-21-2021 13:41:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptoms: NEW OR INCREASE D COUGH Symptom Present: Not Applicable	Initial Entry

090177e196ae3dcc\Final\Final On: 01-Apr-2021 04:41 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit on Dec/23/2020

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

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Site Name: (1117) Sundance Clinical Research

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Subject Initials: ---

Generated By: (b) (4)

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Jan-21-2021 13:40:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptoms: NEW OR INCREASED COUGH Symptom Present:	Changed Information
Dec-23-2020 15:29:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptoms: NEW OR INCREASED COUGH Symptom Present: NO	Initial Entry

4.b Symptoms:

Date	Location	User	Value	Reason
Dec-23-2020 15:29:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NEW OR INCREASED COUGH	Initial Entry

4.b Was symptom present?

Date	Location	User	Value	Reason
Jan-21-2021 13:41:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry
Jan-21-2021 13:40:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Changed Information
Dec-23-2020 15:29:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

4.c

Date	Location	User	Value	Reason
Jan-21-2021 13:41:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptoms: NEW OR INCREASED SHORTNESS OF BREATH Symptom Present: Not Applicable	Initial Entry
Jan-21-2021 13:40:46 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptoms: NEW OR INCREASED SHORTNESS OF BREATH	Changed Information

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Header Text: c4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit on Dec/23/2020

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

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Site No: 1117

Site Name: (1117) Sundance Clinical Research

Subject No: 11171036

Subject Initials: ---

Generated By: (b) (4)

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			H	
			Symptom Present:	
Dec-23-2020 15:29:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom Present: NEW OR INCREASED SHORTNESS OF BREATH H Symptom Present: YES	Initial Entry

4.c Symptoms:

Date	Location	User	Value	Reason
Dec-23-2020 15:29:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NEW OR INCREASED SHORTNESS OF BREATH	Initial Entry

4.c Was symptom present?

Date	Location	User	Value	Reason
Jan-21-2021 13:41:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry
Jan-21-2021 13:40:46 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Changed Information
Dec-23-2020 15:29:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

4.d

Date	Location	User	Value	Reason
Jan-21-2021 13:41:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptoms: CHILLS Symptom Present: Not Applicable	Initial Entry
Jan-21-2021 13:40:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptoms: CHILLS Symptom Present:	Changed Information
Dec-23-2020 15:29:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptoms: CHILLS Symptom Present: NO	Initial Entry

090177e196ae3dcc\Final\Final On: 01-Apr-2021 04:41 (GMT)

Header Text: c4591001**Visit:** POT_COVID_ILL 2 - Unscheduled Visit on Dec/23/2020**Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF Audit Trail History**Form Version:** 10-Dec-2020 02:29**Form Status:** Data Complete, Frozen, Verified**Site No:** 1117**Site Name:** (1117) Sundance Clinical Research**Subject No:** 11171036**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 10:58**4.d Symptoms:**

Date	Location	User	Value	Reason
Dec-23-2020 15:29:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: CHILLS	Initial Entry

4.d Was symptom present?

Date	Location	User	Value	Reason
Jan-21-2021 13:41:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry
Jan-21-2021 13:40:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Changed Information
Dec-23-2020 15:29:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

4.e

Date	Location	User	Value	Reason
Jan-21-2021 13:41:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptoms: NEW OR INCREASED MUSCLE PAIN Symptom Present: Not Applicable	Initial Entry
Jan-21-2021 13:40:23 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptoms: NEW OR INCREASED MUSCLE PAIN Symptom Present:	Changed Information
Dec-23-2020 15:29:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptoms: NEW OR INCREASED MUSCLE PAIN Symptom Present: NO	Initial Entry

Header Text: c4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit on Dec/23/2020

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4.e Symptoms:

Date	Location	User	Value	Reason
Dec-23-2020 15:29:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NEW OR INCREASED MUSCLE PA IN	Initial Entry

4.e Was symptom present?

Date	Location	User	Value	Reason
Jan-21-2021 13:41:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry
Jan-21-2021 13:40:23 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Changed Information
Dec-23-2020 15:29:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

4.f

Date	Location	User	Value	Reason
Jan-21-2021 13:41:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptoms: NEW LOSS OF TAST E OR SMELL Symptom P Not Applicable resent:	Initial Entry
Jan-21-2021 13:40:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptoms: NEW LOSS OF TAST E OR SMELL Symptom P resent:	Changed Information
Dec-23-2020 15:29:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptoms: NEW LOSS OF TAST E OR SMELL Symptom P YES resent:	Initial Entry

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Header Text: c4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit on Dec/23/2020

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

Form Version: 10-Dec-2020 02:29

Form Status: Data Complete, Frozen, Verified

Site No: 1117

Site Name: (1117) Sundance Clinical Research

Subject No: 11171036

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

4.f Symptoms:

Date	Location	User	Value	Reason
Dec-23-2020 15:29:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NEW LOSS OF TASTE OR SMELL	Initial Entry

4.f Was symptom present?

Date	Location	User	Value	Reason
Jan-21-2021 13:41:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry
Jan-21-2021 13:40:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Changed Information
Dec-23-2020 15:29:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

4.g

Date	Location	User	Value	Reason
Jan-21-2021 13:41:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptoms: NEW OR INCREASED SORE THROAT Symptom Present: Not Applicable	Initial Entry
Jan-21-2021 13:40:02 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptoms: NEW OR INCREASED SORE THROAT Symptom Present:	Changed Information
Dec-23-2020 15:29:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptoms: NEW OR INCREASED SORE THROAT Symptom Present: YES	Initial Entry

090177e196ae3dcc\Final\Final On: 01-Apr-2021 04:41 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit on Dec/23/2020

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

Form Version: 10-Dec-2020 02:29

Form Status: Data Complete, Frozen, Verified

Site No: 1117

Site Name: (1117) Sundance Clinical Research

Subject No: 11171036

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

4.g Symptoms:

Date	Location	User	Value	Reason
Dec-23-2020 15:29:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NEW OR INCREASED SORE THRO AT	Initial Entry

4.g Was symptom present?

Date	Location	User	Value	Reason
Jan-21-2021 13:41:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry
Jan-21-2021 13:40:02 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Changed Information
Dec-23-2020 15:29:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

4.h

Date	Location	User	Value	Reason
Jan-21-2021 13:41:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptoms: DIARRHEA Symptom Present: Not Applicable	Initial Entry

090177e196ae3dcc\Final\Final On: 01-Apr-2021 04:41 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit on Dec/23/2020

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

Form Version: 10-Dec-2020 02:29

Form Status: Data Complete, Frozen, Verified

Site No: 1117

Site Name: (1117) Sundance Clinical Research

Subject No: 11171036

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

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4.h

Date	Location	User	Value	Reason
Jan-21-2021 13:39:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptoms: DIARRHEA Symptom Present:	Changed Information
Dec-23-2020 15:29:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptoms: DIARRHEA Symptom Present: NO	Initial Entry

4.h Symptoms:

Date	Location	User	Value	Reason
Dec-23-2020 15:29:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: DIARRHEA	Initial Entry

4.h Was symptom present?

Date	Location	User	Value	Reason
Jan-21-2021 13:41:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry
Jan-21-2021 13:39:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Changed Information
Dec-23-2020 15:29:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

4.i

Date	Location	User	Value	Reason
Jan-21-2021 13:41:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptoms: VOMITING Symptom Present: Not Applicable	Initial Entry
Jan-21-2021 13:39:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptoms: VOMITING Symptom Present:	Changed Information

090177e196ae3dcc\Final\Final On: 01-Apr-2021 04:41 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit on Dec/23/2020

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

Form Version: 10-Dec-2020 02:29

Form Status: Data Complete, Frozen, Verified

Site No: 1117

Site Name: (1117) Sundance Clinical Research

Subject No: 11171036

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

Dec-23-2020 15:29:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptoms: VOMITING Symptom Present: NO	Initial Entry
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4.i Symptoms:

Date	Location	User	Value	Reason
Dec-23-2020 15:29:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: VOMITING	Initial Entry

4.i Was symptom present?

Date	Location	User	Value	Reason
Jan-21-2021 13:41:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry
Jan-21-2021 13:39:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Changed Information
Dec-23-2020 15:29:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

5.a

Date	Location	User	Value	Reason
Jan-21-2021 13:39:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptoms - Other:	Changed Information
Dec-23-2020 15:29:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptoms - Other: SINUS PRESSURE	Initial Entry

5.a Symptoms - Other Text:

Date	Location	User	Value	Reason
Jan-21-2021 13:39:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Changed Information
Dec-23-2020 15:29:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: SINUS PRESSURE	Initial Entry

090177e196ae3dcc\Final\Final On: 01-Apr-2021 04:41 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit on Dec/23/2020

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

Form Version: 10-Dec-2020 02:29

Form Status: Data Complete, Frozen, Verified

Site No: 1117

Site Name: (1117) Sundance Clinical Research

Subject No: 11171036

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

5.b

Date	Location	User	Value	Reason
Jan-21-2021 13:39:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptoms - Other:	Changed Information
Dec-23-2020 15:29:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptoms - Other: HEADACHE	Initial Entry

5.b Symptoms - Other Text:

Date	Location	User	Value	Reason
Jan-21-2021 13:39:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Changed Information
Dec-23-2020 15:29:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: HEADACHE	Initial Entry

5.c

Date	Location	User	Value	Reason
Jan-21-2021 13:39:02 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptoms - Other:	Changed Information
Dec-23-2020 15:30:02 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptoms - Other: BODY ACHE	Initial Entry

5.c Symptoms - Other Text:

Date	Location	User	Value	Reason
Jan-21-2021 13:39:02 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Changed Information
Dec-23-2020 15:30:02 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BODY ACHE	Initial Entry

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Header Text: c4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit on Dec/23/2020 Form: MICROBIOLOGY SPECIMEN - eCRF Audit Trail History

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen, Verified

Site No: 1117

Site Name: (1117) Sundance Clinical Research

Subject No: 11171036

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

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1. Actual Date of Collection:

Date	Location	User	Value	Reason
Jan-21-2021 13:38:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry
Dec-23-2020 15:30:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

2. Specimen Type:

Date	Location	User	Value	Reason
Jan-21-2021 13:38:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry
Dec-23-2020 15:30:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

3. Specimen Collection Location:

Date	Location	User	Value	Reason
Jan-21-2021 13:38:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry
Dec-23-2020 15:30:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

4. Assay Code and Description:

Date	Location	User	Value	Reason
Jan-21-2021 13:38:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry
Dec-23-2020 15:30:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

5. Device Type:

090177e196ae3dcc\Final\Final On: 01-Apr-2021 04:41 (GMT)

Header Text: c4591001**Visit:** POT_COVID_ILL 2 - Unscheduled Visit on Dec/23/2020 **Form:** MICROBIOLOGY SPECIMEN - eCRF Audit Trail History**Form Version:** 06-Jul-2020 21:54**Form Status:** Data Complete, Frozen, Verified**Site No:** 1117**Site Name:** (1117) Sundance Clinical Research**Subject No:** 11171036**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 10:58

Date	Location	User	Value	Reason
Jan-21-2021 13:38:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry
Dec-23-2020 15:30:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

6. Trade Name:

Date	Location	User	Value	Reason
Jan-21-2021 13:38:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry
Dec-23-2020 15:30:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

7. Test Result:

Date	Location	User	Value	Reason
Jan-21-2021 13:38:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry
Dec-23-2020 15:30:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

8. Comments/Findings/Details:

Date	Location	User	Value	Reason
Jan-21-2021 13:38:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry
Dec-23-2020 15:30:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

9. Trade Name Other, Specify:

Date	Location	User	Value	Reason
Jan-21-2021 13:38:34 (UTC-06:00) Central Time	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

Header Text: c4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit on Dec/23/2020 **Form:** MICROBIOLOGY SPECIMEN - eCRF Audit Trail History

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen, Verified

Site No: 1117

Site Name: (1117) Sundance Clinical Research

Subject No: 11171036

Subject Initials: ---

Generated By: (b) (4)

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(US & Canada)		(b) (4), (b) (6)		
Dec-23-2020 15:30:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

Header Text: c4591001**Visit:** POT_COVID_ILL 2 - Unscheduled Visit on Dec/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:** 11171036**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 10:58[Back to Form](#)**1. Data Origin**

Date	Location	User	Value	Reason
Mar-04-2021 11:38:18 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry
Mar-04-2021 11:37:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry:	Initial Entry
Jan-29-2021 16:30:16 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Not Applicable	Initial Entry
Jan-26-2021 08:46:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry:	Changed Information
Dec-08-2020 13:19:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Mar-04-2021 11:38:18 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: NASAL_SWAB_SELF	Initial Entry
Mar-04-2021 11:37:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry:	Initial Entry
Jan-29-2021 16:30:16 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Not Applicable	Initial Entry
Jan-26-2021 08:46:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry:	Changed Information
Dec-08-2020 13:19:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: NASAL_SWAB_SELF	Initial Entry

3. Sample Collected?

Header Text: c4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit on Dec/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: 11171036

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

Date	Location	User	Value	Reason
Mar-04-2021 11:40:32 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 3: Deleted	Close Auto Query
Mar-04-2021 11:39:32 (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.
Mar-04-2021 11:39:32 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Deleted	Close Auto Query
Mar-04-2021 11:38:18 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Mar-04-2021 11:38:18 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Collection: Dec/7/2020	Initial Entry
Mar-04-2021 11:37:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Initial Entry
Jan-26-2021 08:47:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry
Jan-26-2021 08:46:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Changed Information
Dec-08-2020 13:20:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Dec-08-2020 13:19:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Dec-08-2020 13:19:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Collection:	Initial Entry

090177e196ae3dcc\Final\Final On: 01-Apr-2021 04:41 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit on Dec/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: 11171036

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

Dec/7/2020

4. If no sample was collected or sample was not collected according to protocol, please provide reason:

Date	Location	User	Value	Reason
Mar-05-2021 09:07:16 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	data updated
Mar-04-2021 13:26:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Initial Entry
Mar-04-2021 13:26:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: SELF SWAB TAKEN WITHOUT I LLNESS	Initial Entry
Mar-04-2021 12:15:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	Please update comment per CCGs: 8.58 indicating SELF SWAB TAKEN WITHOUT ILLNESS else clarify
Mar-04-2021 11:37:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Initial Entry
Jan-26-2021 08:48:02 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.a

Date	Location	User	Value	Reason
Mar-04-2021 11:40:32 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: CV60869	Initial Entry
Mar-04-2021 11:40:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID:	Initial Entry
Mar-04-2021 11:39:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: Not Applicable	New Information
Mar-04-2021 11:39:32 (UTC-06:00) Central Time	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: Not Applicable	New Information (DELETED)

090177e196ae3dcc\Final\Final On: 01-Apr-2021 04:41 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit on Dec/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: 11171036

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

(US & Canada)		(b) (4), (b) (6)		
Jan-27-2021 13:38:16 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: Not Applicable	Initial Entry
Jan-27-2021 13:38:06 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID:	Changed Information
Jan-27-2021 13:37:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: CV60869	Changed Information
Jan-26-2021 08:47:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: CV60869	New Information (DELETED)
Dec-08-2020 13:20:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: CV60869	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Mar-04-2021 11:40:32 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: CV60869	Initial Entry
Mar-04-2021 11:40:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Initial Entry
Mar-04-2021 11:39:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	New Information
Mar-04-2021 11:39:32 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	New Information (DELETED)
Jan-27-2021 13:38:16	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

090177e196ae3dcc\Final\Final On: 01-Apr-2021 04:41 (GMT)

Header Text: c4591001 Visit: POT_COVID_ILL 2 - Unscheduled Visit on Dec/23/2020 Form Version: 22-Apr-2020 21:03 Site No: 1117 Subject No: 11171036 Generated By: (b) (4)				
Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB SELF - eCRF Audit Trail History Form Status: Data Complete, Frozen, Verified Site Name: (1117) Sundance Clinical Research Subject Initials: --- Generated Time (GMT): 29-Mar-2021 10:58				
(UTC-06:00) Central Time (US & Canada)			le	
Jan-27-2021 13:38:06 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Changed Information
Jan-27-2021 13:37:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: CV60869	Changed Information
Jan-26-2021 10:29:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Jan-26-2021 08:47:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: CV60869	New Information (DELETED)
Jan-25-2021 19:02:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	UPON REVIEW OF MEDICAL RECORDS AND PARTICIPANT INTERVIEW, COVID_A SHOULD NEVER HAVE BEEN CLOSED OUT. PER INVESTIGATOR AND MONITOR, THIS IS ALL COVID_A. REQUEST TO UNLOCK FORMS HAS BEEN SENT TO MAKE FINAL ADJUSTMENTS.
Jan-21-2021 20:12:33 (UTC-06:00) Central Time	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (b) (4)	Query 1: Opened	DMW6947443;This Barcode is already recorded more than once (for the same

Header Text: c4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit on Dec/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: 11171036

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

(US & Canada)				subject). Please review and update as appropriate.
Dec-08-2020 13:20:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: CV60869	Initial Entry

Header Text: c4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit on Dec/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: 11171036

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

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1. Data Origin

Date	Location	User	Value	Reason
Jan-26-2021 08:45:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Not Applicable	Initial Entry
Jan-26-2021 08:45:02 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry:	Transcription Error
Dec-23-2020 15:30:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Jan-26-2021 08:45:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Not Applicable	Initial Entry
Jan-26-2021 08:45:02 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry:	Transcription Error
Dec-23-2020 15:30:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: NASAL_SWAB	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Jan-26-2021 08:45:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry
Jan-26-2021 08:45:02 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Transcription Error
Dec-23-2020 15:30:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

4. If no sample was collected or sample was not collected according to protocol, please provide reason:

090177e196ae3dcc\Final\Final On: 01-Apr-2021 04:41 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit on Dec/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: 11171036

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

Date	Location	User	Value	Reason
Jan-26-2021 08:45:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry
Jan-26-2021 08:45:19 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	New Information
Dec-23-2020 15:30:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: SEE SELF SWAB	Initial Entry

090177e196ae3dcc\Final\Final On: 01-Apr-2021 04:41 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit on Dec/23/2020 Form: HEALTH CARE UTILIZATION - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:26

Form Status: Data Complete, Frozen

Site No: 1117

Site Name: (1117) Sundance Clinical Research

Subject No: 11171036

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

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I.a

Date	Location	User	Value	Reason
Jan-21-2021 13:38:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Type of Practitioner: SPECIALIST Occurrence of Visits or Contacts: Not Applicable	Initial Entry
Jan-21-2021 13:36:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Type of Practitioner: SPECIALIST Occurrence of Visits or Contacts:	Changed Information
Dec-23-2020 15:31:24 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Type of Practitioner: SPECIALIST Occurrence of Visits or Contacts: NO	Initial Entry

I.a Physician or Healthcare Professional:

Date	Location	User	Value	Reason
Dec-23-2020 15:31:24 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: SPECIALIST	Initial Entry

I.a Occurrence of Visits or Contacts:

Date	Location	User	Value	Reason
Jan-26-2021 14:45:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Jan-26-2021 08:48:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Original value is correct

090177e196ae3dcc\Final\Final On: 01-Apr-2021 04:41 (GMT)

090177e196ae3dcc\Final\Final On: 01-Apr-2021 04:41 (GMT)

Header Text: c4591001
Visit: POT_COVID_ILL 2 - Unscheduled Visit on Dec/23/2020 **Form:** HEALTH CARE UTILIZATION - eCRF Audit Trail History
Form Version: 10-Dec-2020 02:26 **Form Status:** Data Complete, Frozen
Site No: 1117 **Site Name:** (1117) Sundance Clinical Research
Subject No: 11171036 **Subject Initials:** ---
Generated By: (b) (4) **Generated Time (GMT):** 29-Mar-2021 10:58

Jan-26-2021 03:22:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued :Opened	Forms are unfrozen. Please proceed to update as per your response. If this visit was performed, then this form should not be marked Not Done / Not Applicable. Please complete this form. All items with Yes/No options should be ticked as YES or NO
Jan-25-2021 19:00:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	UPON REVIEW OF MEDICAL RECORDS AND PARTICIPANT INTERVIEW, COVID_A SHOULD NEVER HAVE BEEN CLOSED OUT. PER INVESTIGATOR AND MONITOR, THIS IS ALL COVID_A. REQUEST TO UNLOCK FORMS HAS BEEN SENT TO MAKE FINAL ADJUSTMENTS.
Jan-22-2021 00:44:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (b) (4)	Query 1: Opened	DMW6947713;Occurrence of Visits or Contacts is not expected to be Not Done or Not Applicable or Unknown. Please review and update appropriately or clarify
Jan-21-2021 13:38:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry
Jan-21-2021 13:36:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Changed Information
Dec-23-2020 15:31:24 (UTC-06:00)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

Header Text: c4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit on Dec/23/2020 **Form:** HEALTH CARE UTILIZATION - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:26

Form Status: Data Complete, Frozen

Site No: 1117

Site Name: (1117) Sundance Clinical Research

Subject No: 11171036

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

Central Time
(US &
Canada)

I.b

Date	Location	User	Value	Reason
Jan-21-2021 13:38:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Type of Practitioner EMERGENC : Y ROOM Occurrence of Visits or Contacts: Not Applicabl e	Initial Entry
Jan-21-2021 13:36:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Type of Practitioner EMERGENC : Y ROOM Occurrence of Visits or Contacts:	Changed Information
Dec-23-2020 15:36:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Type of Practitio EMERGENCY R ner: OOM Occurrence of Vi YES sits or Contacts: <i>Number of Visit s or Contacts:</i> 1	Changed Information
Dec-23-2020 15:31:24 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Type of Practitioner EMERGENC Y ROOM Occurrence of Visits or Contacts: NO	Initial Entry

090177e196ae3dcc\Final\Final On: 01-Apr-2021 04:41 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit on Dec/23/2020 Form: HEALTH CARE UTILIZATION - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:26

Form Status: Data Complete, Frozen

Site No: 1117

Site Name: (1117) Sundance Clinical Research

Subject No: 11171036

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

1.b Physician or Healthcare Professional:

Date	Location	User	Value	Reason
Dec-23-2020 15:31:24 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: EMERGENCY ROOM	Initial Entry

1.b Occurrence of Visits or Contacts:

Date	Location	User	Value	Reason
Jan-26-2021 14:45:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Jan-26-2021 08:48:55 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Original value is correct
Jan-26-2021 03:23:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued :Opened	Forms are unfrozen. Please proceed to update as per your response. If this visit was performed, then this form should not be marked Not Done / Not Applicable. Please complete this form. All items with Yes/No options should be ticked as YES or NO
Jan-25-2021 19:00:23 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	UPON REVIEW OF MEDICAL RECORDS AND PARTICIPANT INTERVIEW, COVID_A SHOULD NEVER HAVE BEEN CLOSED OUT. PER INVESTIGATOR AND MONITOR, THIS IS ALL COVID_A. REQUEST TO UNLOCK FORMS HAS BEEN SENT TO MAKE FINAL ADJUSTMENTS.

090177e196ae3dcc\Final\Final On: 01-Apr-2021 04:41 (GMT)

Header Text: c4591001**Visit:** POT_COVID_ILL 2 - Unscheduled Visit on Dec/23/2020 **Form:** HEALTH CARE UTILIZATION - eCRF Audit Trail History**Form Version:** 10-Dec-2020 02:26**Form Status:** Data Complete, Frozen**Site No:** 1117**Site Name:** (1117) Sundance Clinical Research**Subject No:** 11171036**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 10:58

Jan-22-2021 00:44:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (b) (4)	Query 1: Opened	DMW6947714;Occurrence of Visits or Contacts is not expected to be Not Done or Not Applicable or Unknown. Please review and update appropriately or clarify
Jan-21-2021 13:38:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry
Jan-21-2021 13:36:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Changed Information
Dec-23-2020 15:36:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES <i>Number of Visits or Contacts:</i> 1	Changed Information
Dec-23-2020 15:31:24 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

I.c

Date	Location	User	Value	Reason
Jan-21-2021 13:38:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Type of Practitioner: PRIMARY CARE PHYSICIAN Occurrence of Visits or Contacts: Not Applicable	Initial Entry
Jan-21-2021 13:37:11 (UTC-06:00) Central Time	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Type of Practitioner: PRIMARY CARE	Changed Information

Header Text: c4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit on Dec/23/2020 **Form:** HEALTH CARE UTILIZATION - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:26

Form Status: Data Complete, Frozen

Site No: 1117

Site Name: (1117) Sundance Clinical Research

Subject No: 11171036

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

(US & Canada)		(b) (4), (b) (6)	er: E PHYSICIAN Occurrence of Visits or Contacts:	
Dec-23-2020 15:36:54 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Type of Practitioner: PRIMARY CARE PHYSICIAN Occurrence of Visits or Contacts: YES <i>Number of Visits or Contacts:</i> 1	Changed Information
Dec-23-2020 15:31:24 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Type of Practitioner: PRIMARY CARE PHYSICIAN Occurrence of Visits or Contacts: NO	Initial Entry

090177e196ae3dcc\Final\Final On: 01-Apr-2021 04:41 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit on Dec/23/2020 Form: HEALTH CARE UTILIZATION - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:26

Form Status: Data Complete, Frozen

Site No: 1117

Site Name: (1117) Sundance Clinical Research

Subject No: 11171036

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

I.c Physician or Healthcare Professional:

Date	Location	User	Value	Reason
Dec-23-2020 15:31:24 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: PRIMARY CARE PHYSICIAN	Initial Entry

I.c Occurrence of Visits or Contacts:

Date	Location	User	Value	Reason
Jan-26-2021 14:45:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Jan-26-2021 08:49:06 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Original value is correct
Jan-26-2021 03:23:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued :Opened	Forms are unfrozen. Please proceed to update as per your response. If this visit was performed, then this form should not be marked Not Done / Not Applicable. Please complete this form. All items with Yes/No options should be ticked as YES or NO
Jan-25-2021 19:00:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	UPON REVIEW OF MEDICAL RECORDS AND PARTICIPANT INTERVIEW, COVID_A SHOULD NEVER HAVE BEEN CLOSED OUT. PER INVESTIGATOR AND MONITOR, THIS IS ALL COVID_A. REQUEST TO UNLOCK FORMS HAS BEEN SENT TO MAKE FINAL ADJUSTMENTS.

090177e196ae3dcc\Final\Final On: 01-Apr-2021 04:41 (GMT)

Header Text: c4591001
Visit: POT_COVID_ILL 2 - Unscheduled Visit on Dec/23/2020 **Form:** HEALTH CARE UTILIZATION - eCRF Audit Trail History
Form Version: 10-Dec-2020 02:26 **Form Status:** Data Complete, Frozen
Site No: 1117 **Site Name:** (1117) Sundance Clinical Research
Subject No: 11171036 **Subject Initials:** ---
Generated By: (b) (4) **Generated Time (GMT):** 29-Mar-2021 10:58

Jan-22-2021 00:44:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (b) (4)	Query 1: Opened	DMW6947715;Occurrence of Visits or Contacts is not expected to be Not Done or Not Applicable or Unknown. Please review and update appropriately or clarify
Jan-21-2021 13:38:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry
Jan-21-2021 13:37:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Changed Information
Dec-23-2020 15:36:54 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES <i>Number of Visits or Contacts:</i> 1	Changed Information
Dec-23-2020 15:31:24 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

1.d

Date	Location	User	Value	Reason
Jan-21-2021 13:38:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Type of Practitioner: URGENT CARE Occurrence of Visits or Contacts: Not Applicable	Initial Entry
Jan-21-2021 13:37:28 (UTC-06:00) Central Time	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Type of Practitioner: URGENT	Changed Information

Header Text: c4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit on Dec/23/2020 **Form:** HEALTH CARE UTILIZATION - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:26

Form Status: Data Complete, Frozen

Site No: 1117

Site Name: (1117) Sundance Clinical Research

Subject No: 11171036

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

(US & Canada)		(b) (4), (b) (6)	CARE Occurrence of Visits or Contacts:	
Dec-23-2020 15:31:24 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Type of Practitioner: URGENT CARE Occurrence of Visits or NO Contacts:	Initial Entry

Header Text: c4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit on Dec/23/2020 Form: HEALTH CARE UTILIZATION - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:26

Form Status: Data Complete, Frozen

Site No: 1117

Site Name: (1117) Sundance Clinical Research

Subject No: 11171036

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

1.d Physician or Healthcare Professional:

Date	Location	User	Value	Reason
Dec-23-2020 15:31:24 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: URGENT CARE	Initial Entry

1.d Occurrence of Visits or Contacts:

Date	Location	User	Value	Reason
Jan-26-2021 14:48:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Jan-26-2021 08:49:19 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Original value is correct
Jan-26-2021 03:23:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued :Opened	Forms are unfrozen. Please proceed to update as per your response. If this visit was performed, then this form should not be marked Not Done / Not Applicable. Please complete this form. All items with Yes/No options should be ticked as YES or NO
Jan-25-2021 19:00:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	UPON REVIEW OF MEDICAL RECORDS AND PARTICIPANT INTERVIEW, COVID_A SHOULD NEVER HAVE BEEN CLOSED OUT. PER INVESTIGATOR AND MONITOR, THIS IS ALL COVID_A. REQUEST TO UNLOCK FORMS HAS BEEN SENT TO MAKE FINAL ADJUSTMENTS.

090177e196ae3dcc\Final\Final On: 01-Apr-2021 04:41 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit on Dec/23/2020 **Form:** HEALTH CARE UTILIZATION - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:26

Form Status: Data Complete, Frozen

Site No: 1117

Site Name: (1117) Sundance Clinical Research

Subject No: 11171036

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

Jan-22-2021 00:44:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (b) (4)	Query 1: Opened	DMW6947716;Occurrence of Visits or Contacts is not expected to be Not Done or Not Applicable or Unknown. Please review and update appropriately or clarify
Jan-21-2021 13:38:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

Header Text: c4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit on Dec/23/2020 **Form:** HEALTH CARE UTILIZATION - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:26

Form Status: Data Complete, Frozen

Site No: 1117

Site Name: (1117) Sundance Clinical Research

Subject No: 11171036

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

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I.d Occurrence of Visits or Contacts:

Date	Location	User	Value	Reason
Jan-21-2021 13:37:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Changed Information
Dec-23-2020 15:31:24 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

I.e

Date	Location	User	Value	Reason
Jan-21-2021 13:38:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Type of Practitioner: TELEPHONE CONSULTATION Occurrence of Visits or Contacts: Not Applicable	Initial Entry
Jan-21-2021 13:37:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Type of Practitioner: TELEPHONE CONSULTATION Occurrence of Visits or Contacts:	Changed Information
Dec-23-2020 15:31:24 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Type of Practitioner: TELEPHONE CONSULTATION Occurrence of Visits or Contacts: NO	Initial Entry

090177e196ae3dcc\Final\Final On: 01-Apr-2021 04:41 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit on Dec/23/2020 Form: HEALTH CARE UTILIZATION - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:26

Form Status: Data Complete, Frozen

Site No: 1117

Site Name: (1117) Sundance Clinical Research

Subject No: 11171036

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

I.e Physician or Healthcare Professional:

Date	Location	User	Value	Reason
Dec-23-2020 15:31:24 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: TELEPHONE CONSULTATION	Initial Entry

I.e Occurrence of Visits or Contacts:

Date	Location	User	Value	Reason
Jan-26-2021 10:38:19 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Close erroneous visit
Jan-26-2021 08:49:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Original value is correct
Jan-26-2021 03:23:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued :Opened	Forms are unfrozen. Please proceed to update as per your response. If this visit was performed, then this form should not be marked Not Done / Not Applicable. Please complete this form. All items with Yes/No options should be ticked as YES or NO
Jan-25-2021 19:00:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	UPON REVIEW OF MEDICAL RECORDS AND PARTICIPANT INTERVIEW, COVID_A SHOULD NEVER HAVE BEEN CLOSED OUT. PER INVESTIGATOR AND MONITOR, THIS IS ALL COVID_A. REQUEST TO UNLOCK FORMS HAS BEEN SENT TO MAKE FINAL ADJUSTMENTS.

090177e196ae3dcc\Final\Final On: 01-Apr-2021 04:41 (GMT)

Header Text: c4591001
Visit: POT_COVID_ILL 2 - Unscheduled Visit on Dec/23/2020 **Form:** HEALTH CARE UTILIZATION - eCRF Audit Trail History
Form Version: 10-Dec-2020 02:26 **Form Status:** Data Complete, Frozen
Site No: 1117 **Site Name:** (1117) Sundance Clinical Research
Subject No: 11171036 **Subject Initials:** ---
Generated By: (b) (4) **Generated Time (GMT):** 29-Mar-2021 10:58

Jan-22-2021 00:44:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (b) (4)	Query 1: Opened	DMW6947717;Occurrence of Visits or Contacts is not expected to be Not Done or Not Applicable or Unknown. Please review and update appropriately or clarify
Jan-21-2021 13:38:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Ent ry: Not Appl icable	Initial Entry
Jan-21-2021 13:37:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Ent ry:	Changed Information
Dec-23-2020 15:31:24 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Ent ry: NO	Initial Entry

If

Date	Location	User	Value	Reason
Jan-21-2021 13:38:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Type of Practitioner: OTHER Occurrence of Visits or Contacts: Not Applicable	Initial Entry
Jan-21-2021 13:37:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Type of Practitioner: OTH R Occurrence of Visits or Con tacts:	Changed Information
Dec-23-2020 15:31:24 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Type of Practitioner: OTH R Occurrence of Visits or Con tacts: NO	Initial Entry

Header Text: c4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit on Dec/23/2020 Form: HEALTH CARE UTILIZATION - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:26

Form Status: Data Complete, Frozen

Site No: 1117

Site Name: (1117) Sundance Clinical Research

Subject No: 11171036

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

If Physician or Healthcare Professional:

Date	Location	User	Value	Reason
Dec-23-2020 15:31:24 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: OTHER	Initial Entry

If Occurrence of Visits or Contacts:

Date	Location	User	Value	Reason
Jan-26-2021 14:50:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Jan-26-2021 08:49:46 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Original value is correct
Jan-26-2021 03:24:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued :Opened	Forms are unfrozen. Please proceed to update as per your response. If this visit was performed, then this form should not be marked Not Done / Not Applicable. Please complete this form. All items with Yes/No options should be ticked as YES or NO
Jan-25-2021 19:00:55 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	UPON REVIEW OF MEDICAL RECORDS AND PARTICIPANT INTERVIEW, COVID_A SHOULD NEVER HAVE BEEN CLOSED OUT. PER INVESTIGATOR AND MONITOR, THIS IS ALL COVID_A. REQUEST TO UNLOCK FORMS HAS BEEN SENT TO MAKE FINAL ADJUSTMENTS.

090177e196ae3dcc\Final\Final On: 01-Apr-2021 04:41 (GMT)

Header Text: c4591001**Visit:** POT_COVID_ILL 2 - Unscheduled Visit on Dec/23/2020 **Form:** HEALTH CARE UTILIZATION - eCRF Audit Trail History**Form Version:** 10-Dec-2020 02:26**Form Status:** Data Complete, Frozen**Site No:** 1117**Site Name:** (1117) Sundance Clinical Research**Subject No:** 11171036**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 10:58

Jan-22-2021 00:44:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (b) (4)	Query 1: Opened	DMW6947718;Occurrence of Visits or Contacts is not expected to be Not Done or Not Applicable or Unknown. Please review and update appropriately or clarify
Jan-21-2021 13:38:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry
Jan-21-2021 13:37:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Changed Information
Dec-23-2020 15:31:24 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2. Other Type of Practitioner Specify:

Date	Location	User	Value	Reason
Jan-21-2021 13:38:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

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

Date	Location	User	Value	Reason
Jan-26-2021 14:51:19 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Jan-26-2021 08:49:56 (UTC-06:00)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Original value is correct

Header Text: c4591001**Visit:** POT_COVID_ILL 2 - Unscheduled Visit on Dec/23/2020 **Form:** HEALTH CARE UTILIZATION - eCRF Audit Trail History**Form Version:** 10-Dec-2020 02:26**Form Status:** Data Complete, Frozen**Site No:** 1117**Site Name:** (1117) Sundance Clinical Research**Subject No:** 11171036**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 10:58

Central Time (US & Canada)				
Jan-26-2021 06:35:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued: Opened	DM: Form is unfrozen. Please proceed to update.
Jan-25-2021 19:01:02 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	UPON REVIEW OF MEDICAL RECORDS AND PARTICIPANT INTERVIEW, COVID_A SHOULD NEVER HAVE BEEN CLOSED OUT. PER INVESTIGATOR AND MONITOR, THIS IS ALL COVID_A. REQUEST TO UNLOCK FORMS HAS BEEN SENT TO MAKE FINAL ADJUSTMENTS.
Jan-22-2021 00:44:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (b) (4)	Query 1: Opened	DMW6947831;Response to 'Has the subject been hospitalized due to potential COVID-19 illness?' is not expected to be Not Done or Not Applicable or Unknown. Please review and update appropriately or clarify
Jan-21-2021 13:38:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entr y: Not Appli cable	Initial Entry
Jan-21-2021 13:38:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entr y:	Changed Information

Header Text: c4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit on Dec/23/2020 **Form:** HEALTH CARE UTILIZATION - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:26

Form Status: Data Complete, Frozen

Site No: 1117

Site Name: (1117) Sundance Clinical Research

Subject No: 11171036

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

Dec-23-2020 15:31:24 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entr y: NO	Initial Entry
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090177e196ae3dcc\Final\Final On: 01-Apr-2021 04:41 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit on Dec/23/2020 Form: RESPIRATORY TREATMENT - eCRF Audit Trail History

Form Version: 06-Jul-2020 21:53

Form Status: Data Complete, Frozen

Site No: 1117

Site Name: (1117) Sundance Clinical Research

Subject No: 11171036

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

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1. What is the treatment Identifier?

Date	Location	User	Value	Reason
Jan-21-2021 13:36:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry
Dec-23-2020 15:31:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

2. Concomitant Non-drug Treatment Pre-specified:

Date	Location	User	Value	Reason
Jan-21-2021 13:36:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry
Dec-23-2020 15:31:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

3. Treatment:

Date	Location	User	Value	Reason
Jan-21-2021 13:36:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry
Dec-23-2020 15:31:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

4. Treatment:

Date	Location	User	Value	Reason
Jan-21-2021 13:36:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry
Dec-23-2020 15:31:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

5. Start Date:

090177e196ae3dcc\Final\Final On: 01-Apr-2021 04:41 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit on Dec/23/2020 **Form:** RESPIRATORY TREATMENT - eCRF Audit Trail History

Form Version: 06-Jul-2020 21:53

Form Status: Data Complete, Frozen

Site No: 1117

Site Name: (1117) Sundance Clinical Research

Subject No: 11171036

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

Date	Location	User	Value	Reason
Jan-21-2021 13:36:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry
Dec-23-2020 15:31:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

6. Ongoing?

Date	Location	User	Value	Reason
Jan-21-2021 13:36:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry
Dec-23-2020 15:31:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

090177e196ae3dcc\Final\Final On: 01-Apr-2021 04:41 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit on Dec/23/2020 Form: ILLNESS DETAILS - eCRF Audit Trail History

Form Version: 06-Jul-2020 21:52

Form Status: Data Complete, Frozen

Site No: 1117

Site Name: (1117) Sundance Clinical Research

Subject No: 11171036

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

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1. Category of Clinical Event:

Date	Location	User	Value	Reason
Jan-21-2021 13:35:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Not Applicable	Initial Entry
Jan-21-2021 13:35:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry:	Changed Information
Dec-23-2020 15:37:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: POTENTIAL COVID-19 ILLNESS	Initial Entry

2. Was a diagnosis obtained for Potential COVID-19 Illness?

Date	Location	User	Value	Reason
Jan-26-2021 15:02:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Clo sed	Response satisfies query
Jan-26-2021 08:50:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Ans wered	Original value is correct
Jan-26-2021 03:24:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Reis sued:Opened	Form is unfrozen. Please proceed to update.
Jan-25-2021 19:00:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Ans wered	UPON REVIEW OF MEDICAL RECORDS AND PARTICIPANT INTERVIEW, COVID_A SHOULD NEVER HAVE BEEN CLOSED OUT. PER INVESTIGATOR

090177e196ae3dcc\Final\Final On: 01-Apr-2021 04:41 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit on Dec/23/2020 Form: ILLNESS DETAILS - eCRF Audit Trail History

Form Version: 06-Jul-2020 21:52

Form Status: Data Complete, Frozen

Site No: 1117

Site Name: (1117) Sundance Clinical Research

Subject No: 11171036

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

				AND MONITOR, THIS IS ALL COVID_A. REQUEST TO UNLOCK FORMS HAS BEEN SENT TO MAKE FINAL ADJUSTMENTS.
Jan-25-2021 05:39:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (b) (4)	Query 2: Opened	DMW6947648;Was a diagnosis obtained for Potential COVID-19 Illness? is not expected to be Unknown or Not Applicable. Please review and update appropriately or clarify
Jan-21-2021 13:35:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry
Jan-21-2021 13:35:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Changed Information
Dec-29-2020 11:44:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Dec-28-2020 21:59:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Changed Information
Dec-28-2020 21:59:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Changed Information
Dec-28-2020 11:24:13	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	Clin: Sore throat is already recorded as

090177e196ae3dcc\Final\Final On: 01-Apr-2021 04:41 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit on Dec/23/2020 Form: ILLNESS DETAILS - eCRF Audit Trail History

Form Version: 06-Jul-2020 21:52

Form Status: Data Complete, Frozen

Site No: 1117

Site Name: (1117) Sundance Clinical Research

Subject No: 11171036

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

(UTC-06:00) Central Time (US & Canada)		(b) (4), (b) (6)		symptom of potential illness on SOD CRF. If no diagnosis, please enter No.
Dec-23-2020 15:37:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES <i>Respiratory Illness Diagnosis:</i> SORE TH ROAT Date of Diagnosis: Nov/10/20 20	Initial Entry

3. Toxicity Grade:

Date	Location	User	Value	Reason
Jan-26-2021 15:02:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Closed	Response satisfies query
Jan-26-2021 08:50:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Answered	Original value is correct
Jan-26-2021 06:24:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Reissued: Opened	DM: Pages have been unfrozen. Please correct.
Jan-25-2021 18:59:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Answered	UPON REVIEW OF MEDICAL RECORDS AND PARTICIPANT INTERVIEW, COVID_A SHOULD NEVER HAVE BEEN CLOSED OUT. PER INVESTIGATOR AND

090177e196ae3dcc\Final\Final On: 01-Apr-2021 04:41 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit on Dec/23/2020 **Form:** ILLNESS DETAILS - eCRF Audit Trail History

Form Version: 06-Jul-2020 21:52

Form Status: Data Complete, Frozen

Site No: 1117

Site Name: (1117) Sundance Clinical Research

Subject No: 11171036

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

				MONITOR, THIS IS ALL COVID_A. REQUEST TO UNLOCK FORMS HAS BEEN SENT TO MAKE FINAL ADJUSTMENTS.
Jan-25-2021 05:39:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (b) (4)	Query 2: O pened	DMW6947662;Toxicity Grade is not expected to be Not Done or Not Applicable or Unknown. Please review and update appropriately or clarify
Jan-21-2021 13:35:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entr y: Not Applic able	Initial Entry
Jan-21-2021 13:35:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entr y:	Changed Information
Dec-23-2020 15:38:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: C losed	Close Auto Query
Dec-23-2020 15:38:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entr y: 2	Changed Information
Dec-23-2020 15:37:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: O pened	Per CRF CRs Section 8.33.5, please enter worst toxicity grade (1 to 5) as it relates to reported symptom(s) on SOD CRF. Please review and update as appropriate.
Dec-23-2020 15:37:57 (UTC-06:00)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entr y: 0	Initial Entry

090177e196ae3dcc\Final\Final On: 01-Apr-2021 04:41 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit on Dec/23/2020 **Form:** ILLNESS DETAILS - eCRF Audit Trail History

Form Version: 06-Jul-2020 21:52

Form Status: Data Complete, Frozen

Site No: 1117

Site Name: (1117) Sundance Clinical Research

Subject No: 11171036

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

Central Time (US & Canada)				
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Header Text: c4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit on Dec/23/2020 Form: ILLNESS DETAILS - SEVERE - eCRF Audit Trail History

Form Version: 17-Jul-2020 21:55

Form Status: Data Complete, Frozen

Site No: 1117

Site Name: (1117) Sundance Clinical Research

Subject No: 11171036

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

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1. Category of Clinical Event:

Date	Location	User	Value	Reason
Jan-21-2021 13:02:06 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry
Dec-23-2020 15:39:54 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

2. Subcategory of Clinical Event:

Date	Location	User	Value	Reason
Jan-21-2021 13:02:06 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry
Dec-23-2020 15:39:54 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

3. Was a diagnosis obtained?

Date	Location	User	Value	Reason
Jan-21-2021 13:02:06 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry
Dec-23-2020 15:39:54 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

4. Toxicity Grade:

Date	Location	User	Value	Reason
Jan-21-2021 13:02:06 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry
Dec-23-2020 15:39:54 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

090177e196ae3dcc\Final\Final On: 01-Apr-2021 04:41 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit on Dec/23/2020

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Frozen

Site No: 1117

Site Name: (1117) Sundance Clinical Research

Subject No: 11171036

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

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1. Lab Panel:

Date	Location	User	Value	Reason
Jan-21-2021 13:01:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry
Dec-23-2020 15:40:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

2. Laboratory Name and Address

Date	Location	User	Value	Reason
Jan-21-2021 13:01:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry
Dec-23-2020 15:40:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

3. Collection Date:

Date	Location	User	Value	Reason
Jan-21-2021 13:01:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry
Dec-23-2020 15:40:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

4. Specimen Type:

Date	Location	User	Value	Reason
Jan-21-2021 13:01:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry
Dec-23-2020 15:40:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

5.a

090177e196ae3dcc\Final\Final On: 01-Apr-2021 04:41 (GMT)

Header Text: c4591001**Visit:** POT_COVID_ILL 2 - Unscheduled Visit on Dec/23/2020**Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History**Form Version:** 21-Aug-2020 02:49**Form Status:** Data Complete, Frozen**Site No:** 1117**Site Name:** (1117) Sundance Clinical Research**Subject No:** 11171036**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 10:58

Date	Location	User	Value	Reason
Jan-21-2021 13:01:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sponsor-Defined Identifier: Not Applicable Test:: Not Done Result:: Not Applicable Not Done:: Not Applicable Lab Normal Range: Not Applicable	Initial Entry
Dec-23-2020 15:40:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sponsor-Defined Identifier: Not Done Test:: Not Done Result:: Not Done Not Done:: Not Done Lab Normal Range: Not Done	Initial Entry

5.a Sponsor ID:

Date	Location	User	Value	Reason
Jan-21-2021 13:01:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry
Dec-23-2020 15:40:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

5.a Test:

Date	Location	User	Value	Reason
Dec-23-2020 15:40:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

5.a Result:

Date	Location	User	Value	Reason
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Header Text: c4591001**Visit:** POT_COVID_ILL 2 - Unscheduled Visit on Dec/23/2020**Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History**Form Version:** 21-Aug-2020 02:49**Form Status:** Data Complete, Frozen**Site No:** 1117**Site Name:** (1117) Sundance Clinical Research**Subject No:** 11171036**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 10:58

Jan-21-2021 13:01:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry
Dec-23-2020 15:40:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

5.a Not Done:

Date	Location	User	Value	Reason
Jan-21-2021 13:01:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry
Dec-23-2020 15:40:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

5.a LNMT

Date	Location	User	Value	Reason
Jan-21-2021 13:01:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry
Dec-23-2020 15:40:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

5.b

Date	Location	User	Value	Reason
Jan-21-2021 13:01:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sponsor-Defined Identifier: Not Applicable Test:: Not Done Result:: Not Applicable Not Done:: Not Applicable Lab Normal Range: Not Applicable	Initial Entry
Dec-23-2020 15:40:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sponsor-Defined Identifier: Not Done	Initial Entry

Header Text: c4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit on Dec/23/2020

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Subject No: 11171036

Generated By: (b) (4)

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History

Form Status: Data Complete, Frozen

Site Name: (1117) Sundance Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:58

			Test::	Not Done	
				e	
			Result::	Not Done	
				e	
			Not Done::	Not Done	
				e	
			Lab Normal Range:	Not Done	
				e	

Header Text: c4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit on Dec/23/2020

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History

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Site No: 1117

Site Name: (1117) Sundance Clinical Research

Subject No: 11171036

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

5.b Sponsor ID:

Date	Location	User	Value	Reason
Jan-21-2021 13:01:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry
Dec-23-2020 15:40:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

5.b Test:

Date	Location	User	Value	Reason
Dec-23-2020 15:40:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

5.b Result:

Date	Location	User	Value	Reason
Jan-21-2021 13:01:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry
Dec-23-2020 15:40:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

5.b Not Done:

Date	Location	User	Value	Reason
Jan-21-2021 13:01:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry
Dec-23-2020 15:40:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

5.b LNMT

Date	Location	User	Value	Reason
Jan-21-2021 13:01:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

090177e196ae3dcc\Final\Final On: 01-Apr-2021 04:41 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit on Dec/23/2020

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Dec-23-2020 15:40:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry
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5.c

Date	Location	User	Value	Reason
Jan-21-2021 13:01:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sponsor-Defined Identifier: Not Applicable Test:: Not Done Result:: Not Applicable Not Done:: Not Applicable Lab Normal Range: Not Applicable	Initial Entry
Dec-23-2020 15:40:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sponsor-Defined Identifier: Not Done Test:: Not Done Result:: Not Done Not Done:: Not Done Lab Normal Range: Not Done	Initial Entry

090177e196ae3dcc\Final\Final On: 01-Apr-2021 04:41 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit on Dec/23/2020

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Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

5.c Sponsor ID:

Date	Location	User	Value	Reason
Jan-21-2021 13:01:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Applicable	Initial Entry
Dec-23-2020 15:40:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Done	Initial Entry

5.c Test:

Date	Location	User	Value	Reason
Dec-23-2020 15:40:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Done	Initial Entry

5.c Result:

Date	Location	User	Value	Reason
Jan-21-2021 13:01:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Applicable	Initial Entry
Dec-23-2020 15:40:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Done	Initial Entry

5.c Not Done:

Date	Location	User	Value	Reason
Jan-21-2021 13:01:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Applicable	Initial Entry
Dec-23-2020 15:40:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Done	Initial Entry

5.c LNMT

Date	Location	User	Value	Reason
Jan-21-2021 13:01:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Applicable	Initial Entry

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Header Text: c4591001
Visit: POT_COVID_ILL 2 - Unscheduled Visit on Dec/23/2020 **Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History
Form Version: 21-Aug-2020 02:49 **Form Status:** Data Complete, Frozen
Site No: 1117 **Site Name:** (1117) Sundance Clinical Research
Subject No: 11171036 **Subject Initials:** ---
Generated By: (b) (4) **Generated Time (GMT):** 29-Mar-2021 10:58

Dec-23-2020 15:40:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry
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5.d

Date	Location	User	Value	Reason
Jan-21-2021 13:01:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sponsor-Defined Identifier: Not Applicable Test:: Not Done Result:: Not Applicable Not Done:: Not Applicable Lab Normal Range: Not Applicable	Initial Entry
Dec-23-2020 15:40:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sponsor-Defined Identifier: Not Done Test:: Not Done Result:: Not Done Not Done:: Not Done Lab Normal Range: Not Done	Initial Entry

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Header Text: c4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit on Dec/23/2020

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Site No: 1117

Site Name: (1117) Sundance Clinical Research

Subject No: 11171036

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5.d Sponsor ID:

Date	Location	User	Value	Reason
Jan-21-2021 13:01:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Applicable	Initial Entry
Dec-23-2020 15:40:12 (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
Dec-23-2020 15:40:12 (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
Jan-21-2021 13:01:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Applicable	Initial Entry
Dec-23-2020 15:40:12 (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
Jan-21-2021 13:01:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Applicable	Initial Entry
Dec-23-2020 15:40:12 (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
Jan-21-2021 13:01:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Applicable	Initial Entry

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Generated By: (b) (4)

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Dec-23-2020 15:40:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry
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5.e

Date	Location	User	Value	Reason
Jan-21-2021 13:01:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sponsor-Defined Identifier: Not Applicable Test:: Not Done Result:: Not Applicable Not Done:: Not Applicable Lab Normal Range: Not Applicable	Initial Entry
Dec-23-2020 15:40:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sponsor-Defined Identifier: Not Done Test:: Not Done Result:: Not Done Not Done:: Not Done Lab Normal Range: Not Done	Initial Entry

090177e196ae3dcc\Final\Final On: 01-Apr-2021 04:41 (GMT)

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Site No: 1117

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5.e Sponsor ID:

Date	Location	User	Value	Reason
Jan-21-2021 13:01:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry
Dec-23-2020 15:40:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

5.e Test:

Date	Location	User	Value	Reason
Dec-23-2020 15:40:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

5.e Result:

Date	Location	User	Value	Reason
Jan-21-2021 13:01:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

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5.e Result:

Date	Location	User	Value	Reason
Dec-23-2020 15:40:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

5.e Not Done:

Date	Location	User	Value	Reason
Jan-21-2021 13:01:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry
Dec-23-2020 15:40:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

5.e LNMT

Date	Location	User	Value	Reason
Jan-21-2021 13:01:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry
Dec-23-2020 15:40:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

5.f

Date	Location	User	Value	Reason
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Dec-23-2020 15:40:12 (UTC-06:00) Central Time	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Initial Entry

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Generated Time (GMT): 29-Mar-2021 10:58

(US & Canada)		(b) (4), (b) (6)	Sponsor-Defined Identifier:	Not Done
			Test:	Not Done
			Result:	Not Done
			Not Done:	Not Done
			Lab Normal Range:	Not Done

Header Text: c4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit on Dec/23/2020

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Date	Location	User	Value	Reason
Jan-21-2021 13:01:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry
Dec-23-2020 15:40:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

5.f Test:

Date	Location	User	Value	Reason
Dec-23-2020 15:40:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

5.f Result:

Date	Location	User	Value	Reason
Jan-21-2021 13:01:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry
Dec-23-2020 15:40:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

5.f Not Done:

Date	Location	User	Value	Reason
Jan-21-2021 13:01:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry
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5.f LNMT

Date	Location	User	Value	Reason
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Generated Time (GMT): 29-Mar-2021 10:58

Dec-23-2020 15:40:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry
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5.g

Date	Location	User	Value	Reason
Jan-21-2021 13:01:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sponsor-Defined Identifier: Not Applicable Test:: Not Done Result:: Not Applicable Not Done:: Not Applicable Lab Normal Range: Not Applicable	Initial Entry
Dec-23-2020 15:40:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sponsor-Defined Identifier: Not Done Test:: Not Done Result:: Not Done Not Done:: Not Done Lab Normal Range: Not Done	Initial Entry

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Header Text: c4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit on Dec/23/2020

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Frozen

Site No: 1117

Site Name: (1117) Sundance Clinical Research

Subject No: 11171036

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

5.g Sponsor ID:

Date	Location	User	Value	Reason
Jan-21-2021 13:01:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry
Dec-23-2020 15:40:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

5.g Test:

Date	Location	User	Value	Reason
Dec-23-2020 15:40:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

5.g Result:

Date	Location	User	Value	Reason
Jan-21-2021 13:01:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry
Dec-23-2020 15:40:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

5.g Not Done:

Date	Location	User	Value	Reason
Jan-21-2021 13:01:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry
Dec-23-2020 15:40:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

5.g LNMT

Date	Location	User	Value	Reason
Jan-21-2021 13:01:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

090177e196ae3dcc\Final\Final On: 01-Apr-2021 04:41 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit on Dec/23/2020

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Frozen

Site No: 1117

Site Name: (1117) Sundance Clinical Research

Subject No: 11171036

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

Dec-23-2020 15:40:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry
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Header Text: c4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit on Dec/23/2020

Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete, Frozen

Site No: 1117

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Subject Initials: ---

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1. Lab Panel:

Date	Location	User	Value	Reason
Jan-21-2021 13:01:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry
Dec-23-2020 15:40:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

2. Laboratory Name and Address

Date	Location	User	Value	Reason
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Dec-23-2020 15:40:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

3. Collection Date:

Date	Location	User	Value	Reason
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Dec-23-2020 15:40:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

4. Specimen Type:

Date	Location	User	Value	Reason
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Dec-23-2020 15:40:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

5.a

090177e196ae3dcc\Final\Final On: 01-Apr-2021 04:41 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit on Dec/23/2020

Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

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Form Status: Data Complete, Frozen

Site No: 1117

Site Name: (1117) Sundance Clinical Research

Subject No: 11171036

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

Date	Location	User	Value	Reason
Jan-21-2021 13:01:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sponsor-Defined Identifier: Not Applicable Test:: Not Done Result:: Not Applicable Not Done:: Not Applicable Lab Normal Range: Not Applicable	Initial Entry
Dec-23-2020 15:40:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sponsor-Defined Identifier: Not Done Test:: Not Done Result:: Not Done Not Done:: Not Done Lab Normal Range: Not Done	Initial Entry

5.a Sponsor ID:

Date	Location	User	Value	Reason
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Dec-23-2020 15:40:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

5.a Test:

Date	Location	User	Value	Reason
Dec-23-2020 15:40:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

5.a Result:

Date	Location	User	Value	Reason
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Header Text: c4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit on Dec/23/2020

Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete, Frozen

Site No: 1117

Site Name: (1117) Sundance Clinical Research

Subject No: 11171036

Subject Initials: ---

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Generated Time (GMT): 29-Mar-2021 10:58

Jan-21-2021 13:01:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry
Dec-23-2020 15:40:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

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Date	Location	User	Value	Reason
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Dec-23-2020 15:40:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

5.a LNMT

Date	Location	User	Value	Reason
Jan-21-2021 13:01:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry
Dec-23-2020 15:40:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

5.b

Date	Location	User	Value	Reason
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Dec-23-2020 15:40:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sponsor-Defined Identifier: Not Done	Initial Entry

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Header Text: c4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit on Dec/23/2020

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Site No: 1117

Subject No: 11171036

Generated By: (b) (4)

Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

Form Status: Data Complete, Frozen

Site Name: (1117) Sundance Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:58

			Test::	Not Done	
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			Result::	Not Done	
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			Not Done::	Not Done	
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			Lab Normal Range:	Not Done	
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Header Text: c4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit on Dec/23/2020

Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

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Form Status: Data Complete, Frozen

Site No: 1117

Site Name: (1117) Sundance Clinical Research

Subject No: 11171036

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

5.b Sponsor ID:

Date	Location	User	Value	Reason
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Dec-23-2020 15:40:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Done	Initial Entry

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Date	Location	User	Value	Reason
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5.b Result:

Date	Location	User	Value	Reason
Jan-21-2021 13:01:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Applicable	Initial Entry
Dec-23-2020 15:40:29 (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
Jan-21-2021 13:01:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Applicable	Initial Entry
Dec-23-2020 15:40:29 (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
Jan-21-2021 13:01:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Applicable	Initial Entry

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Header Text: c4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit on Dec/23/2020

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Site No: 1117

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Subject Initials: ---

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Dec-23-2020 15:40:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry
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5.c

Date	Location	User	Value	Reason
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Dec-23-2020 15:40:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sponsor-Defined Identifier: Not Done Test:: Not Done Result:: Not Done Not Done:: Not Done Lab Normal Range: Not Done	Initial Entry

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Visit: POT_COVID_ILL 2 - Unscheduled Visit on Dec/23/2020

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Generated By: (b) (4)

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5.c Sponsor ID:

Date	Location	User	Value	Reason
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Dec-23-2020 15:40:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

5.c Test:

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5.c Result:

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5.c LNMT

Date	Location	User	Value	Reason
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Dec-23-2020 15:40:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry
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5.d

Date	Location	User	Value	Reason
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Dec-23-2020 15:40:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sponsor-Defined Identifier: Not Done Test:: Not Done Result:: Not Done Not Done:: Not Done Lab Normal Range: Not Done	Initial Entry

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Site No: 1117

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5.d Sponsor ID:

Date	Location	User	Value	Reason
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5.d Result:

Date	Location	User	Value	Reason
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Dec-23-2020 15:40:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Done	Initial Entry

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Dec-23-2020 15:40:29 (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
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090177e196ae3dcc\Final\Final On: 01-Apr-2021 04:41 (GMT)

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Site No: 1117

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Dec-23-2020 15:40:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry
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5.e

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
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5.e LNMT

Date	Location	User	Value	Reason
Jan-21-2021 13:01:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry
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5.f

Date	Location	User	Value	Reason
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Dec-23-2020 15:40:29 (UTC-06:00) Central Time	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Initial Entry

090177e196ae3dcc\Final\Final On: 01-Apr-2021 04:41 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit on Dec/23/2020

Form Version: 21-Aug-2020 02:51

Site No: 1117

Subject No: 11171036

Generated By: (b) (4)

Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

Form Status: Data Complete, Frozen

Site Name: (1117) Sundance Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:58

(US & Canada)		(b) (4), (b) (6)	Sponsor-Defined Identifier:	Not Done
			Test:	Not Done
			Result:	Not Done
			Not Done:	Not Done
			Lab Normal Range:	Not Done

Header Text: c4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit on Dec/23/2020

Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete, Frozen

Site No: 1117

Site Name: (1117) Sundance Clinical Research

Subject No: 11171036

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

5.f Sponsor ID:

Date	Location	User	Value	Reason
Jan-21-2021 13:01:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry
Dec-23-2020 15:40:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

5.f Test:

Date	Location	User	Value	Reason
Dec-23-2020 15:40:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

5.f Result:

Date	Location	User	Value	Reason
Jan-21-2021 13:01:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry
Dec-23-2020 15:40:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

5.f Not Done:

Date	Location	User	Value	Reason
Jan-21-2021 13:01:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry
Dec-23-2020 15:40:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

5.f LNMT

Date	Location	User	Value	Reason
Jan-21-2021 13:01:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

090177e196ae3dcc\Final\Final On: 01-Apr-2021 04:41 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit on Dec/23/2020

Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete, Frozen

Site No: 1117

Site Name: (1117) Sundance Clinical Research

Subject No: 11171036

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

Dec-23-2020 15:40:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry
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5.g

Date	Location	User	Value	Reason
Jan-21-2021 13:01:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sponsor-Defined Identifier: Not Applicable Test:: Not Done Result:: Not Applicable Not Done:: Not Applicable Lab Normal Range: Not Applicable	Initial Entry
Dec-23-2020 15:40:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sponsor-Defined Identifier: Not Done Test:: Not Done Result:: Not Done Not Done:: Not Done Lab Normal Range: Not Done	Initial Entry

090177e196ae3dcc\Final\Final On: 01-Apr-2021 04:41 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit on Dec/23/2020

Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete, Frozen

Site No: 1117

Site Name: (1117) Sundance Clinical Research

Subject No: 11171036

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

5.g Sponsor ID:

Date	Location	User	Value	Reason
Jan-21-2021 13:01:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry
Dec-23-2020 15:40:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

5.g Test:

Date	Location	User	Value	Reason
Dec-23-2020 15:40:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

5.g Result:

Date	Location	User	Value	Reason
Jan-21-2021 13:01:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry
Dec-23-2020 15:40:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

5.g Not Done:

Date	Location	User	Value	Reason
Jan-21-2021 13:01:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry
Dec-23-2020 15:40:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

5.g LNMT

Date	Location	User	Value	Reason
Jan-21-2021 13:01:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

090177e196ae3dcc\Final\Final On: 01-Apr-2021 04:41 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit on Dec/23/2020

Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete, Frozen

Site No: 1117

Site Name: (1117) Sundance Clinical Research

Subject No: 11171036

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

Dec-23-2020 15:40:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry
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5.h

Date	Location	User	Value	Reason
Jan-21-2021 13:01:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sponsor-Defined Identifier: Not Applicable Test:: Not Done Result:: Not Applicable Not Done:: Not Applicable Lab Normal Range: Not Applicable	Initial Entry
Dec-23-2020 15:40:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sponsor-Defined Identifier: Not Done Test:: Not Done Result:: Not Done Not Done:: Not Done Lab Normal Range: Not Done	Initial Entry

090177e196ae3dcc\Final\Final On: 01-Apr-2021 04:41 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit on Dec/23/2020

Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete, Frozen

Site No: 1117

Site Name: (1117) Sundance Clinical Research

Subject No: 11171036

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

5.h Sponsor ID:

Date	Location	User	Value	Reason
Jan-21-2021 13:01:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry
Dec-23-2020 15:40:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

5.h Test:

Date	Location	User	Value	Reason
Dec-23-2020 15:40:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

5.h Result:

Date	Location	User	Value	Reason
Jan-21-2021 13:01:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry
Dec-23-2020 15:40:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

5.h Not Done:

Date	Location	User	Value	Reason
Jan-21-2021 13:01:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry
Dec-23-2020 15:40:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

5.h LNMT

Date	Location	User	Value	Reason
Jan-21-2021 13:01:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

090177e196ae3dcc\Final\Final On: 01-Apr-2021 04:41 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit on Dec/23/2020

Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete, Frozen

Site No: 1117

Site Name: (1117) Sundance Clinical Research

Subject No: 11171036

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

Dec-23-2020 15:40:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry
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5.i

Date	Location	User	Value	Reason
Jan-21-2021 13:01:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sponsor-Defined Identifier: Not Applicable Test:: Not Done Result:: Not Applicable Not Done:: Not Applicable Lab Normal Range: Not Applicable	Initial Entry
Dec-23-2020 15:40:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sponsor-Defined Identifier: Not Done Test:: Not Done Result:: Not Done Not Done:: Not Done Lab Normal Range: Not Done	Initial Entry

090177e196ae3dcc\Final\Final On: 01-Apr-2021 04:41 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit on Dec/23/2020

Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete, Frozen

Site No: 1117

Site Name: (1117) Sundance Clinical Research

Subject No: 11171036

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

5.i Sponsor ID:

Date	Location	User	Value	Reason
Jan-21-2021 13:01:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry
Dec-23-2020 15:40:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

5.i Test:

Date	Location	User	Value	Reason
Dec-23-2020 15:40:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

5.i Result:

Date	Location	User	Value	Reason
Jan-21-2021 13:01:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry
Dec-23-2020 15:40:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

5.i Not Done:

Date	Location	User	Value	Reason
Jan-21-2021 13:01:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry
Dec-23-2020 15:40:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

5.i LNMT

Date	Location	User	Value	Reason
Jan-21-2021 13:01:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

090177e196ae3dcc\Final\Final On: 01-Apr-2021 04:41 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit on Dec/23/2020

Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete, Frozen

Site No: 1117

Site Name: (1117) Sundance Clinical Research

Subject No: 11171036

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

Dec-23-2020 15:40:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry
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5.j

Date	Location	User	Value	Reason
Jan-21-2021 13:01:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sponsor-Defined Identifier: Not Applicable Test:: Not Done Result:: Not Applicable Not Done:: Not Applicable Lab Normal Range: Not Applicable	Initial Entry

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Visit: POT_COVID_ILL 2 - Unscheduled Visit on Dec/23/2020

Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete, Frozen

Site No: 1117

Site Name: (1117) Sundance Clinical Research

Subject No: 11171036

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

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5.j				
Date	Location	User	Value	Reason
Dec-23-2020 15:40:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sponsor-Defined Identifier: Not Done Test:: Not Done Result:: Not Done Not Done:: Not Done Lab Normal Range: Not Done	Initial Entry

Header Text: c4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit on Dec/23/2020

Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete, Frozen

Site No: 1117

Site Name: (1117) Sundance Clinical Research

Subject No: 11171036

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

5.j Sponsor ID:

Date	Location	User	Value	Reason
Jan-21-2021 13:01:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Applicable	Initial Entry
Dec-23-2020 15:40:29 (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
Dec-23-2020 15:40:29 (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
Jan-21-2021 13:01:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Applicable	Initial Entry
Dec-23-2020 15:40:29 (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
Jan-21-2021 13:01:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Applicable	Initial Entry
Dec-23-2020 15:40:29 (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
Jan-21-2021 13:01:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Applicable	Initial Entry

090177e196ae3dcc\Final\Final On: 01-Apr-2021 04:41 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit on Dec/23/2020

Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete, Frozen

Site No: 1117

Site Name: (1117) Sundance Clinical Research

Subject No: 11171036

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

Dec-23-2020 15:40:29 (UTC-06:00) Central Time (US & Canada)	ACVOPFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry
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Header Text: c4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit on Dec/23/2020 Form: VITAL SIGNS - COVID - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:50

Form Status: Data Complete, Frozen

Site No: 1117

Site Name: (1117) Sundance Clinical Research

Subject No: 11171036

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

[Back to Form](#)

I. Date:

Date	Location	User	Value	Reason
Jan-21-2021 13:01:24 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry
Dec-23-2020 15:40:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

2.a

Date	Location	User	Value	Reason
Jan-21-2021 13:01:24 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Record Identifier:: Not Done Systolic:: Not Applicable Diastolic:: Not Applicable Respiratory Rate in respirations/minute: Not Applicable Heart Rate in beats/minute: Not Applicable	Initial Entry
Dec-23-2020 15:40:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Record Identifier:: Not Done Systolic:: Not Done Diastolic:: Not Done Respiratory Rate in respirations/minute: Not Done Heart Rate in beats/minute: Not Done	Initial Entry

2.a Record Identifier:

Date	Location	User	Value	Reason
Dec-23-2020 15:40:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

090177e196ae3dcc\Final\Final On: 01-Apr-2021 04:41 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit on Dec/23/2020 Form: VITAL SIGNS - COVID - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:50

Form Status: Data Complete, Frozen

Site No: 1117

Site Name: (1117) Sundance Clinical Research

Subject No: 11171036

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

2.a Systolic:

Date	Location	User	Value	Reason
Jan-21-2021 13:01:24 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry
Dec-23-2020 15:40:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

2.a Diastolic:

Date	Location	User	Value	Reason
Jan-21-2021 13:01:24 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry
Dec-23-2020 15:40:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

2.a Respiratory Rate in respirations/minute:

Date	Location	User	Value	Reason
Jan-21-2021 13:01:24 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry
Dec-23-2020 15:40:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

2.a Heart Rate in beats/minute:

Date	Location	User	Value	Reason
Jan-21-2021 13:01:24 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry
Dec-23-2020 15:40:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

090177e196ae3dcc\Final\Final On: 01-Apr-2021 04:41 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit on Dec/23/2020 Form: VITAL SIGNS - PULSE OX ROOM AIR - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete, Frozen

Site No: 1117

Site Name: (1117) Sundance Clinical Research

Subject No: 11171036

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

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1. Date:

Date	Location	User	Value	Reason
Jan-21-2021 13:01:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry
Dec-23-2020 15:41:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

2.a

Date	Location	User	Value	Reason
Jan-21-2021 13:01:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Record Identifier:: Not Done Oxygen Saturation: Not Applicable	Initial Entry
Dec-23-2020 15:41:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Record Identifier:: Not Done Oxygen Saturation: Not Done	Initial Entry

2.a Record Identifier:

Date	Location	User	Value	Reason
Dec-23-2020 15:41:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

2.a SPO2 Pulse Oximetry %

Date	Location	User	Value	Reason
Jan-21-2021 13:01:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry
Dec-23-2020 15:41:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

090177e196ae3dcc\Final\Final On: 01-Apr-2021 04:41 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit on Dec/23/2020 Form: OXYGENATION PARAMETERS - eCRF Audit Trail History

Form Version: 06-Jul-2020 21:52

Form Status: Data Complete, Frozen

Site No: 1117

Site Name: (1117) Sundance Clinical Research

Subject No: 11171036

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

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1. Date Time of Assessment:

Date	Location	User	Value	Reason
Jan-21-2021 13:00:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry
Dec-23-2020 15:41:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

2. Arterial Blood Gases PaO2 (mmHg):

Date	Location	User	Value	Reason
Jan-21-2021 13:00:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry
Dec-23-2020 15:41:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

3. FiO2 (Fraction of Inhaled Oxygen):

Date	Location	User	Value	Reason
Jan-21-2021 13:00:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry
Dec-23-2020 15:41:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

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090177e196ae3dcc\Final\Final On: 01-Apr-2021 04:41 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit on Dec/23/2020

Form: CONCOMITANT MEDICATIONS - VASOPRESSORS - eCRF Audit Trail History

Form Version: 06-Jul-2020 21:55

Form Status: Data Complete, Frozen

Site No: 1117

Site Name: (1117) Sundance Clinical Research

Subject No: 11171036

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

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1. What is the medication identifier?

Date	Location	User	Value	Reason
Jan-21-2021 13:00:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry
Dec-23-2020 15:41:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

2. Category:

Date	Location	User	Value	Reason
Jan-21-2021 13:00:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry
Dec-23-2020 15:41:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

3. Concomitant Medications Pre-specified:

Date	Location	User	Value	Reason
Jan-21-2021 13:00:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry
Dec-23-2020 15:41:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 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
Jan-21-2021 13:00:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry
Dec-23-2020 15:41:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

Header Text: c4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit on Dec/23/2020

Form: CONCOMITANT MEDICATIONS - VASOPRESSORS - eCRF Audit Trail History

Form Version: 06-Jul-2020 21:55

Form Status: Data Complete, Frozen

Site No: 1117

Site Name: (1117) Sundance Clinical Research

Subject No: 11171036

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

5. Start Date:

Date	Location	User	Value	Reason
Jan-21-2021 13:00:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry
Dec-23-2020 15:41:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

6. Ongoing?

Date	Location	User	Value	Reason
Jan-21-2021 13:00:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry
Dec-23-2020 15:41:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

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Header Text: c4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit on Dec/23/2020 Form: IMAGING - eCRF Audit Trail History

Form Version: 06-Jul-2020 21:53

Form Status: Data Complete, Frozen

Site No: 1117

Site Name: (1117) Sundance Clinical Research

Subject No: 11171036

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

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1. Date of Assessment:

Date	Location	User	Value	Reason
Jan-21-2021 13:00:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry
Dec-23-2020 15:41:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

2. Location of Assessment:

Date	Location	User	Value	Reason
Jan-21-2021 13:00:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry
Dec-23-2020 15:41:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

3. Type of Imaging Exam:

Date	Location	User	Value	Reason
Jan-21-2021 13:00:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry
Dec-23-2020 15:41:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

4. Assessment:

Date	Location	User	Value	Reason
Jan-21-2021 13:00:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry
Dec-23-2020 15:41:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

090177e196ae3dcc\Final\Final On: 01-Apr-2021 04:41 (GMT)

Header Text: c4591001**Visit:** POT_COVID_CONVA 1 - Unscheduled Visit on Nov/05/2020 **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:** 11171036**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 10:58[Back to Form](#)**1. Date of Visit**

Date	Location	User	Value	Reason
Feb-19-2021 01:39:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Feb-18-2021 17:20:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Changed data per query
Feb-15-2021 23:05:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	DM: Erroneous visit is marked. However, strike-off loglines present on SAMP TRK form. Kindly undelete the loglines and erase all data and then add form level comment by selecting Not Done or Not Applicable option on SAMP TRK form or else clarify.
Feb-15-2021 12:47:49 (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 data within this visit as Not Done/Not Applicable at the form level.
Nov-05-2020 18:11:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Nov/5/2020	Initial Entry

2. Erroneous Visit

Date	Location	User	Value	Reason
Feb-15-2021 12:47:49 (UTC-06:00) Central Time	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: ERRONEOUS VISIT	Initial Entry

Header Text: c4591001

Visit: POT_COVID_CONVA 1 - Unscheduled Visit Form: DATE OF VISIT - ILLNESS CONVALESCENT - eCRF Audit Trail on Nov/05/2020 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: 11171036

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

(US & Canada)

(b) (4), (b) (6)

3. COVID-19 Illness Visit:

Date	Location	User	Value	Reason
Feb-15-2021 12:47:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry
Feb-15-2021 12:47:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Changed Information
Jan-27-2021 08:10:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Jan-26-2021 09:23:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	ONGOING ILLNESS THAT REQUIRED TWO CONVALESCENT VISITS. SEE COVID ILL-SOD FORM FOR DATES
Jan-21-2021 23:42:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (b) (4)	Query 1: Opened	DMW6937400;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.
Nov-05-2020 18:11:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: COVID_AI	Initial Entry

090177e196ae3dcc\Final\Final On: 01-Apr-2021 04:41 (GMT)

Header Text: c4591001

Visit: POT_COVID_CONVA 1 - Unscheduled Visit Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF
on Nov/05/2020 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: 11171036

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

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1. Data Origin

Date	Location	User	Value	Reason
Feb-18-2021 17:20:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Not Applicable	Initial Entry
Feb-15-2021 12:49:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry:	Changed Information
Nov-05-2020 18:12:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Feb-18-2021 17:20:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Not Applicable	Initial Entry
Feb-15-2021 12:49:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry:	Changed Information
Nov-05-2020 18:12:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SERUM	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Feb-15-2021 12:50:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry
Feb-15-2021 12:49:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Changed Information
Feb-15-2021 12:44:08	ACV0PFEINFP6000	auto query (autoquery)	Query 4: Closed	Close Auto Query

090177e196ae3dcc\Final\Final On: 01-Apr-2021 04:41 (GMT)

Header Text: c4591001				
Visit: POT_COVID_CONVA 1 - Unscheduled Visit Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF on Nov/05/2020 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: 11171036 Subject Initials: ---				
Generated By: (b) (4) Generated Time (GMT): 29-Mar-2021 10:58				
(UTC-06:00) Central Time (US & Canada)				
Feb-15-2021 12:43:55 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 4: Op ened	'Sample Collected?' is marked as No and 'If no sample was collected or sample was not collected according to protocol, please provide reason' is missing. Please review and update as appropriate.
Feb-15-2021 12:43:55 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 3: Del eted	Close Auto Query
Feb-15-2021 12:43:55 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Changed Information
Feb-15-2021 12:43:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 3: Can didate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Dec-08-2020 01:51:18 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Clo sed	Response satisfies query
Dec-07-2020 12:46:04 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Ans wered	Original value is correct
Dec-06-2020 08:34:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (b) (4)	Query 2: Op ened	DMW6347785;Date of Collection is not equal to Date of Visit. Please clarify or correct.

Header Text: c4591001
Visit: POT_COVID_CONVA 1 - Unscheduled Visit **Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF
 on Nov/05/2020 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: 11171036 **Subject Initials:** ---
Generated By: (b) (4) **Generated Time (GMT):** 29-Mar-2021 10:58

Nov-05-2020 18:12:19 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Nov-05-2020 18:12:09 (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.
Nov-05-2020 18:12:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Collection: Nov/5/2020	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-18-2021 17:20:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry
Feb-15-2021 12:50:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Changed Information
Feb-15-2021 12:44:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: VISIT NOT REQUIRED	Initial Entry

5.a

Date	Location	User	Value	Reason
Feb-18-2021 17:19:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID:	Changed Information
Feb-18-2021 17:18:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BRRSY	Changed Information
Feb-15-2021 12:42:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BRRSY	Changed Information (DELETED)

Header Text: c4591001

Visit: POT_COVID_CONVA 1 - Unscheduled Visit Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF
on Nov/05/2020 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: 11171036

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

Nov-05-2020 18:12:19 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BRSRSY	Initial Entry
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5.a Sample ID

Date	Location	User	Value	Reason
Feb-18-2021 17:19:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Changed Information
Feb-18-2021 17:18:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BRSRSY	Changed Information
Feb-15-2021 12:42:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BRSRSY	Changed Information (DELETED)
Nov-05-2020 18:12:19 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BRSRSY	Initial Entry

5.b

Date	Location	User	Value	Reason
Feb-18-2021 17:19:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID:	Changed Information
Feb-18-2021 17:18:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BRSRSZ	Changed Information
Feb-15-2021 12:43:04 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BRSRSZ	Changed Information (DELETED)
Nov-05-2020 18:12:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BRSRSZ	Initial Entry

090177e196ae3dcc\Final\Final On: 01-Apr-2021 04:41 (GMT)

Header Text: c4591001

Visit: POT_COVID_CONVA 1 - Unscheduled Visit Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF
on Nov/05/2020 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: 11171036

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

5.b Sample ID

Date	Location	User	Value	Reason
Feb-18-2021 17:19:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u>	Changed Information
Feb-18-2021 17:18:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> BRSRSZ	Changed Information
Feb-15-2021 12:43:04 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> BRSRSZ	Changed Information (DELETED)
Nov-05-2020 18:12:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> BRSRSZ	Initial Entry

5.c

Date	Location	User	Value	Reason
Feb-18-2021 17:19:32 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> <u>Sample ID:</u>	Changed Information
Feb-18-2021 17:18:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> <u>Sample ID:</u> BP58YV	Changed Information
Feb-15-2021 12:43:17 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> <u>Sample ID:</u> BP58YV	Changed Information (DELETED)
Nov-05-2020 18:12:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> <u>Sample ID:</u> BP58YV	Initial Entry

090177e196ae3dcc\Final\Final On: 01-Apr-2021 04:41 (GMT)

Header Text: c4591001

Visit: POT_COVID_CONVA 1 - Unscheduled Visit Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF
on Nov/05/2020 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: 11171036

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

5.c Sample ID

Date	Location	User	Value	Reason
Feb-18-2021 17:19:32 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u>	Changed Information
Feb-18-2021 17:18:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> BP58YV	Changed Information
Feb-15-2021 12:43:17 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> BP58YV	Changed Information (DELETED)
Nov-05-2020 18:12:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> BP58YV	Initial Entry

5.d

Date	Location	User	Value	Reason
Feb-18-2021 17:19:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> <u>Sample ID:</u>	Changed Information
Feb-18-2021 17:18:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> <u>Sample ID:</u> BP58YW	Changed Information
Feb-15-2021 12:43:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> <u>Sample ID:</u> BP58YW	Changed Information (DELETED)
Nov-05-2020 18:13:04 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> <u>Sample ID:</u> BP58YW	Initial Entry

090177e196ae3dcc\Final\Final On: 01-Apr-2021 04:41 (GMT)

Header Text: c4591001

Visit: POT_COVID_CONVA 1 - Unscheduled Visit Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF
on Nov/05/2020 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: 11171036

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

5.d Sample ID

Date	Location	User	Value	Reason
Feb-18-2021 17:19:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u>	Changed Information
Feb-18-2021 17:18:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> BP58YW	Changed Information
Feb-15-2021 12:43:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> BP58YW	Changed Information (DELETED)
Nov-05-2020 18:13:04 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> BP58YW	Initial Entry

5.e

Date	Location	User	Value	Reason
Feb-18-2021 17:19:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> <u>Sample ID:</u>	Changed Information
Feb-18-2021 17:18:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> <u>Sample ID:</u> BP58YX	Changed Information
Feb-15-2021 12:43:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> <u>Sample ID:</u> BP58YX	Changed Information (DELETED)
Nov-05-2020 18:13:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> <u>Sample ID:</u> BP58YX	Initial Entry

090177e196ae3dcc\Final\Final On: 01-Apr-2021 04:41 (GMT)

Header Text: c4591001

Visit: POT_COVID_CONVA 1 - Unscheduled Visit **Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF
on Nov/05/2020 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: 11171036

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

5.e Sample ID

Date	Location	User	Value	Reason
Feb-18-2021 17:19:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u>	Changed Information
Feb-18-2021 17:18:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> BP58YX	Changed Information
Feb-15-2021 12:43:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> BP58YX	Changed Information (DELETED)
Nov-05-2020 18:13:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> BP58YX	Initial Entry

090177e196ae3dcc\Final\Final On: 01-Apr-2021 04:41 (GMT)

Header Text: c4591001

Visit: POT_COVID_CONVA 2 - Unscheduled Visit Form: DATE OF VISIT - ILLNESS CONVALESCENT - eCRF Audit Trail on Dec/03/2020 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: 11171036

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

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I. Date of Visit

Date	Location	User	Value	Reason
Feb-19-2021 01:37:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Feb-18-2021 22:51:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Closed	Response satisfies query
Feb-18-2021 17:26:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Changed data per query
Feb-18-2021 17:26:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Answered	Changed data per query
Feb-16-2021 07:01:02 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued:Opened	DM1: Form level comments are not added appropriately on SAMP TRK form. Please check CCG and update data as appropriate. Thank you.
Feb-15-2021 23:04:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Opened	DM: Erroneous visit is marked. However, strike-off loglines present on SAMP TRK form. Kindly undelete the loglines and erase all data and then add form level comment by selecting Not Done or Not Applicable option on SAMP TRK form or else clarify.
Feb-15-2021 12:28:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Changed data per query
Feb-15-2021 12:28:07 (UTC-06:00) Central Time	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Candidate	Erroneous Visit is marked, but date of

090177e196ae3dcc\Final\Final On: 01-Apr-2021 04:41 (GMT)

Header Text: c4591001
Visit: POT_COVID_CONVA 2 - Unscheduled Visit **Form:** DATE OF VISIT - ILLNESS CONVALESCENT - eCRF Audit Trail on Dec/03/2020
Form Version: 22-Apr-2020 21:04 **Form Status:** Data Complete, Frozen, Verified
Site No: 1117 **Site Name:** (1117) Sundance Clinical Research
Subject No: 11171036 **Subject Initials:** ---
Generated By: (b) (4) **Generated Time (GMT):** 29-Mar-2021 10:58

(US & Canada)				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.
Jan-28-2021 14:47:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	See CCG 8.29.2 COVID_B was combined into COVID_A and COVID_B was made Erroneous this Convalescent visit data should be cleared and marked Erroneous. Send in an SCF to VRD for CT29 sample destruction and add FORM level comments of NA to SAMP TRK form.
Dec-04-2020 17:17:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Dec/3/2020	Initial Entry

2. Erroneous Visit

Date	Location	User	Value	Reason
Feb-15-2021 12:28:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: ERRONEOUS VISIT	Initial Entry

3. COVID-19 Illness Visit:

Date	Location	User	Value	Reason
Feb-15-2021 12:28:37 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

Header Text: c4591001**Visit:** POT_COVID_CONVA 2 - Unscheduled Visit **Form:** DATE OF VISIT - ILLNESS CONVALESCENT - eCRF Audit Trail on Dec/03/2020**Form Version:** 22-Apr-2020 21:04**Form Status:** Data Complete, Frozen, Verified**Site No:** 1117**Site Name:** (1117) Sundance Clinical Research**Subject No:** 11171036**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 10:58

Feb-15-2021 12:27:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Changed Information
Jan-28-2021 14:43:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	REWORD query text
Jan-28-2021 00:13:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued: Opened	DM : COVID_A1 is recorded three times with different Date of visits. Please review and update the data as appropriate. Else, clarify.
Jan-26-2021 09:24:23 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	PROLONGED ILLNESS, SEE COVID ILL-SOD FORM FOR DATES
Jan-21-2021 23:42:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (b) (4)	Query 1: Opened	DMW6937401;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-04-2020 17:17:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: COVID_A1	Initial Entry

Header Text: c4591001

Visit: POT_COVID_CONVA 2 - Unscheduled Visit Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF on Dec/03/2020 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: 11171036

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

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1. Data Origin

Date	Location	User	Value	Reason
Feb-18-2021 17:25:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Not Applicable	Initial Entry
Feb-15-2021 12:49:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry:	Changed Information
Dec-04-2020 17:17:46 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Feb-18-2021 17:25:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Not Applicable	Initial Entry
Feb-15-2021 12:49:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry:	Changed Information
Dec-04-2020 17:17:46 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SERUM	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Feb-15-2021 12:49:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry
Feb-15-2021 12:49:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 4: Closed	Close Auto Query
Feb-15-2021 12:49:03	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Changed Information

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Header Text: c4591001**Visit:** POT_COVID_CONVA 2 - Unscheduled Visit **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:** 11171036**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 10:58

(UTC-06:00) Central Time (US & Canada)				
Feb-15-2021 12:48:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 4: Opened	'Sample Collected?' is marked as No and 'If no sample was collected or sample was not collected according to protocol, please provide reason' is missing. Please review and update as appropriate.
Feb-15-2021 12:48:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 3: Deleted	Close Auto Query
Feb-15-2021 12:48:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Changed Information
Feb-15-2021 12:27:21 (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.
Dec-08-2020 01:50:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Closed	Response satisfies query
Dec-07-2020 12:46:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Answered	Original value is correct
Dec-06-2020 08:34:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (b) (4)	Query 2: Opened	DMW6347784;Date of Collection is not equal to Date of Visit. Please clarify or correct.

Header Text: c4591001**Visit:** POT_COVID_CONVA 2 - Unscheduled Visit **Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF
on Dec/03/2020 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:** 11171036**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 10:58

Dec-04-2020 17:17:55 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Dec-04-2020 17:17:46 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Dec-04-2020 17:17:46 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Collection: Dec/3/2020	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-18-2021 17:25:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.a

Date	Location	User	Value	Reason
Feb-18-2021 17:23:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID:	Changed Information
Feb-18-2021 17:22:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BM8YYZ	Changed Information
Feb-15-2021 12:26:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BM8YYZ	Changed Information (DELETED)
Dec-04-2020 17:17:55 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BM8YYZ	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
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Header Text: c4591001

Visit: POT_COVID_CONVA 2 - Unscheduled Visit **Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF
on Dec/03/2020 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: 11171036

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

Feb-18-2021 17:23:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Changed Information
Feb-18-2021 17:22:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BM8YYZ	Changed Information
Feb-15-2021 12:26:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BM8YYZ	Changed Information (DELETED)
Dec-04-2020 17:17:55 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BM8YYZ	Initial Entry

5.b

Date	Location	User	Value	Reason
Feb-18-2021 17:23:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID:	Changed Information
Feb-18-2021 17:22:24 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BM8YZ0	Changed Information
Feb-15-2021 12:26:18 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BM8YZ0	Changed Information (DELETED)
Dec-04-2020 17:18:06 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BM8YZ0	Initial Entry

090177e196ae3dcc\Final\Final On: 01-Apr-2021 04:41 (GMT)

Header Text: c4591001

Visit: POT_COVID_CONVA 2 - Unscheduled Visit Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF
on Dec/03/2020 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: 11171036

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

5.b Sample ID

Date	Location	User	Value	Reason
Feb-18-2021 17:23:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u>	Changed Information
Feb-18-2021 17:22:24 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> BM8YZ0	Changed Information
Feb-15-2021 12:26:18 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> BM8YZ0	Changed Information (DELETED)
Dec-04-2020 17:18:06 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> BM8YZ0	Initial Entry

5.c

Date	Location	User	Value	Reason
Feb-18-2021 17:24:04 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Sample ID:	Changed Information
Feb-18-2021 17:22:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Sample ID: BM8YZ1	Changed Information
Feb-15-2021 12:26:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Sample ID: BM8YZ1	Changed Information (DELETED)
Dec-04-2020 17:18:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Sample ID: BM8YZ1	Initial Entry

090177e196ae3dcc\Final\Final On: 01-Apr-2021 04:41 (GMT)

Header Text: c4591001

Visit: POT_COVID_CONVA 2 - Unscheduled Visit Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF
on Dec/03/2020 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: 11171036

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

5.c Sample ID

Date	Location	User	Value	Reason
Feb-18-2021 17:24:04 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u>	Changed Information
Feb-18-2021 17:22:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> BM8YZ1	Changed Information
Feb-15-2021 12:26:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> BM8YZ1	Changed Information (DELETED)
Dec-04-2020 17:18:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> BM8YZ1	Initial Entry

5.d

Date	Location	User	Value	Reason
Feb-18-2021 17:24:19 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> <u>Sample ID:</u>	Changed Information
Feb-18-2021 17:22:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> <u>Sample ID:</u> BRSRB9	Changed Information
Feb-15-2021 12:26:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> <u>Sample ID:</u> BRSRB9	Changed Information (DELETED)
Dec-04-2020 18:15:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> <u>Sample ID:</u> BRSRB9	Initial Entry

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Header Text: c4591001

Visit: POT_COVID_CONVA 2 - Unscheduled Visit Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF
on Dec/03/2020 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: 11171036

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

5.d Sample ID

Date	Location	User	Value	Reason
Feb-18-2021 17:24:19 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u>	Changed Information
Feb-18-2021 17:22:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> BRSRB9	Changed Information
Feb-15-2021 12:26:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> BRSRB9	Changed Information (DELETED)
Dec-04-2020 18:15:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> BRSRB9	Initial Entry

5.e

Date	Location	User	Value	Reason
Feb-18-2021 17:24:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> <u>Sample ID:</u>	Changed Information
Feb-18-2021 17:23:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> <u>Sample ID:</u> BRSRBB	Changed Information
Feb-15-2021 12:26:54 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> <u>Sample ID:</u> BRSRBB	Changed Information (DELETED)
Dec-04-2020 18:15:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> <u>Sample ID:</u> BRSRBB	Initial Entry

090177e196ae3dcc\Final\Final On: 01-Apr-2021 04:41 (GMT)

Header Text: c4591001

Visit: POT_COVID_CONVA 2 - Unscheduled Visit Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF
on Dec/03/2020 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: 11171036

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

5.e Sample ID

Date	Location	User	Value	Reason
Feb-18-2021 17:24:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u>	Changed Information
Feb-18-2021 17:23:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> BRSRBB	Changed Information
Feb-15-2021 12:26:54 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> BRSRBB	Changed Information (DELETED)
Dec-04-2020 18:15:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> BRSRBB	Initial Entry

5.f

Date	Location	User	Value	Reason
Feb-18-2021 17:24:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> <u>Sample ID:</u>	Changed Information
Feb-18-2021 17:23:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> <u>Sample ID:</u> BRSRBC	Changed Information
Feb-15-2021 12:27:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> <u>Sample ID:</u> BRSRBC	Changed Information (DELETED)
Dec-04-2020 18:15:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> <u>Sample ID:</u> BRSRBC	Initial Entry

090177e196ae3dcc\Final\Final On: 01-Apr-2021 04:41 (GMT)

Header Text: c4591001

Visit: POT_COVID_CONVA 2 - Unscheduled Visit **Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF
on Dec/03/2020 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: 11171036

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

5.f Sample ID

Date	Location	User	Value	Reason
Feb-18-2021 17:24:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u>	Changed Information
Feb-18-2021 17:23:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> BRSRBC	Changed Information
Feb-15-2021 12:27:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> BRSRBC	Changed Information (DELETED)
Dec-04-2020 18:15:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> BRSRBC	Initial Entry

5.g

Date	Location	User	Value	Reason
Feb-18-2021 17:24:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Sample ID:	Changed Information
Feb-18-2021 17:23:23 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Sample ID: BRSRBD	Changed Information

090177e196ae3dcc\Final\Final On: 01-Apr-2021 04:41 (GMT)

Header Text: c4591001

Visit: POT_COVID_CONVA 2 - Unscheduled Visit Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF
on Dec/03/2020 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: 11171036

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

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5.g				
Date	Location	User	Value	Reason
Feb-15-2021 12:27:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BRSRBD	Changed Information (DELETED)
Dec-04-2020 18:16:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BRSRBD	Initial Entry

5.g Sample ID				
Date	Location	User	Value	Reason
Feb-18-2021 17:24:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Changed Information
Feb-18-2021 17:23:23 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BRSRBD	Changed Information
Feb-15-2021 12:27:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BRSRBD	Changed Information (DELETED)
Dec-04-2020 18:16:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BRSRBD	Initial Entry

090177e196ae3dcc\Final\Final On: 01-Apr-2021 04:41 (GMT)

Header Text: c4591001**Visit:** POT_COVID_CONVA 3 - Unscheduled Visit **Form:** DATE OF VISIT - ILLNESS CONVALESCENT - eCRF Audit Trail History on Jan/07/2021**Form Version:** 22-Apr-2020 21:04**Form Status:** Data Complete, Frozen, Verified**Site No:** 1117**Site Name:** (1117) Sundance Clinical Research**Subject No:** 11171036**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 10:58[Back to Form](#)**1. Date of Visit**

Date	Location	User	Value	Reason
Feb-16-2021 15:49:18 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Feb-15-2021 12:51:19 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Changed data per query
Jan-28-2021 14:47:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	See CCG 8.29.2 COVID_B was combined into COVID_A and COVID_B was made Erroneous this Convalescent visit data should be cleared and marked Erroneous. Send in an SCF to VRD for CT29 sample destruction and add FORM level comments of NA to SAMP TRK form.
Jan-26-2021 11:27:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Jan/7/2021	Initial Entry

3. COVID-19 Illness Visit:

Date	Location	User	Value	Reason
Feb-15-2021 20:41:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (b) (4)	Query 1: Closed	Auto closed by Validation Check: VC_SV001_10
Feb-15-2021 12:51:02 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Changed data per query

Header Text: c4591001

Visit: POT_COVID_CONVA 3 - Unscheduled Visit **Form:** DATE OF VISIT - ILLNESS CONVALESCENT - eCRF Audit Trail
on Jan/07/2021 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: 11171036

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

Canada)				
Jan-28-2021 00:13:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued: Opened	DM : COVID_A1 is recorded three times with different Date of visits. Please review and update the data as appropriate. Else, clarify.
Jan-27-2021 13:40:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	IT WAS DETERMINED THAT THIS WAS ON ILLNESS EVENT REQUIRING THREE ADDITIONAL FOLLOW UP APPTS TO RESOLUTION. DATUM IS CORRECT.
Jan-27-2021 00:35:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (b) (4)	Query 1: Opened	DMW7004163;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-26-2021 11:27:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: COVID_A1	Initial Entry

090177e196ae3dcc\Final\Final On: 01-Apr-2021 04:41 (GMT)

Header Text: c4591001

Visit: POT_COVID_CONVA 3 - Unscheduled Visit Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF
on Jan/07/2021 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: 11171036

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

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1. Data Origin

Date	Location	User	Value	Reason
Jan-26-2021 11:28:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Jan-26-2021 11:28:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SERUM	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Feb-15-2021 12:46:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 4: Closed	Close Auto Query
Feb-15-2021 12:46:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 3: Closed	Close Auto Query
Feb-15-2021 12:46:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Collection: Jan/7/2021	Changed Information
Feb-15-2021 12:44:32 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 4: Opened	Response to "Sample Collected?" is No, but Barcodes are present on the page.
Feb-15-2021 12:42:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 3: Opened	'Sample Collected?' is marked as No and 'If no sample was collected or sample was not collected according to protocol, please provide reason' is missing. Please review and update as appropriate.

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Header Text: c4591001**Visit:** POT_COVID_CONVA 3 - Unscheduled Visit **Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF
on Jan/07/2021 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:** 11171036**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 10:58

Feb-15-2021 12:42:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Deleted	Close Auto Query
Feb-15-2021 12:42:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Changed Information
Feb-15-2021 12:41:54 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Jan-26-2021 11:28:17 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Jan-26-2021 11:28:07 (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-26-2021 11:28:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Collection: Jan/7/2021	Initial Entry

5.a

Date	Location	User	Value	Reason
Feb-15-2021 12:44:32 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BRDFPG	Changed Information
Feb-15-2021 12:41:54 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BRDFPG	Changed Information (DELETED)
Jan-26-2021 11:28:17 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BRDFPG	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Feb-15-2021 12:44:32 (UTC-06:00) Central Time	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BRDFPG	Changed Information

Header Text: c4591001**Visit:** POT_COVID_CONVA 3 - Unscheduled Visit **Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF
on Jan/07/2021 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:** 11171036**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 10:58

(US & Canada)		(b) (4), (b) (6)		
Feb-15-2021 12:41:54 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BRDFPG	Changed Information (DELETED)
Jan-26-2021 11:28:17 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BRDFPG	Initial Entry

5.b

Date	Location	User	Value	Reason
Feb-15-2021 12:44:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BRDFPH	Changed Information
Feb-15-2021 12:41:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BRDFPH	Changed Information (DELETED)
Jan-26-2021 11:28:32 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BRDFPH	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Feb-15-2021 12:44:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BRDFPH	Changed Information
Feb-15-2021 12:41:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BRDFPH	Changed Information (DELETED)
Jan-26-2021 11:28:32 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BRDFPH	Initial Entry

5.c

Date	Location	User	Value	Reason
Feb-15-2021 12:45:04 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BRDFPJ	Changed Information
Feb-15-2021 12:41:27 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BRDFPJ	Changed Information (DELETED)

Header Text: c4591001

Visit: POT_COVID_CONVA 3 - Unscheduled Visit Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF
on Jan/07/2021 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: 11171036

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

Jan-26-2021 11:28:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BRDFPJ	Initial Entry
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5.c Sample ID

Date	Location	User	Value	Reason
Feb-15-2021 12:45:04 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BRDFPJ	Changed Information
Feb-15-2021 12:41:27 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BRDFPJ	Changed Information (DELETED)
Jan-26-2021 11:28:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BRDFPJ	Initial Entry

5.d

Date	Location	User	Value	Reason
Feb-15-2021 12:45:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BSFB3F	Changed Information
Feb-15-2021 12:41:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BSFB3F	Changed Information (DELETED)
Jan-27-2021 14:28:46 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BSFB3F	Initial Entry

5.d Sample ID

Date	Location	User	Value	Reason
Feb-15-2021 12:45:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BSFB3F	Changed Information
Feb-15-2021 12:41:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BSFB3F	Changed Information (DELETED)
Jan-27-2021 14:28:46 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BSFB3F	Initial Entry

090177e196ae3dcc\Final\Final On: 01-Apr-2021 04:41 (GMT)

Header Text: c4591001

Visit: POT_COVID_CONVA 3 - Unscheduled Visit **Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF
on Jan/07/2021 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: 11171036

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

5.e

Date	Location	User	Value	Reason
Feb-15-2021 12:45:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BSFB3G	Changed Information
Feb-15-2021 12:40:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BSFB3G	Changed Information (DELETED)
Jan-27-2021 14:30:02 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BSFB3G	Initial Entry

5.e Sample ID

Date	Location	User	Value	Reason
Feb-15-2021 12:45:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BSFB3G	Changed Information
Feb-15-2021 12:40:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BSFB3G	Changed Information (DELETED)
Jan-27-2021 14:30:02 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BSFB3G	Initial Entry

090177e196ae3dcc\Final\Final On: 01-Apr-2021 04:41 (GMT)

Header Text: c4591001

Visit: End of Treatment - Unscheduled

Form: DISPOSITION - TREATMENT - eCRF Audit Trail History

Form Version: 15-Sep-2020 21:55

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1117

Site Name: (1117) Sundance Clinical Research

Subject No: 11171036

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

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1. Date of Completion/Discontinuation/Death :

Date	Location	User	Value	Reason
Oct-13-2020 13:21:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Oct/8/2020	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Oct-13-2020 13:21:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: VACCINATION	Initial Entry

3. Status:

Date	Location	User	Value	Reason
Oct-13-2020 13:21:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: COMPLETED	Initial Entry

090177e196ae3dcc\Final\Final On: 01-Apr-2021 04:41 (GMT)

Header Text: c4591001**Visit:** POT_COVID_REPEAT_SWAB 1 -
Unscheduled Visit on Dec/07/2020**Form:** DATE OF VISIT - REPEAT SWAB - eCRF Audit Trail History**Form Version:** 10-Oct-2020 15:57**Form Status:** Data Complete, Frozen, Verified**Site No:** 1117**Site Name:** (1117) Sundance Clinical Research**Subject No:** 11171036**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 10:58[Back to Form](#)**1. Date of Visit**

Date	Location	User	Value	Reason
Mar-01-2021 06:01:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Feb-26-2021 11:55:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Changed data per query
Feb-26-2021 04:09:40 (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-25-2021 11:23:31 (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 data within this visit as Not Done/Not Applicable at the form level.
Jan-21-2021 13:45:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Dec/7/2020	Initial Entry

2. Erroneous Visit

Date	Location	User	Value	Reason
Feb-25-2021 11:23:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: ERRONEOUS VISIT	Initial Entry

3. COVID-19 Repeat Swab:

Header Text: c4591001

Visit: POT_COVID_REPEAT_SWAB 1 -
Unscheduled Visit on Dec/07/2020

Form: DATE OF VISIT - REPEAT SWAB - eCRF Audit Trail History

Form Version: 10-Oct-2020 15:57

Form Status: Data Complete, Frozen, Verified

Site No: 1117

Site Name: (1117) Sundance Clinical Research

Subject No: 11171036

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

Date	Location	User	Value	Reason
Feb-25-2021 11:23:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry
Feb-25-2021 11:23:02 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Changed Information
Jan-21-2021 13:45:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: COVID_AR1	Initial Entry

Header Text: c4591001**Visit:** POT_COVID_REPEAT_SWAB 1 -
Unscheduled Visit on Dec/07/2020**Form Version:** 10-Oct-2020 15:57**Site No:** 1117**Subject No:** 11171036**Generated By:** (b) (4)**Form:** ELECTRONIC SAMPLE TRACKING - REPEAT SWAB - eCRF Audit
Trail History**Form Status:** Data Complete, Frozen, Verified**Site Name:** (1117) Sundance Clinical Research**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 10:58[Back to Form](#)**1. Data Origin**

Date	Location	User	Value	Reason
Mar-05-2021 08:53:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Not Applicable	Initial Entry
Mar-04-2021 11:36:27 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry:	Initial Entry
Feb-25-2021 11:22:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Not Applicable	Initial Entry
Feb-25-2021 11:22:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry:	Changed Information
Jan-21-2021 13:46:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Mar-05-2021 08:53:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry
Mar-04-2021 11:36:27 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Initial Entry
Feb-25-2021 11:22:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry
Feb-25-2021 11:22:19 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Changed Information
Jan-21-2021 13:46:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NASAL_SWAB_SELF	Initial Entry

3. Sample Collected?

Header Text: c4591001**Visit:** POT_COVID_REPEAT_SWAB 1 -
Unscheduled Visit on Dec/07/2020**Form Version:** 10-Oct-2020 15:57**Site No:** 1117**Subject No:** 11171036**Generated By:** (b) (4)**Form:** ELECTRONIC SAMPLE TRACKING - REPEAT SWAB - eCRF Audit
Trail History**Form Status:** Data Complete, Frozen, Verified**Site Name:** (1117) Sundance Clinical Research**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 10:58

Date	Location	User	Value	Reason
Mar-05-2021 09:49:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Closed	Response satisfies query
Mar-05-2021 08:53:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry
Mar-05-2021 08:53:23 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Answered	Changed data per query
Mar-05-2021 00:17:19 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Opened	DM: Kindly review the form and update the missing data with yellow background.
Mar-04-2021 11:36:27 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Initial Entry
Feb-25-2021 11:22:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry
Feb-25-2021 11:22:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Deleted	Close Auto Query
Feb-25-2021 11:22:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Changed Information
Feb-25-2021 11:21:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Jan-21-2021 13:46:18 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Jan-21-2021 13:46:01 (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-21-2021 13:46:01 (UTC-06:00) Central Time	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

Header Text: c4591001

Visit: POT_COVID_REPEAT_SWAB 1 -
Unscheduled Visit on Dec/07/2020

Form: ELECTRONIC SAMPLE TRACKING - REPEAT SWAB - eCRF Audit
Trail History

Form Version: 10-Oct-2020 15:57

Form Status: Data Complete, Frozen, Verified

Site No: 1117

Site Name: (1117) Sundance Clinical Research

Subject No: 11171036

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

(US & Canada)			Date of Collection:	
			Dec/7/2020	

4. If no sample was collected or sample was not collected according to protocol, please provide reason:

Date	Location	User	Value	Reason
Mar-05-2021 08:53:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry
Mar-04-2021 11:36:27 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Initial Entry
Feb-25-2021 11:22:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.a

Date	Location	User	Value	Reason
Feb-25-2021 11:21:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID:	Changed Information
Jan-21-2021 13:46:18 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: CV60869	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Feb-25-2021 11:21:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Changed Information
Jan-26-2021 14:53:55 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (b) (4)	Query 1: Cl osed	Auto closed by Validation Check: VC_BEETRK001_01
Jan-25-2021 19:01:55 (UTC-06:00) Central Time	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: An swered	Original value is correct

090177e196ae3dcc\Final\Final On: 01-Apr-2021 04:41 (GMT)

Header Text: c4591001

Visit: POT_COVID_REPEAT_SWAB 1 -
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Site No: 1117

Subject No: 11171036

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - REPEAT SWAB - eCRF Audit
Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1117) Sundance Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:58

(US & Canada)				
Jan-21-2021 20:12:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (b) (4)	Query 1: Opened	DMW6947444;This Barcode is already recorded more than once (for the same subject). Please review and update as appropriate.
Jan-21-2021 13:46:18 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: CV60869	Initial Entry

Header Text: c4591001

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Subject No: 11171036

Generated By: (b) (4)

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Form Status:

Site Name: (1117) Sundance Clinical Research

Subject Initials: ---

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Date	Location	User	Value	Reason
Sep-03-2020 08:23:47 (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: 11171036

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - Audit Trail

Form Status:

Site Name: (1117) Sundance Clinical Research

Subject Initials: ---

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Date	Location	User	Value	Reason
Sep-15-2020 14:27:37 (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: 11171036

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - Audit Trail

Form Status:

Site Name: (1117) Sundance Clinical Research

Subject Initials: ---

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Date	Location	User	Value	Reason
Oct-02-2020 09:21:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

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Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1117

Subject No: 11171036

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - Audit Trail

Form Status:

Site Name: (1117) Sundance Clinical Research

Subject Initials: ---

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Date	Location	User	Value	Reason
Oct-02-2020 09:23:23 (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: 11171036

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - Audit Trail

Form Status:

Site Name: (1117) Sundance Clinical Research

Subject Initials: ---

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Date	Location	User	Value	Reason
Oct-09-2020 14:44:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

090177e196ae3dcc\Final\Final On: 01-Apr-2021 04:41 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1117

Subject No: 11171036

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - Audit Trail

Form Status:

Site Name: (1117) Sundance Clinical Research

Subject Initials: ---

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Date	Location	User	Value	Reason
Oct-09-2020 14:46:33 (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: 11171036

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - Audit Trail

Form Status:

Site Name: (1117) Sundance Clinical Research

Subject Initials: ---

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*** THIS REPEATING FORM HAS BEEN DELETED ***

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Date	Location	User	Value	Reason
Nov-07-2020 21:40:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Deleted	Changed Information
Nov-04-2020 14:52:45 (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: 11171036

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - Audit Trail

Form Status:

Site Name: (1117) Sundance Clinical Research

Subject Initials: ---

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*** THIS REPEATING FORM HAS BEEN DELETED ***

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Date	Location	User	Value	Reason
Nov-07-2020 21:40:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Deleted	Changed Information
Nov-04-2020 14:53:43 (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: 11171036

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - Audit Trail

Form Status:

Site Name: (1117) Sundance Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:58

*** THIS REPEATING FORM HAS BEEN DELETED ***

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Date	Location	User	Value	Reason
Nov-07-2020 21:39:27 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Deleted	Changed Information
Nov-04-2020 14:54:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

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Header Text: c4591001

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Generated By: (b) (4)

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Form Status:

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Date	Location	User	Value	Reason
Dec-04-2020 17:58:26 (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: 11171036

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - Audit Trail

Form Status:

Site Name: (1117) Sundance Clinical Research

Subject Initials: ---

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Date	Location	User	Value	Reason
Jan-04-2021 15:19:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

090177e196ae3dcc\Final\Final On: 01-Apr-2021 04:41 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1117

Subject No: 11171036

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - Audit Trail

Form Status:

Site Name: (1117) Sundance Clinical Research

Subject Initials: ---

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Date	Location	User	Value	Reason
Jan-04-2021 15:22:30 (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: 11171036

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - Audit Trail

Form Status:

Site Name: (1117) Sundance Clinical Research

Subject Initials: ---

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Date	Location	User	Value	Reason
Jan-04-2021 15:24:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

090177e196ae3dcc\Final\Final On: 01-Apr-2021 04:41 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

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Site No: 1117

Subject No: 11171036

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - Audit Trail

Form Status:

Site Name: (1117) Sundance Clinical Research

Subject Initials: ---

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Date	Location	User	Value	Reason
Jan-04-2021 15:25:17 (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: 11171036

Generated By: (b) (4)

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Form Status:

Site Name: (1117) Sundance Clinical Research

Subject Initials: ---

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Date	Location	User	Value	Reason
Jan-04-2021 15:26:24 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

090177e196ae3dcc\Final\Final On: 01-Apr-2021 04:41 (GMT)

Header Text: c4591001

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Generated By: (b) (4)

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Form Status:

Site Name: (1117) Sundance Clinical Research

Subject Initials: ---

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Date	Location	User	Value	Reason
Jan-21-2021 12:53:07 (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: 11171036

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - Audit Trail

Form Status:

Site Name: (1117) Sundance Clinical Research

Subject Initials: ---

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Date	Location	User	Value	Reason
Jan-21-2021 12:55:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

090177e196ae3dcc\Final\Final On: 01-Apr-2021 04:41 (GMT)

Header Text: c4591001

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Subject No: 11171036

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1117) Sundance Clinical Research

Subject Initials: ---

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1. Category:

Date	Location	User	Value	Reason
Sep-03-2020 08:23:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: ADVERSE EVENT	Initial Entry

2. AE ID:

Date	Location	User	Value	Reason
Sep-03-2020 08:23:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 1	Initial Entry

3. Adverse Event:

(If possible specify diagnosis, not individual symptoms)

Date	Location	User	Value	Reason
Oct-07-2020 22:11:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Closed	moved to Med Hx
Oct-06-2020 09:19:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Opened	CLINICAL - SAE safety update included a past medical history of type 2 Diabetes mellitus (2019); based on renal issues during this event, please consider addition of DM to Med History CRF
Oct-02-2020 07:22:55 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Closed	event term updated in SDB. issue resolved
Sep-17-2020 09:38:19 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Reissued:Opened	SAE RECON 1: Per latest SAE listing from Safety, Term still shows as 'FALL' Please submit a follow up AEM form to update Term in Safety database.
Sep-16-2020 13:09:37 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Answered	Original value is correct
Sep-16-2020 07:03:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Opened	SAE RECON:AER#2020343046 The term in AE CRF was

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Header Text: c4591001

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Site No: 1117

Subject No: 11171036

Generated By: (b) (4)

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				updated to SYNCOPAL EPISODE while retained as FALL in Safety database. Please confirm.If safety update is required, please submit a follow-up form.
Sep-16-2020 06:17:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	event entered in AE CRF
Sep-15-2020 14:04:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Changed Information
Sep-15-2020 14:04:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Syncopal Episode	Changed Information
Sep-07-2020 04:49:19 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	SAE RECON:AER#2020343046 Suicidal Ideation(onset date:27Aug2020)was reported as serious in Safety database but missing in AE CRF. Please confirm and update CRF. If safety update is required, submit a follow-up SAE Form.
Sep-03-2020 08:23:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Fall resulting in Hospitalization	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason
Sep-16-2020 07:00:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	updated to 26Aug2020 on both database. issue resolved
Sep-15-2020 14:02:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Changed Information
Sep-15-2020 14:02:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Aug/26/2020 UNK:UNK	Changed Information
Sep-04-2020 05:18:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	SAE RECON: AER#2020343046 ,onset date was

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Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1117

Subject No: 11171036

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

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				reported as 08Aug2020 in SDB however, recorded as 02Sep2020 on AE CRF. Please confirm correct Onset Date. If safety update is required, please submit a follow-up SAE form.
Sep-03-2020 08:23:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sep/2/2020 11:00	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Sep-15-2020 14:04:37 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO End Date Time: Aug/30/2020 UNK:UNK	Changed Information
Sep-03-2020 08:23:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
Sep-03-2020 08:23:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 4	Initial Entry

7. Is the adverse event serious?

If Yes, NOTIFY PFIZER IMMEDIATELY.

Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).

Date	Location	User	Value	Reason
Nov-16-2020 14:32:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Closed	Query closed; will follow for SAE update with the requested COVID test info
Oct-26-2020 21:00:18	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Reissued:Opened	Clinical – Thank you.

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Header Text: c4591001**Visit:** Logs - Unscheduled**Form Version:** 22-Apr-2020 21:02**Site No:** 1117**Subject No:** 11171036**Generated By:** (b) (4)**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History**Form Status:** Data Complete, Locked, Frozen, Verified**Site Name:** (1117) Sundance Clinical Research**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 10:58

(UTC-06:00) Central Time (US & Canada)		(b) (4), (b) (6)		If NO hospital Covid test performed is known, please submit this information on a follow-up SAE form, as pertinent information for this trial.
Oct-23-2020 15:10:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Answered	PER PARTICIPANT INTERVIEW, HE IS NOT AWARE THAT COVID TESTING WAS DONE WITH THIS HOSPITAL ADMISSION. ALSO, PER MEDICAL RECORD REVIEW, THERE WAS NO COVID TESTING REPORTED IN THE RECORD.
Oct-22-2020 22:23:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Opened	Clinical - COVID testing has not been reported in the SAE submitted to safety. Please submit a follow-up SAE form [#2020343046] to provide whether COVID testing was performed (yes/no) and if yes, the results.
Sep-04-2020 05:10:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Sep-03-2020 08:23:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	For AE Fall resulting in Hospitalization: Response to "Is the adverse event serious?" is 'Yes' but "Serious Adverse Event Number" is blank.
Sep-03-2020 08:23:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Is this serious event associated with congenital anomaly or birth defe	Initial Entry

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			ct?	
			NO	
			Did this serious event result in death?	
			NO	
			Did this serious event require or prolong hospitalization?	
			YES	
			Did this serious event result in persistent or significant disability/incapacity?	
			NO	
			Is this serious event life threatening?	
			NO	
			Other medically important serious event	
			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.

Date	Location	User	Value	Reason
Sep-03-2020 08:23:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Nov-16-2020 19:52:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 4: Closed	Response satisfies query
Nov-16-2020 16:04:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 4: Answered	UPDATED SOURCE DOCUMENTATION TO REFLECT THE SAME VERBIAGE AS

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090177e196ae3dcc\Final\Final On: 01-Apr-2021 04:41 (GMT)

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				EDC. AE SHEET TO BE SCANNED AND REUPLOADED TO CLOUD DOCUMENT REPOSITORY.
Nov-14-2020 18:20:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 4: Opened	Per source, not related due to unknown. Please confirm and upload updated source in Complion.
Oct-08-2020 11:16:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Closed	Response satisfies query
Oct-06-2020 09:17:06 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Closed	Response satisfies query
Oct-02-2020 14:39:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Answered	SAE UPDATE BEING SUBMITTED 02OCT2020
Oct-02-2020 09:26:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Answered	Changed data per query
Sep-28-2020 13:49:02 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Opened	CLINQUERY - please submit a safety followup containing laboratory or other information underlying Other conditions of acute kidney injury and rhabdomyolysis
Sep-23-2020 03:38:24 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Charu Sabharwal (b) (4)	Query 2: Reissued:Opened	Clinical_ if the subject experienced the additional adverse events noted, please assess for seriousness and report accordingly
Sep-16-2020 04:49:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Sep-15-2020 14:10:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Answered	New Information
Sep-15-2020 14:10:10	ACV0PFEINFP6000	auto query	Query 1: Answered	New Information

Header Text: c4591001**Visit:** Logs - Unscheduled**Form Version:** 22-Apr-2020 21:02**Site No:** 1117**Subject No:** 11171036**Generated By:** (b) (4)**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History**Form Status:** Data Complete, Locked, Frozen, Verified**Site Name:** (1117) Sundance Clinical Research**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 10:58

(UTC-06:00) Central Time (US & Canada)		(autoquery)		
Sep-15-2020 14:10:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NOT RELATED If Not Related to study treatment(s), this event is due to: OTHER <i>If Other, specify:</i> Due to heat, acute kidney injury, rhabdomyolysis	New Information
Sep-08-2020 14:10:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Opened	SAE followup states that subject reported heat exhaustion as the presumed cause for his fall; please enter this cause if the Investigator is in agreement.
Sep-04-2020 09:35:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	DM: The response for "Is this event related to study treatment" is reported as 'Not related' however indication for AE is missing? kindly review and update.
Sep-03-2020 08:23:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NOT RELATED	Initial Entry

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Sep-03-2020 08:23:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NOT APPLICABLE	Initial Entry

11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
Sep-03-2020 08:23:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

12. Was a Non-Drug Treatment given?

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Date	Location	User	Value	Reason
Sep-03-2020 08:23:47 (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
Sep-16-2020 07:01:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Closed	resolved
Sep-15-2020 14:11:24 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Answered	New Information

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Subject No: 11171036

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13. What was the outcome of this adverse event?:

Date	Location	User	Value	Reason
Sep-15-2020 14:11:24 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Sep-15-2020 14:11:24 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: RECOVERED/RESOLVED	New Information
Sep-15-2020 14:04:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	For AE Syncopal Episode: Response to "What was the outcome of this adverse event?" is 'Unknown' but End Date/Time is provided or "Is the adverse event still ongoing?" is marked "Yes".
Sep-07-2020 04:00:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Opened	SAE RECON:AER# 2020343046 ,outcome was updated to RECOVERED/RESOLVED in SAE form however, reported as UNKNOWN on AE CRF. Please confirm correct outcome. If safety update is required, please submit a follow-up form.
Sep-03-2020 08:23:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	For AE Fall resulting in Hospitalization: Response to "What was the outcome of this adverse event?" is 'Unknown' but End Date/Time is provided or "Is the adverse event still ongoing?" is marked "Yes".
Sep-03-2020 08:23:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNKNOWN	Initial Entry

14. Did the adverse event cause the subject to be discontinued from the study?

Date	Location	User	Value	Reason
Sep-03-2020 08:23:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

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15. Serious Adverse Event Number: For Pfizer Use Only

Date	Location	User	Value	Reason
Sep-04-2020 05:10:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 2020343046	Initial Entry

Header Text: c4591001

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Subject No: 11171036

Generated By: (b) (4)

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1. Category:

Date	Location	User	Value	Reason
Sep-15-2020 14:27:37 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: ADVERSE EVENT	Initial Entry

2. AE ID:

Date	Location	User	Value	Reason
Sep-15-2020 14:27:37 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 2	Initial Entry

3. Adverse Event:

(If possible specify diagnosis, not individual symptoms)

Date	Location	User	Value	Reason
Sep-15-2020 14:27:37 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Suicidal ideation	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason
Sep-15-2020 14:27:37 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Aug/27/2020 UNK:UNK	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Sep-15-2020 14:27:37 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO End Date Time: Aug/30/2020 UNK:UNK	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
Sep-17-2020 05:48:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query

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Sep-16-2020 13:10:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Initial Entry
Sep-16-2020 13:10:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 4	Initial Entry
Sep-16-2020 09:28:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	DM: Kindly review and consider to update the missing data. Thank you.

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
Sep-16-2020 05:54:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Sep-15-2020 14:27:37 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	For AE Suicidal ideation: Response to "Is the adverse event serious?" is 'Yes' but "Serious Adverse Event Number" is blank.
Sep-15-2020 14:27:37 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Is this serious event associated with congenital anomaly or birth defect? NO Did this serious event result in death ? NO Did this serious event require or prol ong hospitalization? YES	Initial Entry

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			<p>Did this serious event result in persistent or significant disability/incapacity?</p> <p>NO</p> <p>Is this serious event life threatening?</p> <p>NO</p> <p>Other medically important serious event</p> <p>NO</p>	
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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
Sep-15-2020 14:27:37 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Sep-15-2020 14:27:37 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NOT RELATED If Not Related to study treatment(s), this event is due to: OTHER If Other, specify: Per participant: "due to being in the hospital"	Initial Entry

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Sep-15-2020 14:27:37 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NOT APPLICABLE	Initial Entry

11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
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Header Text: c4591001**Visit:** Logs - Unscheduled**Form Version:** 22-Apr-2020 21:02**Site No:** 1117**Subject No:** 11171036**Generated By:** (b) (4)**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History**Form Status:** Data Complete, Locked, Frozen, Verified**Site Name:** (1117) Sundance Clinical Research**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 10:58

Sep-15-2020 14:27:37 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry
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12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Sep-15-2020 14:27:37 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

13. What was the outcome of this adverse event?:

Date	Location	User	Value	Reason
Sep-15-2020 14:30:06 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Sep-15-2020 14:30:06 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: RECOVERED/RESOLVED	Changed Information
Sep-15-2020 14:27:37 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	For AE Suicidal ideation: Response to "What was the outcome of this adverse event?" is 'Not Recovered/Not Resolved' but AE End Date/Time is present.
Sep-15-2020 14:27:37 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NOT RECOVERED/NOT RESOLVE D	Initial Entry

14. Did the adverse event cause the subject to be discontinued from the study?

Date	Location	User	Value	Reason
Sep-15-2020 14:27:37 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

15. Serious Adverse Event Number: For Pfizer Use Only

Date	Location	User	Value	Reason
Sep-16-2020 05:54:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 2020343046	Initial Entry

Header Text: c4591001

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1. Category:

Date	Location	User	Value	Reason
Oct-02-2020 09:21:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: ADVERSE EVENT	Initial Entry

2. AE ID:

Date	Location	User	Value	Reason
Oct-02-2020 09:21:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 3	Initial Entry

3. Adverse Event:

(If possible specify diagnosis, not individual symptoms)

Date	Location	User	Value	Reason
Oct-02-2020 15:13:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	PFETMS Oracle (b) (4)	Query 1: Closed	Discrepancy has been closed.
Oct-02-2020 13:36:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Transcription Error
Oct-02-2020 13:36:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: ACUTE KIDNEY INJURY	Transcription Error
Oct-02-2020 11:18:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	PFETMS Oracle (b) (4)	Query 1: Opened	Clarify ACUTE KINDEY INJURY as follows...Should the spelling be ACUTE KIDNEY INJURY? If so, edit. Otherwise clarify. Thank you.
Oct-02-2020 09:21:30	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Acute Kindey injur	Initial Entry

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(UTC-06:00)
Central Time (US
& Canada)

y

4. Start Date Time:

Date	Location	User	Value	Reason
Oct-02-2020 09:21:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Closed	Close Auto Query
Oct-02-2020 09:21:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Oct-02-2020 09:21:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Aug/26/2020 UNK:UNK	Transcription Error
Oct-02-2020 09:21:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Opened	For Acute Kindey injury: Start date 26/Apr/2020 is before VID1VX1L visit date 20/Aug/2020. Please review and update as appropriate.
Oct-02-2020 09:21:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	Start date is before Consent Date 20/Aug/2020.
Oct-02-2020 09:21:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Apr/26/2020 UNK:UNK	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Oct-02-2020 09:22:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Oct-02-2020 09:22:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO End Date Time: Aug/30/2020 UNK:UNK	Transcription Error
Oct-02-2020 09:21:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	For Acute Kindey injury End Date & Time 30/Apr/2020

090177e196ae3dcc\Final\Final On: 01-Apr-2021 04:41 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1117

Subject No: 11171036

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1117) Sundance Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:58

				UNK:UNK is before the Start Date & Time 26/Aug/2020 UNK:UNK.
Oct-02-2020 09:21:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO End Date Time: Apr/30/2020 UNK:UNK	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
Oct-02-2020 09:21:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 1	Initial Entry

7. Is the adverse event serious?

If Yes, NOTIFY PFIZER IMMEDIATELY.

Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).

Date	Location	User	Value	Reason
Oct-02-2020 09:21:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

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

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

Date	Location	User	Value	Reason
Oct-02-2020 09:21:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Oct-02-2020 09:21:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NOT RELATED If Not Related to study treatment(s), this event is due to: OTHER	Initial Entry

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Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1117

Site Name: (1117) Sundance Clinical Research

Subject No: 11171036

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

			If Other, specify: HEAT RELATED EVENT	
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10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Oct-02-2020 09:21:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NOT APPLICABLE	Initial Entry

11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
Oct-02-2020 09:21:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Oct-02-2020 09:21:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

13. What was the outcome of this adverse event?:

Date	Location	User	Value	Reason
Oct-02-2020 09:21:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: RECOVERED/RESOLVED	Initial Entry

14. Did the adverse event cause the subject to be discontinued from the study?

Date	Location	User	Value	Reason
Oct-02-2020 09:21:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

090177e196ae3dcc\Final\Final On: 01-Apr-2021 04:41 (GMT)

Header Text: c4591001

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Site No: 1117

Subject No: 11171036

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1117) Sundance Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:58

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1. Category:

Date	Location	User	Value	Reason
Oct-02-2020 09:23:23 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: ADVERSE EVENT	Initial Entry

2. AE ID:

Date	Location	User	Value	Reason
Oct-02-2020 09:23:23 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 4	Initial Entry

3. Adverse Event:

(If possible specify diagnosis, not individual symptoms)

Date	Location	User	Value	Reason
Oct-02-2020 09:23:23 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: RHABDOMYOLYSIS	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason
Oct-02-2020 09:23:23 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Aug/26/2020 UNK:UNK	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Oct-02-2020 09:23:23 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO End Date Time: Aug/30/2020 UNK:UNK	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
Oct-02-2020 09:23:23 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 1	Initial Entry

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Header Text: c4591001

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Subject No: 11171036

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

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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
Oct-02-2020 09:23:23 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

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

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

Date	Location	User	Value	Reason
Oct-02-2020 09:23:23 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Oct-02-2020 09:23:23 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NOT RELATED If Not Related to study treatment(s), this event is due to: OTHER If Other, specify: HEAT RELATED EVENT	Initial Entry

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Oct-02-2020 09:23:23 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NOT APPLICABLE	Initial Entry

11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
Oct-02-2020 09:23:23 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

090177e196ae3dcc\Final\Final On: 01-Apr-2021 04:41 (GMT)

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Generated By: (b) (4)

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Site Name: (1117) Sundance Clinical Research

Subject Initials: ---

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12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Oct-02-2020 09:23:23 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

13. What was the outcome of this adverse event?:

Date	Location	User	Value	Reason
Oct-02-2020 09:23:23 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: RECOVERED/RESOLVED	Initial Entry

14. Did the adverse event cause the subject to be discontinued from the study?

Date	Location	User	Value	Reason
Oct-02-2020 09:23:23 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

090177e196ae3dcc\Final\Final On: 01-Apr-2021 04:41 (GMT)

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Subject No: 11171036

Generated By: (b) (4)

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1. Category:

Date	Location	User	Value	Reason
Oct-09-2020 14:44:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: ADVERSE EVENT	Initial Entry

2. AE ID:

Date	Location	User	Value	Reason
Oct-09-2020 14:44:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 5	Initial Entry

3. Adverse Event:

(If possible specify diagnosis, not individual symptoms)

Date	Location	User	Value	Reason
Oct-09-2020 14:44:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: ARM SORENESS, LEFT	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason
Oct-09-2020 14:44:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sep/22/2020 08:00	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Oct-09-2020 14:44:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO End Date Time: Oct/2/2020 UNK:UNK	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
Oct-09-2020 14:44:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 2	Initial Entry

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Header Text: c4591001**Visit:** Logs - Unscheduled**Form Version:** 22-Apr-2020 21:02**Site No:** 1117**Subject No:** 11171036**Generated By:** (b) (4)**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History**Form Status:** Data Complete, Locked, Frozen, Verified**Site Name:** (1117) Sundance Clinical Research**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 10:58**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
Oct-09-2020 14:44:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

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

Date	Location	User	Value	Reason
Oct-09-2020 14:44:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Oct-09-2020 14:44:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NOT RELATED If Not Related to study treatment(s), this event is due to: OTHER If Other, specify: ETIOLOGY NOT KNOWN PER INVESTIGATOR	Initial Entry

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Oct-09-2020 14:44:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NOT APPLICABLE	Initial Entry

11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
Oct-09-2020 14:44:47 (UTC-06:00) Central Time	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

Header Text: c4591001

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Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1117) Sundance Clinical Research

Subject Initials: ---

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(US & Canada)

(b) (4), (b) (6)

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Oct-09-2020 14:44:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

13. What was the outcome of this adverse event?:

Date	Location	User	Value	Reason
Oct-09-2020 14:44:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: RECOVERED/RESOLVED	Initial Entry

14. Did the adverse event cause the subject to be discontinued from the study?

Date	Location	User	Value	Reason
Oct-09-2020 14:44:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

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Subject No: 11171036

Generated By: (b) (4)

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Subject Initials: ---

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1. Category:

Date	Location	User	Value	Reason
Oct-09-2020 14:46:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: ADVERSE EVENT	Initial Entry

2. AE ID:

Date	Location	User	Value	Reason
Oct-09-2020 14:46:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 6	Initial Entry

3. Adverse Event:

(If possible specify diagnosis, not individual symptoms)

Date	Location	User	Value	Reason
Oct-09-2020 14:46:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NECK STIFFNESS	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason
Oct-09-2020 14:47:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Oct-09-2020 14:47:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sep/21/2020 08:00	Transcription Error
Oct-09-2020 14:46:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	For NECK STIFFNESS Start Date 21/Oct/2020, is a future date relative to when it was entered on 09/Oct/2020. Please correct.
Oct-09-2020 14:46:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Oct/21/2020 08:00	Initial Entry

5. Is the adverse event still ongoing?

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Subject No: 11171036

Subject Initials: ---

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Date	Location	User	Value	Reason
Nov-20-2020 13:42:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Closed	Response satisfies query
Nov-20-2020 12:52:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Answered	New Information
Nov-20-2020 12:52:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO End Date Time: Oct/24/2020 UNK:UNK	New Information
Nov-19-2020 14:48:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Opened	CLINQUERY - Please verify if AE is still ongoing, or update END DATE and OUTCOME as applicable.
Nov-16-2020 14:50:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Per study team directive non-critical query closed for FDA/EUA snapshot, will be issued at a later date.
Nov-10-2020 11:38:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	CLINQUERY - Please verify if AE is still ongoing, or update END DATE and OUTCOME as applicable.
Oct-09-2020 14:46:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
Oct-09-2020 14:46:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 1	Initial Entry

7. Is the adverse event serious?

If Yes, NOTIFY PFIZER IMMEDIATELY.

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Subject Initials: ---

Generated By: (b) (4)

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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
Dec-07-2020 04:40:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	All other forms are locked. Event added as a separate SAE in Inform
Dec-04-2020 17:55:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	THIS IS AN INAPPROPRIATE PLACE FOR THIS QUERY, PLEASE BE MINDFUL OF WHERE QUERIES ARE PLACE WITHIN THE DATABASE. SAE IS BEING ADDED.
Dec-04-2020 04:52:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	SAE RECON:AER#2020479673 suicidal ideation W/ admission(onset date:20Nov2020)was reported as a new SAE in Safety database. Please confirm if it is a separate SAE from suicidal ideation with onset date of 27Aug2020.
Oct-09-2020 14:46:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

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

Date	Location	User	Value	Reason
Oct-09-2020 14:46:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Oct-09-2020 14:46:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NOT RELATED If Not Related to study treatment(s), this event is due to:	Initial Entry

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Header Text: c4591001

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Generated By: (b) (4)

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			OTHER <i>If Other, specify:</i> ETIOLOGY UNKNOWN PER INVESTIGATOR	
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10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Oct-09-2020 14:46:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NOT APPLICABLE	Initial Entry

11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
Oct-09-2020 14:46:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Oct-09-2020 14:46:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

13. What was the outcome of this adverse event?:

Date	Location	User	Value	Reason
Nov-20-2020 12:52:46 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Nov-20-2020 12:52:46 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: RECOVERED/RESOLVED	Changed Information
Nov-20-2020 12:52:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	For AE NECK STIFFNESS: Response to "What was the outcome of this adverse event?" is 'Recovering/Resolving' but AE End Date/Time is present.

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Generated By: (b) (4)

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Oct-09-2020 14:46:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: RECOVERING/RESOLVING	Initial Entry
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14. Did the adverse event cause the subject to be discontinued from the study?

Date	Location	User	Value	Reason
Oct-09-2020 14:46:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

Header Text: c4591001

Visit: Logs - Unscheduled

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Site No: 1117

Subject No: 11171036

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Deleted, Verified

Site Name: (1117) Sundance Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:58

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1. Category:

Date	Location	User	Value	Reason
Nov-04-2020 14:52:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: ADVERSE EVENT	Initial Entry

2. AE ID:

Date	Location	User	Value	Reason
Nov-04-2020 14:52:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 7	Initial Entry

3. Adverse Event:

(If possible specify diagnosis, not individual symptoms)

Date	Location	User	Value	Reason
Nov-08-2020 11:41:37 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Nov-07-2020 21:38:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Changed data per query
Nov-06-2020 10:33:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	CLINQUERY - Per Sec 8.1, AE of SORE THROAT should have triggered a COVID ILLNESS VISIT irrespective of causality. Please confirm a visit and nasal swab was performed and capture term on SOD form only. Please review and update.
Nov-04-2020 14:52:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: SORE THROAT	Initial Entry

4. Start Date Time:

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Header Text: c4591001

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Site Name: (1117) Sundance Clinical Research

Subject No: 11171036

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

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Date	Location	User	Value	Reason
Nov-04-2020 14:52:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Oct/8/2020 UNK:UNK	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Nov-04-2020 14:52:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> YES	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
Nov-04-2020 14:52:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> 1	Initial Entry

7. Is the adverse event serious?

If Yes, NOTIFY PFIZER IMMEDIATELY.

Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).

Date	Location	User	Value	Reason
Nov-04-2020 14:52:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

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

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

Date	Location	User	Value	Reason
Nov-04-2020 14:52:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Nov-04-2020 14:52:45 (UTC-06:00) Central Time	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NOT RELATED	Initial Entry

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(US & Canada)		(b) (4), (b) (6)	If Not Related to study treatment(s), this event is due to: OTHER <i>If Other, specify:</i> SUSPECT VIRAL ILLNESS
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10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Nov-04-2020 14:52:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NOT APPLICABLE	Initial Entry

11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
Nov-04-2020 14:52:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Nov-04-2020 14:52:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

13. What was the outcome of this adverse event?:

Date	Location	User	Value	Reason
Nov-04-2020 14:52:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: RECOVERING/RESOLVING	Initial Entry

14. Did the adverse event cause the subject to be discontinued from the study?

Date	Location	User	Value	Reason
Nov-04-2020 14:52:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

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1. Category:

Date	Location	User	Value	Reason
Nov-04-2020 14:53:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: ADVERSE EVENT	Initial Entry

2. AE ID:

Date	Location	User	Value	Reason
Nov-04-2020 14:53:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 8	Initial Entry

3. Adverse Event:

(If possible specify diagnosis, not individual symptoms)

Date	Location	User	Value	Reason
Nov-16-2020 14:58:55 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Per study team directive non-critical query closed for FDA/EUA snapshot, will be issued at a later date.
Nov-08-2020 11:42:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued:Opened	CLINQUERY2 - Please note SHORTNESS OF BREATH is not captured on the SOD CRF within the COVID ILLNESS VISIT. Please review and update, or clarify. Thank you.
Nov-07-2020 21:38:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Changed data per query
Nov-06-2020 10:31:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	CLINQUERY - Per Sec 8.1, AE of SHORTNESS OF BREATH should have triggered a COVID ILLNESS VISIT

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				irrespective of causality. Please confirm a visit and nasal swab was performed and capture term on SOD form only. Please review and update.
Nov-04-2020 14:53:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: SHORTNESS OF BREATH	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason
Nov-04-2020 14:53:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Oct/8/2020 21:00	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Nov-04-2020 14:53:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
Nov-04-2020 14:53:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 1	Initial Entry

7. Is the adverse event serious?

If Yes, NOTIFY PFIZER IMMEDIATELY.

Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).

Date	Location	User	Value	Reason
Nov-04-2020 14:53:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

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Generated By: (b) (4)

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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-04-2020 14:53:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Nov-04-2020 14:53:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NOT RELATED If Not Related to study treatment(s), t his event is due to: OTHER If Other, specify: SUSPECT VIRUS INFECTION	Initial Entry

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Nov-04-2020 14:53:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NOT APPLICABLE	Initial Entry

11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
Nov-04-2020 14:53:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Nov-04-2020 14:53:43 (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
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Subject No: 11171036

Generated By: (b) (4)

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Nov-04-2020 14:53:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: RECOVERING/RESOLVING	Initial Entry
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14. Did the adverse event cause the subject to be discontinued from the study?

Date	Location	User	Value	Reason
Nov-04-2020 14:53:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

090177e196ae3dcc\Final\Final On: 01-Apr-2021 04:41 (GMT)

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Subject No: 11171036

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

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1. Category:

Date	Location	User	Value	Reason
Nov-04-2020 14:54:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: ADVERSE EVENT	Initial Entry

2. AE ID:

Date	Location	User	Value	Reason
Nov-04-2020 14:54:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 9	Initial Entry

3. Adverse Event:

(If possible specify diagnosis, not individual symptoms)

Date	Location	User	Value	Reason
Nov-08-2020 11:41:37 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Nov-07-2020 21:39:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Changed data per query
Nov-06-2020 10:34:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	CLINQUERY - Per Sec 8.1, AE of MYALGIA should have triggered a COVID ILLNESS VISIT irrespective of causality. Please confirm a visit and nasal swab was performed and capture term on SOD form only. Please review and update.
Nov-04-2020 14:54:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: MYALGIA	Initial Entry

4. Start Date Time:

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Site Name: (1117) Sundance Clinical Research

Subject No: 11171036

Subject Initials: ---

Generated By: (b) (4)

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*** THIS REPEATING FORM HAS BEEN DELETED ***

Date	Location	User	Value	Reason
Nov-04-2020 14:54:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Oct/9/2020 UNK:UNK	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Nov-04-2020 14:54:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> YES	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
Nov-04-2020 14:54:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> 1	Initial Entry

7. Is the adverse event serious?

If Yes, NOTIFY PFIZER IMMEDIATELY.

Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).

Date	Location	User	Value	Reason
Nov-04-2020 14:54:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

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

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

Date	Location	User	Value	Reason
Nov-04-2020 14:54:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Nov-04-2020 14:54:52 (UTC-06:00) Central Time	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NOT RELATED	Initial Entry

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Generated By: (b) (4)

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*** THIS REPEATING FORM HAS BEEN DELETED ***

(US & Canada)		(b) (4), (b) (6)	If Not Related to study treatment(s), this event is due to: OTHER If Other, specify: SUSPECT VIRAL ILLNESS
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10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Nov-04-2020 14:54:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NOT APPLICABLE	Initial Entry

11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
Nov-04-2020 14:54:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Nov-04-2020 14:54:52 (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-04-2020 14:54:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> RECOVERING/RESOLVING	Initial Entry

14. Did the adverse event cause the subject to be discontinued from the study?

Date	Location	User	Value	Reason
Nov-04-2020 14:54:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

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1. Category:

Date	Location	User	Value	Reason
Dec-04-2020 17:59:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: ADVERSE EVENT	Initial Entry

2. AE ID:

Date	Location	User	Value	Reason
Dec-04-2020 17:59:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 10	Initial Entry

3. Adverse Event:

(If possible specify diagnosis, not individual symptoms)

Date	Location	User	Value	Reason
Jan-25-2021 16:41:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Giselle Castillo (b) (4)	Query 1: Closed	Response satisfies query
Jan-21-2021 12:32:17 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	PARTICIPANT WAS TRANSITIONED TO EOT 08OCT2020 AND WAS IN THE SAFETY FOLLOW UP PERIOD. INC/EXC WILL BE REEXAMINED IF PARTICIPANT CHOOSES TO ENTER INTO VACCINE TRANSITION. PER INVESTIGATOR, WE WILL CONTINUE TO FOLLOW PARTICIPANT FOR SAFETY REGARDLESS.
Dec-16-2020 10:30:19 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Giselle Castillo (b) (4)	Query 1: Opened	Per SAE report, the subject has had two episodes of Suicidal ideation and hospitalization in 3

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				months. Based on the MHx (schizophrenia and depression), please re-assess eligibility against Inclusion #3 and Exclusion #1.
Dec-04-2020 17:59:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: SUICIDAL IDEATION	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason
Dec-04-2020 17:58:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Nov/20/2020 UNK:UNK	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Dec-04-2020 17:58:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO End Date Time: Nov/25/2020 UNK:UNK	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
Dec-04-2020 17:58:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 4	Initial Entry

7. Is the adverse event serious?

If Yes, NOTIFY PFIZER IMMEDIATELY.

Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).

Date	Location	User	Value	Reason
Dec-07-2020 04:41:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Dec-04-2020 17:59:00 (UTC-06:00) Central Time	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	For AE SUICIDAL IDEATION: Response

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Subject No: 11171036

Generated By: (b) (4)

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Subject Initials: ---

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(US & Canada)				to "Is the adverse event serious?" is 'Yes' but "Serious Adverse Event Number" is blank.
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Dec-04-2020 17:58:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<p>Data Entry:</p> <p>YES</p> <p>Is this serious event associated with congenital anomaly or birth defect?</p> <p>NO</p> <p>Did this serious event result in death ?</p> <p>NO</p> <p>Did this serious event require or prolonged hospitalization?</p> <p>YES</p> <p>Did this serious event result in persistent or significant disability/incapacity?</p> <p>NO</p> <p>Is this serious event life threatening?</p> <p>NO</p> <p>Other medically important serious event</p> <p>NO</p>	Initial Entry
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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
Dec-04-2020 17:58:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

9. Is this event related to study treatment:

Date	Location	User	Value	Reason
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090177e196ae3dcc\Final\Final On: 01-Apr-2021 04:41 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1117

Subject No: 11171036

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1117) Sundance Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:58

Dec-04-2020 17:58:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NOT RELATED If Not Related to study treatment(s), this event is due to: OTHER <i>If Other, specify:</i> MENTAL HEALTH DISORDER	Initial Entry
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10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Dec-04-2020 17:58:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NOT APPLICABLE	Initial Entry

11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
Dec-04-2020 17:58:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Dec-04-2020 17:58:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

13. What was the outcome of this adverse event?:

Date	Location	User	Value	Reason
Dec-04-2020 17:58:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: RECOVERED/RESOLVED	Initial Entry

14. Did the adverse event cause the subject to be discontinued from the study?

Date	Location	User	Value	Reason
Dec-04-2020 17:58:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

090177e196ae3dcc\Final\Final On: 01-Apr-2021 04:41 (GMT)

Header Text: c4591001

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Site No: 1117

Subject No: 11171036

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1117) Sundance Clinical Research

Subject Initials: ---

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15. Serious Adverse Event Number: For Pfizer Use Only

Date	Location	User	Value	Reason
Dec-07-2020 04:41:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 2020479673	Initial Entry

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1117

Subject No: 11171036

Generated By: (b) (4)

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Form Status: Data Complete

Site Name: (1117) Sundance Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:58

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1. Category:

Date	Location	User	Value	Reason
Jan-04-2021 15:19:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: ADVERSE EVENT	Initial Entry

2. AE ID:

Date	Location	User	Value	Reason
Jan-04-2021 15:19:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 11	Initial Entry

3. Adverse Event:

(If possible specify diagnosis, not individual symptoms)

Date	Location	User	Value	Reason
Jan-04-2021 15:19:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: WORSENING DIABETES MELLIT US TYPE 2	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason
Jan-04-2021 15:19:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Nov/10/2020 UNK:UNK	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Jan-21-2021 14:05:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Jan-21-2021 12:37:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	PER PARTICIPANT, MEDICATIONS ARE STILL BE ADJUSTED. PER INVESTIGATOR, AE TO REMAIN ONGOING AT PRESENT TIME.

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Header Text: c4591001

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Subject Initials: ---

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Jan-06-2021 11:11:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	CLINQUERY - Please verify if AE is still ongoing, or update END DATE and OUTCOME as applicable.
Jan-04-2021 15:19:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
Jan-04-2021 15:19:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 2	Initial Entry

7. Is the adverse event serious?

If Yes, NOTIFY PFIZER IMMEDIATELY.

Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).

Date	Location	User	Value	Reason
Jan-04-2021 15:19:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 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
Jan-04-2021 15:19:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Jan-04-2021 15:19:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NOT RELATED If Not Related to study treatment(s), this event is due to: OTHER	Initial Entry

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Header Text: c4591001

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Subject Initials: ---

Generated By: (b) (4)

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			If Other, specify: DISEASE PROGRESSION	
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10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Jan-04-2021 15:19:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NOT APPLICABLE	Initial Entry

11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
Jan-04-2021 15:19:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Jan-04-2021 15:19:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

13. What was the outcome of this adverse event?:

Date	Location	User	Value	Reason
Jan-04-2021 15:19:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: RECOVERING/RESOLVING	Initial Entry

14. Did the adverse event cause the subject to be discontinued from the study?

Date	Location	User	Value	Reason
Jan-04-2021 15:19:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

090177e196ae3dcc\Final\Final On: 01-Apr-2021 04:41 (GMT)

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Generated By: (b) (4)

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1. Category:

Date	Location	User	Value	Reason
Jan-04-2021 15:22:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: ADVERSE EVENT	Initial Entry

2. AE ID:

Date	Location	User	Value	Reason
Jan-04-2021 15:22:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 12	Initial Entry

3. Adverse Event:

(If possible specify diagnosis, not individual symptoms)

Date	Location	User	Value	Reason
Jan-04-2021 15:22:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: SNORING	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason
Jan-04-2021 15:22:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sep/UNK/2020 UNK:UNK	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Jan-21-2021 14:13:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Jan-21-2021 12:39:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	PER PARTICIPANT, SNORING IS NOT TREATED PRESENTLY. PARTICIPANT HAS REFERRAL TO PULMONARY DOC. PER INVESTIGATOR, AE

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Subject Initials: ---

Generated By: (b) (4)

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				SHOULD REMAIN OPEN UNTIL FOLLOW UP COMPLETE.
Jan-06-2021 11:13:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	CLINQUERY - Please verify if AE is still ongoing, or update END DATE and OUTCOME as applicable.
Jan-04-2021 15:22:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> YES	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
Jan-04-2021 15:22:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> 2	Initial Entry

7. Is the adverse event serious?

If Yes, NOTIFY PFIZER IMMEDIATELY.

Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).

Date	Location	User	Value	Reason
Jan-04-2021 15:22:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

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

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

Date	Location	User	Value	Reason
Jan-04-2021 15:22:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Jan-04-2021 15:22:30 (UTC-06:00) Central Time	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NOT RELATED	Initial Entry

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Subject Initials: ---

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(US & Canada)		(b) (4), (b) (6)	If Not Related to study treatment(s), this event is due to: OTHER If Other, specify: ETIOLOGY UNKNOWN
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10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Jan-04-2021 15:22:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NOT APPLICABLE	Initial Entry

11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
Jan-04-2021 15:22:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Jan-04-2021 15:22:30 (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
Jan-04-2021 15:22:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NOT RECOVERED/NOT RESOLVED	Initial Entry

14. Did the adverse event cause the subject to be discontinued from the study?

Date	Location	User	Value	Reason
Jan-04-2021 15:22:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

090177e196ae3dcc\Final\Final On: 01-Apr-2021 04:41 (GMT)

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Subject No: 11171036

Generated By: (b) (4)

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Form Status: Data Complete

Site Name: (1117) Sundance Clinical Research

Subject Initials: ---

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1. Category:

Date	Location	User	Value	Reason
Jan-04-2021 15:24:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: ADVERSE EVENT	Initial Entry

2. AE ID:

Date	Location	User	Value	Reason
Jan-04-2021 15:24:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 13	Initial Entry

3. Adverse Event:

(If possible specify diagnosis, not individual symptoms)

Date	Location	User	Value	Reason
Jan-04-2021 20:30:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	PFETMS Oracle (b) (4)	Query 1: Closed	Discrepancy has been closed.
Jan-04-2021 19:46:32 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Transcription Error
Jan-04-2021 19:46:32 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: HYPOCALCEMIA	Transcription Error
Jan-04-2021 17:18:19 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	PFETMS Oracle (b) (4)	Query 1: Opened	Clarify HYPOCALEMIA as follows...Should the spelling be HYPOCALCEMIA? Or HYPOKALEMIA? If so, edit as such. Otherwise clarify and edit as appropriate. Thank you.

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Header Text: c4591001

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Subject No: 11171036

Subject Initials: ---

Generated By: (b) (4)

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Jan-04-2021 15:24:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: HYPOCALEMI A	Initial Entry
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4. Start Date Time:

Date	Location	User	Value	Reason
Jan-04-2021 15:24:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sep/UNK/2020 UNK:UNK	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Jan-21-2021 14:13:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Jan-21-2021 12:45:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	PER PARTICIPANT, NO BLOOD LABS HAVE BEEN COMPLETED BY PRIMARY MD. PARTICIPANT HAS APPT SCHEDULED IN LATE FEB TO HAVE REASSESSED. PER INVESTIGATOR, AE TO REMAIN ONGOING.
Jan-06-2021 11:18:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	CLINQUERY - Please verify if AE is still ongoing, or update END DATE and OUTCOME as applicable.
Jan-04-2021 15:24:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
Jan-04-2021 15:24:09	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Initial Entry

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(UTC-06:00) Central Time (US & Canada)		(b) (4), (b) (6)	2	
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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
Jan-04-2021 15:24:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 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
Jan-04-2021 15:24:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Jan-04-2021 15:24:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NOT RELATED If Not Related to study treatment(s), this event is due to: OTHER If Other, specify: ETIOLOGY UNKNOWN	Initial Entry

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Jan-04-2021 15:24:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NOT APPLICABLE	Initial Entry

11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
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Site Name: (1117) Sundance Clinical Research

Subject No: 11171036

Subject Initials: ---

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Jan-04-2021 15:24:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry
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12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Jan-04-2021 15:24:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

13. What was the outcome of this adverse event?:

Date	Location	User	Value	Reason
Jan-04-2021 15:24:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NOT RECOVERED/NOT RESOLVE D	Initial Entry

14. Did the adverse event cause the subject to be discontinued from the study?

Date	Location	User	Value	Reason
Jan-04-2021 15:24:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

090177e196ae3dcc\Final\Final On: 01-Apr-2021 04:41 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1117

Subject No: 11171036

Generated By: (b) (4)

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Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:58

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1. Category:

Date	Location	User	Value	Reason
Jan-04-2021 15:25:17 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: ADVERSE EVENT	Initial Entry

2. AE ID:

Date	Location	User	Value	Reason
Jan-04-2021 15:25:17 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 14	Initial Entry

3. Adverse Event:

(If possible specify diagnosis, not individual symptoms)

Date	Location	User	Value	Reason
Jan-22-2021 07:47:19 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Close d	Response satisfies query
Jan-21-2021 12:47:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answ ered	New Information
Jan-21-2021 12:47:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: WORSENING INSOMNIA	New Information
Jan-05-2021 04:36:27 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	PFE SDQ PROD (b) (4)	Query 1: Open ed	The AE INSOMNIA was reported but is also listed in Medical History. Please clarify if this is a worsening of the baseline condition, and if so, please

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Subject No: 11171036

Generated By: (b) (4)

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				consider adding "worsening" to the AE term. AE as baseline conditions should only be reported as AEs if they worsen. (b) (4)
Jan-04-2021 15:25:17 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: INSOMNIA	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason
Jan-04-2021 15:25:17 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sep/UNK/2020 UNK:UNK	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Jan-21-2021 14:13:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Jan-21-2021 12:48:37 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	PER PARTICIPANT, CONDITION IS BETTER BUT NOT RESOLVED. WILL SEE PRIMARY MD IN LATE FEB FOR MEDICATION ADJUSTMENT. PER INVESTIGATOR, AE TO REMAIN ONGOING.
Jan-06-2021 11:20:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	CLINQUERY - Please verify if AE is still ongoing, or update END DATE and OUTCOME as applicable.

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Jan-04-2021 15:25:17 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry
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6. Toxicity Grade:

Date	Location	User	Value	Reason
Jan-04-2021 15:25:17 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 2	Initial Entry

7. Is the adverse event serious?

If Yes, NOTIFY PFIZER IMMEDIATELY.

Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).

Date	Location	User	Value	Reason
Jan-04-2021 15:25:17 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 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
Jan-04-2021 15:25:17 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Jan-04-2021 15:25:17 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NOT RELATED If Not Related to study treatment(s), this event is due to: OTHER If Other, specify: ETIOLOGY UNKNOWN	Initial Entry

10. Latest Action Taken with Study Treatment:

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Date	Location	User	Value	Reason
Jan-04-2021 15:25:17 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NOT APPLICABLE	Initial Entry

11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
Jan-04-2021 15:25:17 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Jan-04-2021 15:25:17 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

13. What was the outcome of this adverse event?:

Date	Location	User	Value	Reason
Jan-21-2021 12:50:04 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Jan-21-2021 12:50:04 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: RECOVERING/RESOLVING	New Information
Jan-21-2021 12:47:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	For AE WORSENING INSOMNIA: Response to "What was the outcome of this adverse event?" is 'Unknown' but End Date/Time is provided or "Is the adverse event still ongoing?" is marked "Yes".
Jan-05-2021 23:40:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued:Opened	DM: Thanks for your response. Please update CRF once update is obtained and confirm.
Jan-04-2021 19:47:34 (UTC-06:00) Central Time	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	THE PARTICIPANT WILL BE ONSITE

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(US & Canada)				LATER IN THE WEEK (07JAN2020), INVESTIGATOR TO OBTAIN UPDATE AT THAT TIME.
Jan-04-2021 15:25:17 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	For AE INSOMNIA: Response to "What was the outcome of this adverse event?" is 'Unknown' but End Date/Time is provided or "Is the adverse event still ongoing?" is marked "Yes".
Jan-04-2021 15:25:17 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNKNOWN	Initial Entry

14. Did the adverse event cause the subject to be discontinued from the study?

Date	Location	User	Value	Reason
Jan-04-2021 15:25:17 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

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1. Category:

Date	Location	User	Value	Reason
Jan-04-2021 15:26:24 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: ADVERSE EVENT	Initial Entry

2. AE ID:

Date	Location	User	Value	Reason
Jan-04-2021 15:26:24 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 15	Initial Entry

3. Adverse Event:

(If possible specify diagnosis, not individual symptoms)

Date	Location	User	Value	Reason
Jan-04-2021 15:26:24 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: WORSENING HYPERTENSION	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason
Jan-04-2021 15:26:24 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sep/UNK/2020 UNK:UNK	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Jan-21-2021 14:13:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Jan-21-2021 12:51:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	PER PARTICIPANT, HAS NOT STARTED ON THIS MEDICATION OUTSIDE OF HOSPITAL. WILL SEE PRIMARY MD IN LATE FEB AND HAVE CHECKED.

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				PER INVESTIGATOR, AE TO REMAIN ONGOING.
Jan-06-2021 11:22:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	CLINQUERY - Please verify if AE is still ongoing, or update END DATE and OUTCOME as applicable.
Jan-04-2021 15:26:24 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> YES	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
Jan-04-2021 15:26:24 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> 2	Initial Entry

7. Is the adverse event serious?

If Yes, NOTIFY PFIZER IMMEDIATELY.

Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).

Date	Location	User	Value	Reason
Jan-04-2021 15:26:24 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

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

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

Date	Location	User	Value	Reason
Jan-04-2021 15:26:24 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Jan-04-2021 15:26:24 (UTC-06:00) Central Time	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NOT RELATED	Initial Entry

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(US & Canada)		(b) (4), (b) (6)	If Not Related to study treatment(s), this event is due to: OTHER If Other, specify: NON COMPLIANCE WITH PLAN OF CARE
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10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Jan-04-2021 15:26:24 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NOT APPLICABLE	Initial Entry

11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
Jan-04-2021 15:26:24 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Jan-04-2021 15:26:24 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

13. What was the outcome of this adverse event?:

Date	Location	User	Value	Reason
Jan-04-2021 15:26:24 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NOT RECOVERED/NOT RESOLVED	Initial Entry

14. Did the adverse event cause the subject to be discontinued from the study?

Date	Location	User	Value	Reason
Jan-04-2021 15:26:24 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

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1. Category:

Date	Location	User	Value	Reason
Jan-21-2021 12:53:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: ADVERSE EVENT	Initial Entry

2. AE ID:

Date	Location	User	Value	Reason
Jan-21-2021 12:53:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 16	Initial Entry

3. Adverse Event:

(If possible specify diagnosis, not individual symptoms)

Date	Location	User	Value	Reason
Mar-01-2021 11:07:18 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Closed	Response satisfies query
Mar-01-2021 09:50:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Answered	Changed Information
Mar-01-2021 09:50:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: CHRONIC KIDNEY DISEASE, ST AGE 2, WORSENING	Changed Information
Feb-26-2021 14:07:23 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Opened	CLINQUERY - CHRONIC KIDNEY DISEASE STAGE 2 with start date of 31 Dec 2020 is already reported in MH (start Jan 2020). Per guidelines, unless condition "Worsens", then it is not to be duplicated as an AE. Please review and update.
Jan-26-2021 08:53:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query

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Jan-25-2021 19:07:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	WE CAN CONFIRM THAT THIS IS THE FIRST TIME IT HAS APPEARED IN THE MEDICAL RECORD.
Jan-25-2021 09:50:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	clinical: pls confirm no prior hx of CKD. Thanks
Jan-21-2021 12:53:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: CHRONIC KIDNEY DISEASE, ST AGE 2	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason
Jan-21-2021 12:53:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Dec/31/2020 UNK:UNK	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Jan-21-2021 12:53:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
Jan-21-2021 12:53:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 2	Initial Entry

7. Is the adverse event serious?

If Yes, NOTIFY PFIZER IMMEDIATELY.

Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).

Date	Location	User	Value	Reason
Jan-21-2021 12:53:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

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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
Jan-21-2021 12:53:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Jan-21-2021 12:53:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NOT RELATED If Not Related to study treatment(s), this event is due to: OTHER If Other, specify: DIABETES MELLITUS II DISEASE PROGRESSION	Initial Entry

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Jan-21-2021 12:53:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NOT APPLICABLE	Initial Entry

11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
Jan-21-2021 12:53:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Jan-21-2021 12:53:07 (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
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Jan-21-2021 12:53:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: RECOVERING/RESOLVING	Initial Entry
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14. Did the adverse event cause the subject to be discontinued from the study?

Date	Location	User	Value	Reason
Jan-21-2021 12:53:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

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1. Category:

Date	Location	User	Value	Reason
Jan-21-2021 12:55:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: ADVERSE EVENT	Initial Entry

2. AE ID:

Date	Location	User	Value	Reason
Jan-21-2021 12:55:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 17	Initial Entry

3. Adverse Event:

(If possible specify diagnosis, not individual symptoms)

Date	Location	User	Value	Reason
Jan-21-2021 12:55:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: MODERATE EPISODE OF MAJOR DEPRESSIVE DISORDER W/ PSYC HOSIS	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason
Jan-21-2021 12:55:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Dec/30/2020 UNK:UNK	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Jan-21-2021 12:55:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO End Date Time: Jan/1/2021 UNK:UNK	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
Jan-21-2021 12:55:11 (UTC-06:00) Central Time	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 3	Initial Entry

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(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
Jan-25-2021 03:52:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Jan-21-2021 12:55:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	For AE MODERATE EPISODE OF MAJOR DEPRESSIVE DISORDER W/ PSYCHOSIS: Response to "Is the adverse event serious?" is 'Yes' but "Serious Adverse Event Number" is blank.
Jan-21-2021 12:55:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Is this serious event associated with congenital anomaly or birth defect? NO Did this serious event result in death? NO Did this serious event require or prolong hospitalization? YES Did this serious event result in persistent or significant disability/incapacity? NO Is this serious event life threatening?	Initial Entry

090177e196ae3dcc\Final\Final On: 01-Apr-2021 04:41 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1117

Subject No: 11171036

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Frozen

Site Name: (1117) Sundance Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:58

			NO	
			Other medically important serious event	
			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.

Date	Location	User	Value	Reason
Jan-21-2021 12:55:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Jan-21-2021 12:55:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NOT RELATED If Not Related to study treatment(s), this event is due to: OTHER If Other, specify: BIPOLAR DISORDER	Initial Entry

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Jan-21-2021 12:55:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NOT APPLICABLE	Initial Entry

11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
Jan-21-2021 12:55:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason

090177e196ae3dcc\Final\Final On: 01-Apr-2021 04:41 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1117

Subject No: 11171036

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Frozen

Site Name: (1117) Sundance Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:58

Jan-21-2021 12:55:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry
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13. What was the outcome of this adverse event?:

Date	Location	User	Value	Reason
Jan-21-2021 12:55:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: RECOVERED/RESOLVED	Initial Entry

14. Did the adverse event cause the subject to be discontinued from the study?

Date	Location	User	Value	Reason
Jan-21-2021 12:55:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

15. Serious Adverse Event Number: For Pfizer Use Only

Date	Location	User	Value	Reason
Jan-25-2021 03:52:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 2021011278	Initial Entry

090177e196ae3dcc\Final\Final On: 01-Apr-2021 04:41 (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: 11171036

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

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Date	Location	User	Value	Reason
Oct-09-2020 14:48:48 (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: 11171036

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

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1. What is the medication identifier?

Date	Location	User	Value	Reason
Oct-09-2020 14:48:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 1	Initial Entry

2. Category:

Date	Location	User	Value	Reason
Oct-09-2020 14:48:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: VACCINATIONS	Initial Entry

3. Concomitant Medications Pre-specified:

Date	Location	User	Value	Reason
Oct-09-2020 14:48:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 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
Oct-09-2020 14:48:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: INFLUENZA VACCINE	Initial Entry

5. Date:

Date	Location	User	Value	Reason
Oct-09-2020 14:48:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sep/14/2020	Initial Entry

090177e196ae3dcc\Final\Final On: 01-Apr-2021 04:41 (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: 11171036

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

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I. Date of Visit

Date	Location	User	Value	Reason
Jan-28-2021 13:23:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Jan/28/2021	Initial Entry

Header Text: c4591001

Visit: Potential ReVax Initial Contact - Unscheduled **Form:** FURTHER VACCINATION CONFIRMATION - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:25

Form Status: Data Complete, Frozen, Verified

Site No: 1117

Site Name: (1117) Sundance Clinical Research

Subject No: 11171036

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

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

Date	Location	User	Value	Reason
Jan-28-2021 13:23:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 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	Initial Entry

Header Text: c4591001**Visit:** Disposition - Unscheduled**Form Version:** 22-Apr-2020 21:03**Site No:** 1117**Subject No:** 11171036**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):** 29-Mar-2021 10:58[Back to Form](#)**1. Date Treatment Unblinded :**

Date	Location	User	Value	Reason
Feb-26-2021 15:20:54 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (b) (4)	Query 1: Closed	Auto closed by Validation Check: VC_DS001_36
Feb-26-2021 11:53:19 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Changed Information
Feb-26-2021 11:53:19 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Jan/28/2021	Changed Information
Feb-23-2021 08:19:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (b) (4)	Query 1: Opened	DMW7352226;Date Treatment Unblinded should be equal to or after DOV in REVAX CONTACT visit when Reason is ASSESS ELIGIBILITY FOR ADDITIONAL VACCINATION.Please review and update as appropriate.
Jan-28-2021 13:23:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Jan/19/2021	Initial Entry

2. Primary Reason for Unblinding:

Date	Location	User	Value	Reason
Jan-28-2021 13:23:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: ASSESS ELIGIBILITY FOR ADDITIONAL VACCINATION	Initial Entry

Header Text: c4591001

Visit: V101_VAX3

Form Version: 22-Apr-2020 21:02

Site No: 1117

Subject No: 11171036

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): 29-Mar-2021 10:58

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I. Date of Visit

Date	Location	User	Value	Reason
Jan-28-2021 13:24:02 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Jan/28/2021	Initial Entry

Header Text: c4591001

Visit: V101_VAX3

Form: INFORMED CONSENT - FURTHER VACCINATION - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:31

Form Status: Data Complete, Frozen, Verified

Site No: 1117

Site Name: (1117) Sundance Clinical Research

Subject No: 11171036

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

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I. Consent Was:

Date	Location	User	Value	Reason
Jan-28-2021 13:24:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: OBTAINED Date Written Consent Obtained Jan/28/2021	Initial Entry

Header Text: c4591001

Visit: V101_VAX3

Form: INCLUSION/EXCLUSION CRITERIA - FURTHER VACCINATION - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:30

Form Status: Data Complete, Frozen, Verified

Site No: 1117

Site Name: (1117) Sundance Clinical Research

Subject No: 11171036

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

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1.a

Date	Location	User	Value	Reason
Jan-28-2021 13:24:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Crit Healthy participants, determine erio d by medical history, physical e n De xamination (if required), and cli scri nical judgment of the investigat ptio or to be eligible for the study. S n: pecific criteria apply for HIV/H CV/HBV	Initial Entry

1.a Description of Inclusion Criterion Not Met

Date	Location	User	Value	Reason
Jan-28-2021 13:24:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Healthy participants, determined by m edical history, physical examination (if required), and clinical judgment of the investigator to be eligible for the study . Specific criteria apply for HIV/HCV/ HBV	Initial Entry

2.a

Date	Location	User	Value	Reason
Jan-28-2021 13:24:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Crite Other medical or psychiatric co riion ndition incl. recent (within past Desc year) or active suicidal ideation ripti /behavior/lab abnormality that on: may increase the risk of study participation	Initial Entry

2.a Description of Exclusion Criterion Met

Date	Location	User	Value	Reason
Jan-28-2021 13:24:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Other medical or psychiatric condition incl. recent (within past year) or active suicidal ideation/behavior/lab abnormality that may increase the risk of study participation	Initial Entry

090177e196ae3dcc\Final\Final On: 01-Apr-2021 04:41 (GMT)

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: 11171036

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

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1. Date of Completion/Discontinuation/Death :

Date	Location	User	Value	Reason
Jan-28-2021 13:25:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Jan/28/2021	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Jan-28-2021 13:25:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: REPEAT SCREENING 1	Initial Entry

3. Status:

Date	Location	User	Value	Reason
Jan-28-2021 13:25:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Jan-28-2021 13:25:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	Response to "Status" is NO LONGER MEETS ELIGIBILITY CRITERIA but "Specify Status" is missing.
Jan-28-2021 13:25:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO LONGER MEETS ELIGIBILIT Y CRITERIA	Initial Entry

4. Specify Status:

Date	Location	User	Value	Reason
Jan-28-2021 13:25:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: INC 3, EXC 1	Initial Entry

090177e196ae3dcc\Final\Final On: 01-Apr-2021 04:41 (GMT)

Header Text: c4591001

Visit: Subject Status - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1117

Subject No: 11171036

Generated By: (b) (4)

Form: SUBJECT STATUS - eCRF Audit Trail History

Form Status: Data Complete, Verified

Site Name: (1117) Sundance Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:58

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1. Subject Status

Date	Location	User	Value	Reason
Oct-13-2020 13:21:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: FOLLOW-UP	Initial Entry
Aug-21-2020 12:39:24 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: ENROLLED/RANDOMIZED	Initial Entry
Aug-21-2020 12:36:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SCREENED	Initial Entry

2. Subject Status Date

Date	Location	User	Value	Reason
Jan-22-2021 11:54:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Jan-21-2021 13:57:06 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Changed data per query
Jan-11-2021 06:10:18 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	SAE RECON:AER#2021011278 'moderate episode of recurrent major depressive disorder (MDD) with psychosis' was reported as serious in Safety database but missing in AE CRF. Please confirm and update CRF. If safety update is required, submit ffup form
Oct-13-2020 13:21:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Oct/8/2020	Initial Entry
Aug-21-2020 12:39:24 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Aug/20/2020	Initial Entry
Aug-21-2020 12:36:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Aug/20/2020	Initial Entry

090177e196ae3dcc\Final\Final On: 01-Apr-2021 04:41 (GMT)

Header Text: c4591001

Visit: Investigator Signature - Unscheduled

Form: CASEBOOK SIGNATURE FORM - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Signed, Verified

Site No: 1117

Site Name: (1117) Sundance Clinical Research

Subject No: 11171036

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

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I. Casebook Signature

Date	Location	User	Value	Reason
Oct-15-2020 18:40:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Click Here to Enable	Initial Entry