

Header Text: c4591001

Visit: COHORT_SELECTION

Form: COHORT_SELECTION

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: 11171146

Subject Initials: ---

Generated By: (b) (4)

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	08 SEP 2020
2.	Select appropriate response - What cohort does the subject belong to?	STAGE 3 COHORTS

Header Text: c4591001

Visit: COHORT_SELECTION

Form Version: 22-Apr-2020 21:02

Site No: 1117

Subject No: 11171146

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 Sep/22/2020
----	--------------	--

Header Text: c4591001

Visit: COHORT_SELECTION

Form Version: 15-Sep-2020 21:54

Site No: 1117

Subject No: 11171146

Generated By: (b) (4)

Form: DEMOGRAPHY

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](#)

Demography

1.	Subject ID	[11171146]
2.	Birth Date:	(b) (6) 1949
3.	Sex:	FEMALE
4.	Ethnicity:	NOT HISPANIC OR LATINO(A) OR OF SPANISH ORIGIN
5.	Race: (Check X all that apply):	WHITE
6.	Racial Designation:	

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:02

Site No: 1117

Subject No: 11171146

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/22/2020	
2.	Erroneous Visit		Comments

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 15-Sep-2020 21:53

Site No: 1117

Subject No: 11171146

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
----	---	----------------

090177e196ae3da4\Final\Final On: 01-Apr-2021 04:40 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 15-Sep-2020 21:52

Site No: 1117

Subject No: 11171146

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	Sep/22/2020	
2.	Phase of Disposition:	SCREENING	
3.	Status:	COMPLETED	
4.	Specify Status:	Not Applicable _____ []	Comments

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1117

Subject No: 11171146

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:	[HYSTERECTOMY, TOTAL]
	Start Date:	UNK/UNK/2014
	Ongoing:	NO End Date: UNK/UNK/2014
1.b	Line/MH Number:	[2]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[UTERINE FIBROIDS]
	Start Date:	UNK/UNK/1990
	Ongoing:	NO End Date: UNK/UNK/2014
1.c	Line/MH Number:	[3]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[MENOPAUSE]
	Start Date:	UNK/UNK/2000
	Ongoing:	YES
1.d	Line/MH Number:	[4]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[ALLERGY, PENCILLIN]
	Start Date:	UNK/UNK/1959
	Ongoing:	YES

090177e196ae3da4\Final\Final On: 01-Apr-2021 04:40 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1117

Subject No: 11171146

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.e	Line/MH Number:	[5]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[SLEEP APNEA]
	Start Date:	Sep/UNK/2018
	Ongoing:	YES
1.f	Line/MH Number:	[6]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[HYPERTENSION]
	Start Date:	Jun/UNK/2018
	Ongoing:	YES
1.g	Line/MH Number:	[7]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[OSTEOPOROSIS]
	Start Date:	UNK/UNK/2012
	Ongoing:	YES
1.h	Line/MH Number:	[8]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[BONE SPUR, SHOULDER, RIGHT]
	Start Date:	UNK/UNK/2016
	Ongoing:	NO End Date: UNK/UNK/2016

090177e196ae3da4\Final\Final On: 01-Apr-2021 04:40 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1117

Subject No: 11171146

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.i	Line/MH Number:	[9]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[BONE SPUR REMOVAL, SHOULDER, RIGHT]
	Start Date:	UNK/UNK/2016
	Ongoing:	NO End Date: UNK/UNK/2016
1.j	Line/MH Number:	[10]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[IRREGULAR HEART BEAT]
	Start Date:	UNK/UNK/2018
	Ongoing:	YES
1.k	Line/MH Number:	[11]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[HEARING IMPAIRMENT, BILATERAL]
	Start Date:	UNK/UNK/2012
	Ongoing:	YES
1.l	Line/MH Number:	[12]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[VISION IMPAIRMENT, BILATERAL]
	Start Date:	UNK/UNK/1990
	Ongoing:	YES

090177e196ae3da4\Final\Final On: 01-Apr-2021 04:40 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1117

Subject No: 11171146

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.m	Line/MH Number:	[13]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[PEPTIC ULCERS]
	Start Date:	UNK/UNK/2015
	Ongoing:	NO End Date: UNK/UNK/2017
1.n	Line/MH Number:	[14]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[NEUROPATHY, LOWER EXTREMITY, BILATERAL]
	Start Date:	UNK/UNK/2015
	Ongoing:	YES
1.o	Line/MH Number:	[15]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[OSTEOARTHRITIS, HIP, BILATERAL]
	Start Date:	UNK/UNK/2015
	Ongoing:	YES
1.p	Line/MH Number:	[16]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[OSTEOARTHRITIS, THUMB, BILATERAL]
	Start Date:	UNK/UNK/2015
	Ongoing:	YES

090177e196ae3da4\Final\Final On: 01-Apr-2021 04:40 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1117

Subject No: 11171146

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.q	Line/MH Number:	[17]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[CELLULITIS, ANKLE, RIGHT]
	Start Date:	Jan/31/2019
	Ongoing:	NO End Date: Feb/9/2019
1.r	Line/MH Number:	[18]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[ALLERGY, SEASONAL]
	Start Date:	UNK/UNK/1965
	Ongoing:	YES
1.s	Line/MH Number:	[19]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[ALCOHOL USE, 7 DRINKS/WEEK]
	Start Date:	UNK/UNK/1968
	Ongoing:	YES
1.t	Line/MH Number:	[20]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[OSTEOARTHRITIS, KNEE, BILATERAL]
	Start Date:	UNK/UNK/2017
	Ongoing:	YES
1.u	Line/MH Number:	[21]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[GASTROESOPHAGEAL REFLUX DISEASE]
	Start Date:	UNK/UNK/2015
	Ongoing:	YES

090177e196ae3da4\Final\Final On: 01-Apr-2021 04:40 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1117

Subject No: 11171146

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.v	Line/MH Number:	[22]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[VERTIGO]
	Start Date:	UNK/UNK/2015
	Ongoing:	YES
1.w	Line/MH Number:	[23]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[DEEP VEIN THROMBOSIS, LOWER EXTREMITY, BILATERAL]
	Start Date:	UNK/UNK/2019
	Ongoing:	NO End Date: UNK/UNK/2019
1.x	Line/MH Number:	[24]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[ULCERS, GASTRIC]
	Start Date:	UNK/UNK/2015
	Ongoing:	YES
1.y	Line/MH Number:	[25]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[KIDNEY STONE]
	Start Date:	UNK/UNK/2018
	Ongoing:	NO End Date: UNK/UNK/2019

090177e196ae3da4\Final\Final On: 01-Apr-2021 04:40 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1117

Subject No: 11171146

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.z	Line/MH Number:	[26]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[MUSCLE SPASM]
	Start Date:	UNK/UNK/2010
	Ongoing:	YES
1.aa	Line/MH Number:	[27]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[HYPERCHOLESTEROLEMIA]
	Start Date:	UNK/UNK/2015
	Ongoing:	YES
1.ab	Line/MH Number:	[28]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[VITAMIN D DEFICIENCY]
	Start Date:	UNK/UNK/2017
	Ongoing:	YES
1.ac	Line/MH Number:	[29]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[PULMONARY ARTERIAL HYPERTENSION]
	Start Date:	Jan/22/2018
	Ongoing:	YES
1.ad	Line/MH Number:	[30]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[AORTIC ANEURYSM]
	Start Date:	Jan/22/2018
	Ongoing:	YES

090177e196ae3da4\Final\Final On: 01-Apr-2021 04:40 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1117

Subject No: 11171146

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.ae	Line/MH Number:	[31]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[VENTRICULAR ENLARGEMENT, RIGHT]
	Start Date:	Jan/22/2010
	Ongoing:	YES
1.af	Line/MH Number:	[32]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[ATHEROSCLEROTIC DISEASE]
	Start Date:	Jan/22/2018
	Ongoing:	YES
1.ag	Line/MH Number:	[33]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[CATARACTS, BILATERAL]
	Start Date:	Jun/UNK/2020
	Ongoing:	YES

090177e196ae3da4\Final\Final On: 01-Apr-2021 04:40 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 15-Sep-2020 21:57

Site No: 1117

Subject No: 11171146

Generated By: (b) (4)

Form: HIV STATUS

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](#)

HIV Status

1.	Select appropriate response - What is the subject HIV status?	The subject is NOT known to be HIV POSITIVE
----	---	---

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 15-Sep-2020 21:56

Site No: 1117

Subject No: 11171146

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:	Sep/22/2020
2.	Weight:	[166.8]
3.	Unit:	LB
4.	Height:	[62.4]
5.	Unit:	in
6.	Body Mass Index:	[30.1]

Vital Signs Details

7.a	Record Identifier:	1
	Temperature:	[96.5]
	Unit:	F
	Temperature Location:	ORAL CAVITY

090177e196ae3da4\Final\Final On: 01-Apr-2021 04:40 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 15-Sep-2020 21:51

Site No: 1117

Subject No: 11171146

Generated By: (b) (4)

Form: LAB URINALYSIS - PREGNANCY TEST

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1117) Sundance Clinical Research

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Lab Urinalysis

1.	Lab Panel:	URINALYSIS
2.	Lab Sub-Panel:	PREGNANCY
3.	Collection Date:	Sep/22/2020
4.	Laboratory Name and Address (Derived)	[STUDY SITE]
5.	Specimen Type:	URINE

Lab Result

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

090177e196ae3da4\Final\Final On: 01-Apr-2021 04:40 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1117

Subject No: 11171146

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 :	Sep/22/2020
2.	Randomization Number:	[263521]
3.	Randomization Group:	[]

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1117

Subject No: 11171146

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: Sep/22/2020	
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[]	Comments

Aliquot

Please enter barcode for each aliquot.

5.a	Sample ID	[BM8YNL]
5.b	Sample ID	[BM8YNK]
5.c	Sample ID	[BM8YNJ]
5.d	Sample ID	[BPRV5C]
5.e	Sample ID	[BPRV5D]

090177e196ae3da4\Final\Final On: 01-Apr-2021 04:40 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1117

Subject No: 11171146

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/22/2020	
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[]	Comments

Aliquot

Please enter barcode for each aliquot.

5.a	Sample ID	[BM8YMW]
-----	-----------	----------

090177e196ae3da4\Final\Final On: 01-Apr-2021 04:40 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:04

Site No: 1117

Subject No: 11171146

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/22/2020 15:57
5.	Anatomical Location:	DELTOID MUSCLE
6.	Body Side:	LEFT
7.	Route:	INTRAMUSCULAR
8.	Actual Dose:	[]
9.	Unit:	
10.	Timeframe Subject Was Observed	THE PROTOCOL SPECIFIED OBSERVATION PERIOD
11.	Was the subject observed for at least the protocol specified observation period after investigational product administration?	YES

090177e196ae3da4\Final\Final On: 01-Apr-2021 04:40 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 06-Jul-2020 21:53

Site No: 1117

Subject No: 11171146

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
----	---	--

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 1117

Subject No: 11171146

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	Oct/12/2020
2.	Erroneous Visit	

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 10-Oct-2020 16:01

Site No: 1117

Subject No: 11171146

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:	Oct/12/2020
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Vital Signs Details

2.a	Record Identifier:	1
	Temperature:	[97.4]
	Unit:	F
	Temperature Location:	ORAL CAVITY

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 15-Sep-2020 21:51

Site No: 1117

Subject No: 11171146

Generated By: (b) (4)

Form: LAB URINALYSIS - PREGNANCY TEST

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1117) Sundance Clinical Research

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Lab Urinalysis

1.	Lab Panel:	URINALYSIS
2.	Lab Sub-Panel:	PREGNANCY
3.	Collection Date:	Oct/12/2020
4.	Laboratory Name and Address (Derived)	[STUDY SITE]
5.	Specimen Type:	URINE

Lab Result

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

090177e196ae3da4\Final\Final On: 01-Apr-2021 04:40 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:03

Site No: 1117

Subject No: 11171146

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: Oct/12/2020
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	[BRJ8FV]
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090177e196ae3da4\Final\Final On: 01-Apr-2021 04:40 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1117

Subject No: 11171146

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:	Oct/12/2020 14:13
5.	Anatomical Location:	DELTOID MUSCLE
6.	Body Side:	LEFT
7.	Route:	INTRAMUSCULAR
8.	Actual Dose:	[]
9.	Unit:	
10.	Timeframe Subject Was Observed	THE PROTOCOL SPECIFIED OBSERVATION PERIOD
11.	Was the subject observed for at least the protocol specified observation period after investigational product administration?	YES

090177e196ae3da4\Final\Final On: 01-Apr-2021 04:40 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 1117

Subject No: 11171146

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	Nov/12/2020
2.	Erroneous Visit	

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form Version: 22-Apr-2020 21:03

Site No: 1117

Subject No: 11171146

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: Nov/12/2020
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	[BRSRX2]
5.b	Sample ID	[BRSRX3]
5.c	Sample ID	[BM8YTW]
5.d	Sample ID	[BM8YTX]
5.e	Sample ID	[BM8YTY]

090177e196ae3da4\Final\Final On: 01-Apr-2021 04:40 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL - New Unscheduled Visit

Form: DATE OF VISIT - ILLNESS ONSET

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1117

Site Name: (1117) Sundance Clinical Research

Subject No: 11171146

Subject Initials: ---

Generated By: (b) (4)

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

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

COVID-19 Illness Visit

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

Header Text: c4591001

Visit: POT_COVID_ILL - New Unscheduled Visit

Form: SIGNS AND SYMPTOMS OF POTENTIAL COVID-19

Form Version: 20-Feb-2021 02:17

Form Status: Not Started

Site No: 1117

Site Name: (1117) Sundance Clinical Research

Subject No: 11171146

Subject Initials: ---

Generated By: (b) (4)

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

Signs and Symptoms

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

Symptoms

4.	Symptoms:	
	Was symptom present?	

Symptoms - Other

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

090177e196ae3da4\Final\Final On: 01-Apr-2021 04:40 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL - New Unscheduled Visit

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB SELF

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1117

Site Name: (1117) Sundance Clinical Research

Subject No: 11171146

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: POT_COVID_ILL - New Unscheduled Visit

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: 11171146

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	[]
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090177e196ae3da4\Final\Final On: 01-Apr-2021 04:40 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL - New Unscheduled Visit

Form: HEALTH CARE UTILIZATION

Form Version: 20-Feb-2021 02:19

Form Status: Not Started

Site No: 1117

Site Name: (1117) Sundance Clinical Research

Subject No: 11171146

Subject Initials: ---

Generated By: (b) (4)

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

Health Care Utilization

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

Health Care Utilization Other

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

Health Care Utilization

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

Header Text: c4591001

Visit: POT_COVID_ILL - New Unscheduled Visit

Form: ILLNESS DETAILS

Form Version: 06-Jul-2020 21:52

Form Status: Not Started

Site No: 1117

Site Name: (1117) Sundance Clinical Research

Subject No: 11171146

Subject Initials: ---

Generated By: (b) (4)

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

Illness Details

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

Header Text: c4591001

Visit: POT_COVID_CONVA - New
Unscheduled Visit

Form: DATE OF VISIT - ILLNESS CONVALESCENT

Form Version: 22-Apr-2020 21:04

Form Status: Not Started

Site No: 1117

Site Name: (1117) Sundance Clinical Research

Subject No: 11171146

Subject Initials: ---

Generated By: (b) (4)

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

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

COVID-19 Illness Visit

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

Header Text: c4591001

Visit: POT_COVID_CONVA - New
Unscheduled Visit

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1117

Site Name: (1117) Sundance Clinical Research

Subject No: 11171146

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	[]
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090177e196ae3da4\Final\Final On: 01-Apr-2021 04:40 (GMT)

Header Text: c4591001

Visit: POT_COVID_REPEAT_SWAB - New
Unscheduled Visit

Form: DATE OF VISIT - REPEAT SWAB

Form Version: 10-Oct-2020 15:57

Form Status: Not Started

Site No: 1117

Site Name: (1117) Sundance Clinical Research

Subject No: 11171146

Subject Initials: ---

Generated By: (b) (4)

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

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

COVID-19 Repeat Swab

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

Header Text: c4591001

Visit: POT_COVID_REPEAT_SWAB - New
Unscheduled Visit

Form: ELECTRONIC SAMPLE TRACKING - REPEAT SWAB

Form Version: 10-Oct-2020 15:57

Form Status: Not Started

Site No: 1117

Site Name: (1117) Sundance Clinical Research

Subject No: 11171146

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	[]
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090177e196ae3da4\Final\Final On: 01-Apr-2021 04:40 (GMT)

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: 11171146

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: 11171146

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: Logs

Form: ADVERSE EVENT REPORT

Form Version: 22-Apr-2020 21:02

Site No: 1117

Site Name: (1117) Sundance Clinical Research

Subject No: 11171146

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	PULMONARY EMBOLI	Jan/21/2021 UNK:UNK	NO End Date Time: Jan/23/2021 UN K:UNK	Repeating Pages
2. DELETED	ADVERSE EVENT	2	WORSENING AORTIC ANEURYSM	Jan/21/2021 UNK:UNK	YES	Repeating Pages
3.	ADVERSE EVENT	3	DEEP VEIN THROMBOSIS, LOWER EXTREMITY, RIGHT	Jan/21/2021 UNK:UNK	NO End Date Time: Jan/23/2021 UN K:UNK	Repeating Pages
4.	ADVERSE EVENT	4	HIATAL HERNIA	Jan/21/2021 UNK:UNK	YES	Repeating Pages
5.	ADVERSE EVENT	5	CATARACTS, WORSENING CONDITION	Feb/3/2021 UNK:UNK	YES	Repeating Pages

090177e196ae3da4\Final\Final On: 01-Apr-2021 04:40 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1117

Subject No: 11171146

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

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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Adverse Event Report

1.	Category:	ADVERSE EVENT
2.	AE ID:	[1]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[PULMONARY EMBOLI]
4.	Start Date Time:	Jan/21/2021 UNK:UNK
5.	Is the adverse event still ongoing?	NO End Date Time: Jan/23/2021 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).	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

090177e196ae3da4\Final\Final On: 01-Apr-2021 04:40 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1117

Subject No: 11171146

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Frozen, Verified

Site Name: (1117) Sundance Clinical Research

Subject Initials: ---

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

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: [CURRENT DVT, PRIOR HX OF DVT]
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	[2021064848]

090177e196ae3da4\Final\Final On: 01-Apr-2021 04:40 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1117

Subject No: 11171146

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Deleted, Frozen, Verified

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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Adverse Event Report

1.	Category:	ADVERSE EVENT
2.	AE ID:	[2]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[WORSENING AORTIC ANEURYSM]
4.	Start Date Time:	Jan/21/2021 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: [PREEXISTING CONDITION]
10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE

090177e196ae3da4\Final\Final On: 01-Apr-2021 04:40 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1117

Subject No: 11171146

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Deleted, Frozen, Verified

Site Name: (1117) Sundance Clinical Research

Subject Initials: ---

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

*** THIS REPEATING FORM HAS BEEN DELETED ***

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

090177e196ae3da4\Final\Final On: 01-Apr-2021 04:40 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1117

Subject No: 11171146

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Frozen, Not Complete

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)	[DEEP VEIN THROMBOSIS, LOWER EXTREMITY, RIGHT]
4.	Start Date Time:	Jan/21/2021 UNK:UNK
5.	Is the adverse event still ongoing?	NO End Date Time: Jan/23/2021 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).	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

090177e196ae3da4\Final\Final On: 01-Apr-2021 04:40 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1117

Subject No: 11171146

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Frozen, Not Complete

Site Name: (1117) Sundance Clinical Research

Subject Initials: ---

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

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: [PRIOR HISTORY OF DVT]
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	[2021064848]

090177e196ae3da4\Final\Final On: 01-Apr-2021 04:40 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1117

Subject No: 11171146

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

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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Adverse Event Report

1.	Category:	ADVERSE EVENT
2.	AE ID:	[4]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[HIATAL HERNIA]
4.	Start Date Time:	Jan/21/2021 UNK:UNK
5.	Is the adverse event still ongoing?	YES
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]
10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE

090177e196ae3da4\Final\Final On: 01-Apr-2021 04:40 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1117

Subject No: 11171146

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, 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?:	NOT RECOVERED/NOT RESOLVED
14.	Did the adverse event cause the subject to be discontinued from the study?	NO
15.	Serious Adverse Event Number: For Pfizer Use Only	[]

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1117

Subject No: 11171146

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

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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)	[CATARACTS, WORSENING CONDITION]
4.	Start Date Time:	Feb/3/2021 UNK:UNK
5.	Is the adverse event still ongoing?	YES
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: [PRE EXISTING CONDITON]
10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE

090177e196ae3da4\Final\Final On: 01-Apr-2021 04:40 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1117

Subject No: 11171146

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

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

Header Text: c4591001

Visit: Logs

Form: MEDICATION ERROR

Form Version: 17-Jul-2020 21:54

Site No: 1117

Site Name: (1117) Sundance Clinical Research

Subject No: 11171146

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: 11171146

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	[]

090177e196ae3da4\Final\Final On: 01-Apr-2021 04:40 (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: 11171146

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.						Repeating Pages

Header Text: c4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - NON STUDY
VACCINATIONS

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1117

Site Name: (1117) Sundance Clinical Research

Subject No: 11171146

Subject Initials: ---

Generated By: (b) (4)

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

[Back to Form](#)

Concomitant Medications

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

090177e196ae3da4\Final\Final On: 01-Apr-2021 04:40 (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: 11171146

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

090177e196ae3da4\Final\Final On: 01-Apr-2021 04:40 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1117

Subject No: 11171146

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

[Back to Form](#)

Concomitant Medications

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

090177e196ae3da4\Final\Final On: 01-Apr-2021 04:40 (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: 11171146

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

090177e196ae3da4\Final\Final On: 01-Apr-2021 04:40 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1117

Subject No: 11171146

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

[Back to Form](#)

Radiation Treatment

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

Header Text: c4591001

Visit: Logs

Form: TRANSFUSIONS

Form Version: 22-Apr-2020 21:03

Site No: 1117

Site Name: (1117) Sundance Clinical Research

Subject No: 11171146

Subject Initials: ---

Generated By: (b) (4)

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

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

090177e196ae3da4\Final\Final On: 01-Apr-2021 04:40 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1117

Subject No: 11171146

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

[Back to Form](#)

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

Header Text: c4591001

Visit: End of Treatment - Unscheduled

Form Version: 15-Sep-2020 21:55

Site No: 1117

Subject No: 11171146

Generated By: (b) (4)

Form: DISPOSITION - TREATMENT

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1117) Sundance Clinical Research

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Disposition - Treatment

1.	Date of Completion/Discontinuation/Death :	Nov/12/2020
2.	Phase of Disposition:	VACCINATION
3.	Status:	COMPLETED
4.	Specify Status:	[]

Header Text: c4591001

Visit: Unplanned Vaccination - Unscheduled

Form: DATE OF VISIT

Form Version: 22-Apr-2020 21:02

Form Status: Not Started

Site No: 1117

Site Name: (1117) Sundance Clinical Research

Subject No: 11171146

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: 11171146

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: LAB URINALYSIS - PREGNANCY TEST

Form Version: 20-Feb-2021 02:14

Form Status: Not Started

Site No: 1117

Site Name: (1117) Sundance Clinical Research

Subject No: 11171146

Subject Initials: ---

Generated By: (b) (4)

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

Lab Urinalysis

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

Lab Result

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

090177e196ae3da4\Final\Final On: 01-Apr-2021 04:40 (GMT)

Header Text: c4591001

Visit: Unplanned Vaccination - Unscheduled

Form: VACCINATION

Form Version: 10-Dec-2020 02:26

Form Status: Not Started

Site No: 1117

Site Name: (1117) Sundance Clinical Research

Subject No: 11171146

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?	

090177e196ae3da4\Final\Final On: 01-Apr-2021 04:40 (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: 11171146

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: 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: 11171146

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: Follow-Up - Unscheduled

Form Version: 15-Sep-2020 21:53

Site No: 1117

Subject No: 11171146

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: 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: 11171146

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/15/2021
2.	Erroneous Visit	

Header Text: c4591001

Visit: Potential ReVax Initial Contact -
Unscheduled

Form: FURTHER VACCINATION CONFIRMATION

Form Version: 10-Dec-2020 02:25

Form Status: Data Complete, Frozen

Site No: 1117

Site Name: (1117) Sundance Clinical Research

Subject No: 11171146

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: 11171146

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

Header Text: c4591001

Visit: Disposition - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1117

Subject No: 11171146

Generated By: (b) (4)

Form: WITHDRAWAL OF CONSENT

Form Status: Not Started

Site Name: (1117) Sundance Clinical Research

Subject Initials: ---

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

Withdrawal Of Consent

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

Header Text: c4591001

Visit: Disposition - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1117

Subject No: 11171146

Generated By: (b) (4)

Form: DEATH DETAILS CODED

Form Status: Not Started

Site Name: (1117) Sundance Clinical Research

Subject Initials: ---

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: 11171146

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/19/2021
2.	Erroneous Visit	

Header Text: c4591001

Visit: V101_VAX3

Form Version: 10-Dec-2020 02:31

Site No: 1117

Subject No: 11171146

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/19/2021
----	--------------	--

Header Text: c4591001

Visit: V101_VAX3

Form: INCLUSION/EXCLUSION CRITERIA - FURTHER VACCINATION

Form Version: 10-Dec-2020 02:30

Form Status: Data Complete, Frozen, Verified

Site No: 1117

Site Name: (1117) Sundance Clinical Research

Subject No: 11171146

Subject Initials: ---

Generated By: (b) (4)

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: V101_VAX3

Form Version: 10-Dec-2020 02:31

Site No: 1117

Subject No: 11171146

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/19/2021
2.	Phase of Disposition:	REPEAT SCREENING 1
3.	Status:	COMPLETED
4.	Specify Status:	[]

Header Text: c4591001

Visit: V101_VAX3

Form Version: 14-Jan-2021 02:21

Site No: 1117

Subject No: 11171146

Generated By: (b) (4)

Form: LAB URINALYSIS - PREGNANCY TEST

Form Status: Data Complete, Frozen, Verified

Site Name: (1117) Sundance Clinical Research

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Lab Urinalysis

1.	Lab Panel:	URINALYSIS
2.	Lab Sub-Panel:	PREGNANCY
3.	Collection Date:	Jan/19/2021
4.	Laboratory Name and Address (Derived)	[STUDY SITE]
5.	Specimen Type:	URINE

Lab Result

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

090177e196ae3da4\Final\Final On: 01-Apr-2021 04:40 (GMT)

Header Text: c4591001

Visit: V101_VAX3

Form Version: 22-Apr-2020 21:03

Site No: 1117

Subject No: 11171146

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Status: Data Complete, Frozen, Verified

Site Name: (1117) Sundance Clinical Research

Subject Initials: ---

Generated Time (GMT): 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: Jan/19/2021
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	[BRSRHZ]
5.b	Sample ID	[BRSRJ0]
5.c	Sample ID	[BR6RNS]
5.d	Sample ID	[BR6RNT]
5.e	Sample ID	[BR6RNV]

090177e196ae3da4\Final\Final On: 01-Apr-2021 04:40 (GMT)

Header Text: c4591001

Visit: V101_VAX3

Form Version: 22-Apr-2020 21:03

Site No: 1117

Subject No: 11171146

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB

Form Status: Data Complete, Frozen, Verified

Site Name: (1117) Sundance Clinical Research

Subject Initials: ---

Generated Time (GMT): 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: Jan/19/2021
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	[BP58ZY]
-----	-----------	----------

090177e196ae3da4\Final\Final On: 01-Apr-2021 04:40 (GMT)

Header Text: c4591001

Visit: V101_VAX3

Form Version: 10-Dec-2020 02:26

Site No: 1117

Subject No: 11171146

Generated By: (b) (4)

Form: 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](#)

Vaccination

1.	Was there a temporary delay of vaccination?	NO
2.	Treatment Name	[BNT162b2]
3.	Formulation:	INJECTION
4.	Dose Date Time:	Jan/19/2021 14:55
5.	Anatomical Location:	DELTOID MUSCLE
6.	Body Side:	LEFT
7.	Route:	INTRAMUSCULAR
8.	Actual Dose:	[30.0]
9.	Unit:	ug
10.	Timeframe Subject Was Observed	30 MINUTES
11.	Was the subject observed for at least the protocol specified observation period after investigational product administration?	YES

090177e196ae3da4\Final\Final On: 01-Apr-2021 04:40 (GMT)

Header Text: c4591001

Visit: V102_VAX4

Form Version: 22-Apr-2020 21:02

Site No: 1117

Subject No: 11171146

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	Feb/9/2021
2.	Erroneous Visit	

Header Text: c4591001

Visit: V102_VAX4

Form Version: 14-Jan-2021 02:21

Site No: 1117

Subject No: 11171146

Generated By: (b) (4)

Form: LAB URINALYSIS - PREGNANCY TEST

Form Status: Data Complete, Frozen, Verified

Site Name: (1117) Sundance Clinical Research

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Lab Urinalysis

1.	Lab Panel:	URINALYSIS
2.	Lab Sub-Panel:	PREGNANCY
3.	Collection Date:	Feb/9/2021
4.	Laboratory Name and Address (Derived)	[STUDY SITE]
5.	Specimen Type:	URINE

Lab Result

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

090177e196ae3da4\Final\Final On: 01-Apr-2021 04:40 (GMT)

Header Text: c4591001

Visit: V102_VAX4

Form Version: 22-Apr-2020 21:03

Site No: 1117

Subject No: 11171146

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB

Form Status: Data Complete, Frozen, Verified

Site Name: (1117) Sundance Clinical Research

Subject Initials: ---

Generated Time (GMT): 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: Feb/9/2021
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	[BR6RV6]
-----	-----------	----------

090177e196ae3da4\Final\Final On: 01-Apr-2021 04:40 (GMT)

Header Text: c4591001

Visit: V102_VAX4

Form Version: 10-Dec-2020 02:26

Site No: 1117

Subject No: 11171146

Generated By: (b) (4)

Form: 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](#)

Vaccination

1.	Was there a temporary delay of vaccination?	NO
2.	Treatment Name	[BNT162b2]
3.	Formulation:	INJECTION
4.	Dose Date Time:	Feb/9/2021 14:45
5.	Anatomical Location:	DELTOID MUSCLE
6.	Body Side:	LEFT
7.	Route:	INTRAMUSCULAR
8.	Actual Dose:	[30.0]
9.	Unit:	ug
10.	Timeframe Subject Was Observed	30 MINUTES
11.	Was the subject observed for at least the protocol specified observation period after investigational product administration?	YES

090177e196ae3da4\Final\Final On: 01-Apr-2021 04:40 (GMT)

Header Text: c4591001

Visit: V103_MONTH1

Form Version: 22-Apr-2020 21:02

Site No: 1117

Subject No: 11171146

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: V103_MONTH1

Form Version: 22-Apr-2020 21:04

Site No: 1117

Subject No: 11171146

Generated By: (b) (4)

Form: CONTACT OUTCOME

Form Status: Not Started

Site Name: (1117) Sundance Clinical Research

Subject Initials: ---

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

Contact Outcome

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

Header Text: c4591001

Visit: V104_MONTH6

Form Version: 22-Apr-2020 21:02

Site No: 1117

Subject No: 11171146

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: V104_MONTH6

Form Version: 22-Apr-2020 21:04

Site No: 1117

Subject No: 11171146

Generated By: (b) (4)

Form: CONTACT OUTCOME

Form Status: Not Started

Site Name: (1117) Sundance Clinical Research

Subject Initials: ---

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

Contact Outcome

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

Header Text: c4591001

Visit: V105_MONTH18

Form Version: 22-Apr-2020 21:02

Site No: 1117

Subject No: 11171146

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: V105_MONTH18

Form Version: 22-Apr-2020 21:04

Site No: 1117

Subject No: 11171146

Generated By: (b) (4)

Form: CONTACT OUTCOME

Form Status: Not Started

Site Name: (1117) Sundance Clinical Research

Subject Initials: ---

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

Contact Outcome

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

Header Text: c4591001

Visit: FURTHER_VACCINATION_EOT -
Unscheduled

Form: DISPOSITION - TREATMENT

Form Version: 20-Feb-2021 02:26

Form Status: Not Started

Site No: 1117

Site Name: (1117) Sundance Clinical Research

Subject No: 11171146

Subject Initials: ---

Generated By: (b) (4)

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

Disposition - Treatment

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

Header Text: c4591001

Visit: Subject Status - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1117

Subject No: 11171146

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	Nov/12/2020

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: 11171146

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
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Header Text: c4591001

Visit: Investigator Signature - Unscheduled

Form: CASEBOOK SIGNATURE FORM

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Signed, Verified

Site No: 1117

Site Name: (1117) Sundance Clinical Research

Subject No: 11171146

Subject Initials: ---

Generated By: (b) (4)

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 11:09:37 (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.

090177e196ae3da4\Final\Final On: 01-Apr-2021 04:40 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:02

Site No: 1117

Subject No: 11171146

Generated By: (b) (4)

Form: DATE OF VISIT - Comments

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1117) Sundance Clinical Research

Subject Initials: ---

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

[Back to Form](#)

Item	Date	User	Comment
2	Oct-06-2020 16:29:22 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	
2	Sep-28-2020 14:05:08 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 15-Sep-2020 21:53

Site No: 1117

Subject No: 11171146

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

[Back to Form](#)

Item	Date	User	Comment
Form	Sep-28-2020 14:05:39 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 15-Sep-2020 21:52

Site No: 1117

Subject No: 11171146

Generated By: (b) (4)

Form: DISPOSITION - SCREENING - Comments

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1117) Sundance Clinical Research

Subject Initials: ---

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

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Item	Date	User	Comment
4	Sep-28-2020 14:06:10 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - Comments

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1117

Site Name: (1117) Sundance Clinical Research

Subject No: 11171146

Subject Initials: ---

Generated By: (b) (4)

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

[Back to Form](#)

Item	Date	User	Comment
4	Oct-06-2020 16:29:41 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	
4	Sep-29-2020 16:52:42 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB -
Comments

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1117

Site Name: (1117) Sundance Clinical Research

Subject No: 11171146

Subject Initials: ---

Generated By: (b) (4)

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

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Item	Date	User	Comment
4	Oct-06-2020 16:29:55 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	
4	Sep-29-2020 16:49:57 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

Header Text: c4591001

Visit: V101_VAX3

Form: INCLUSION/EXCLUSION CRITERIA - FURTHER
VACCINATION - Comments

Form Version: 10-Dec-2020 02:30

Form Status: Data Complete, Frozen, Verified

Site No: 1117

Site Name: (1117) Sundance Clinical Research

Subject No: 11171146

Subject Initials: ---

Generated By: (b) (4)

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

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Item	Date	User	Comment
Form	Jan-22-2021 21:19:35 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

Header Text: c4591001

Visit: Investigator Signature - Unscheduled

Form: CASEBOOK SIGNATURE FORM - Signature History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Signed, Verified

Site No: 1117

Site Name: (1117) Sundance Clinical Research

Subject No: 11171146

Subject Initials: ---

Generated By: (b) (4)

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

[Back to Form](#)

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

- CRF_Sign

Name	Signature Meaning	Date	Type	Action
(b) (6)	Approved	Mar-10-2021 11:09:37 (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-25-2020 20:35:21 (UTC-06:00) Central Time (US & Canada)		Edit - All signatures invalidated
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Affidavit:

N/A

(b) (6)	Approved	Nov-16-2020 16:28:25 (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-12-2020 18:20:03 (UTC-06:00) Central Time (US & Canada)		Edit - All signatures invalidated
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Affidavit:

N/A

090177e196ae3da4\Final\Final On: 01-Apr-2021 04:40 (GMT)

Header Text: c4591001

Visit: Investigator Signature - Unscheduled

Form: CASEBOOK SIGNATURE FORM - Signature History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Signed, Verified

Site No: 1117

Site Name: (1117) Sundance Clinical Research

Subject No: 11171146

Subject Initials: ---

Generated By: (b) (4)

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

Larkin Wadsworth	Approved	Nov-12-2020 10:39:13 (UTC-06:00) Central Time (US & Canada)	BOOK	Signed
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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.

090177e196ae3da4\Final\Final On: 01-Apr-2021 04:40 (GMT)

Header Text: c4591001

Visit: COHORT_SELECTION

Form Version: 15-Sep-2020 21:55

Site No: 1117

Subject No: 11171146

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
Sep-28-2020 14:04:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 08 SEP 2020	Initial Entry

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

Date	Location	User	Value	Reason
Sep-28-2020 14:04:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: STAGE 3 COHORTS	Initial Entry

090177e196ae3da4\Final\Final On: 01-Apr-2021 04:40 (GMT)

Header Text: c4591001

Visit: COHORT_SELECTION

Form Version: 22-Apr-2020 21:02

Site No: 1117

Subject No: 11171146

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
Sep-28-2020 14:04:17 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: OBTAINED Date Written Consent Obtained Sep/22/2020	Initial Entry

Header Text: c4591001

Visit: COHORT_SELECTION

Form Version: 15-Sep-2020 21:54

Site No: 1117

Subject No: 11171146

Generated By: (b) (4)

Form: DEMOGRAPHY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1117) Sundance Clinical Research

Subject Initials: ---

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

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1. Subject ID

Date	Location	User	Value	Reason
Sep-28-2020 14:03:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 11171146	Item copied from previous form

2. Birth Date:

Date	Location	User	Value	Reason
Sep-28-2020 14:03:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: (b) (6)/1949	Enrollment Entry

3. Sex:

Date	Location	User	Value	Reason
Sep-28-2020 14:04:27 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: FEMALE	Initial Entry

4. Ethnicity:

Date	Location	User	Value	Reason
Sep-28-2020 14:04:27 (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
Sep-28-2020 14:04:27 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: WHITE	Initial Entry

090177e196ae3da4\Final\Final On: 01-Apr-2021 04:40 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:02

Site No: 1117

Subject No: 11171146

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
Oct-01-2020 06:49:24 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Sep-30-2020 15:02:32 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Original value is correct
Sep-29-2020 11:57:37 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	DM: Kindly review and complete 'Immunogenicity, Nasal Swab forms' at this visit. Thank you
Sep-28-2020 14:05:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sep/22/2020	Initial Entry

2. Erroneous Visit

Date	Location	User	Value	Reason
Oct-07-2020 07:09:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query.
Oct-06-2020 16:29:32 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Changed data per query
Oct-06-2020 16:29:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Initial Entry
Oct-06-2020 00:06:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued:Opened	DM1: Data is not updated as per query. As this visit was performed on 22Sep2020, kindly consider to remove item level comment 'Not Applicable' at 'Erroneous visit'

090177e196ae3da4\Final\Final On: 01-Apr-2021 04:40 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:02

Site No: 1117

Subject No: 11171146

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

				field on this page.
Oct-04-2020 19:37:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Changed data per query
Oct-01-2020 06:49:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	DM: As this visit was performed on 22Sep2020, kindly consider to remove item level comment 'Not Applicable' added at 'Erroneous visit' field.
Sep-28-2020 14:05:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

090177e196ae3da4\Final\Final On: 01-Apr-2021 04:40 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 15-Sep-2020 21:52

Site No: 1117

Subject No: 11171146

Generated By: (b) (4)

Form: DISPOSITION - SCREENING - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1117) Sundance Clinical Research

Subject Initials: ---

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

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1. Date of Completion/Discontinuation/Death

Date	Location	User	Value	Reason
Sep-28-2020 14:06:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sep/22/2020	Initial Entry

2. Phase of Disposition:

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

3. Status:

Date	Location	User	Value	Reason
Sep-28-2020 14:06:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: COMPLETED	Initial Entry

4. Specify Status:

Date	Location	User	Value	Reason
Sep-28-2020 14:06:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

090177e196ae3da4\Final\Final On: 01-Apr-2021 04:40 (GMT)

Header Text: c4591001**Visit:** V1_DAY1_VAX1_L**Form Version:** 22-Apr-2020 21:03**Site No:** 1117**Subject No:** 11171146**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[Back to Form](#)***1.a***

Date	Location	User	Value	Reason
Sep-28-2020 14:06:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Nu 1 mber: Medical Histo HYSTERECTOM ry Term: Y, TOTAL Start Date: UNK/UNK/2014 Ongoing: NO End Date: UNK/UNK/2014	Initial Entry

1.a Line/MH Number:

Date	Location	User	Value	Reason
Sep-28-2020 14:06:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 1	Initial Entry

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

Date	Location	User	Value	Reason
Sep-28-2020 14:06:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: HYSTERECTOMY, TOTAL	Initial Entry

1.a Start Date:

Date	Location	User	Value	Reason
Sep-28-2020 14:06:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNK/UNK/2014	Initial Entry

1.a Ongoing:

Date	Location	User	Value	Reason
Sep-28-2020 14:06:57	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1117

Subject No: 11171146

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)	NO End Date: UNK/UNK/2014
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I.b

Date	Location	User	Value	Reason
Sep-28-2020 14:07:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: Medical History Term: UTERINE FIBR Start Date: OIDS Ongoing: UNK/UNK/1990 NO End Date: UNK/UNK/2014	Initial Entry

090177e196ae3da4\Final\Final On: 01-Apr-2021 04:40 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1117

Subject No: 11171146

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.b Line/MH Number:

Date	Location	User	Value	Reason
Sep-28-2020 14:07:26 (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
Sep-28-2020 14:07:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UTERINE FIBROIDS	Initial Entry

1.b Start Date:

Date	Location	User	Value	Reason
Sep-28-2020 14:07:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNK/UNK/1990	Initial Entry

1.b Ongoing:

Date	Location	User	Value	Reason
Sep-28-2020 14:07:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO End Date: UNK/UNK/2014	Initial Entry

1.c

Date	Location	User	Value	Reason
Sep-28-2020 14:07:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 3 Medical History Term: MENOPAUS E Start Date: UNK/UNK/2 000 Ongoing: YES	Initial Entry

090177e196ae3da4\Final\Final On: 01-Apr-2021 04:40 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1117

Subject No: 11171146

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
Sep-28-2020 14:07:45 (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
Sep-28-2020 14:07:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: MENOPAUSE	Initial Entry

I.c Start Date:

Date	Location	User	Value	Reason
Sep-28-2020 14:07:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNK/UNK/2000	Initial Entry

I.c Ongoing:

Date	Location	User	Value	Reason
Sep-28-2020 14:07:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

I.d

Date	Location	User	Value	Reason
Sep-28-2020 14:08:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 4 Medical History Term: ALLERGY, PEN CILLIN Start Date: UNK/UNK/1959 Ongoing: YES	Initial Entry

090177e196ae3da4\Final\Final On: 01-Apr-2021 04:40 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1117

Subject No: 11171146

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.d Line/MH Number:

Date	Location	User	Value	Reason
Sep-28-2020 14:08:36 (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
Sep-28-2020 14:08:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: ALLERGY, PENCILLIN	Initial Entry

1.d Start Date:

Date	Location	User	Value	Reason
Sep-28-2020 14:08:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNK/UNK/1959	Initial Entry

1.d Ongoing:

Date	Location	User	Value	Reason
Sep-28-2020 14:08:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

1.e

Date	Location	User	Value	Reason
Sep-28-2020 14:08:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 5 Medical History Term: SLEEP APN EA Start Date: Sep/UNK/20 18 Ongoing: YES	Initial Entry

090177e196ae3da4\Final\Final On: 01-Apr-2021 04:40 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1117

Subject No: 11171146

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.e Line/MH Number:

Date	Location	User	Value	Reason
Sep-28-2020 14:08:58 (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
Sep-28-2020 14:08:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: SLEEP APNEA	Initial Entry

I.e Start Date:

Date	Location	User	Value	Reason
Sep-28-2020 14:08:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sep/UNK/2018	Initial Entry

I.e Ongoing:

Date	Location	User	Value	Reason
Sep-28-2020 14:08:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

I.f

Date	Location	User	Value	Reason
Sep-28-2020 14:09:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number 6 : Medical History T HYPERTENS erm: ION Start Date: Jun/UNK/201 8 Ongoing: YES	Initial Entry

090177e196ae3da4\Final\Final On: 01-Apr-2021 04:40 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1117

Subject No: 11171146

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: ---

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1.f Line/MH Number:

Date	Location	User	Value	Reason
Sep-28-2020 14:09:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 6	Initial Entry

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

Date	Location	User	Value	Reason
Sep-28-2020 14:09:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: HYPERTENSION	Initial Entry

1.f Start Date:

Date	Location	User	Value	Reason
Sep-28-2020 14:09:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Jun/UNK/2018	Initial Entry

1.f Ongoing:

Date	Location	User	Value	Reason
Sep-28-2020 14:09:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

1.g

Date	Location	User	Value	Reason
Sep-28-2020 14:09:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number 7 : Medical History Term: OSTEOPOROSIS Start Date: UNK/UNK/2012 Ongoing: YES	Initial Entry

090177e196ae3da4\Final\Final On: 01-Apr-2021 04:40 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1117

Subject No: 11171146

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.g Line/MH Number:

Date	Location	User	Value	Reason
Sep-28-2020 14:09:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 7	Initial Entry

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

Date	Location	User	Value	Reason
Sep-28-2020 14:09:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: OSTEOPOROSIS	Initial Entry

1.g Start Date:

Date	Location	User	Value	Reason
Sep-28-2020 14:09:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNK/UNK/2012	Initial Entry

1.g Ongoing:

Date	Location	User	Value	Reason
Sep-28-2020 14:09:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

1.h

Date	Location	User	Value	Reason
Sep-28-2020 14:10:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH N umber: 8 Medical His tory Term: BONE SPUR, SHO ULDER, RIGHT Start Date: UNK/UNK/2016 Ongoing: NO End Date: UNK/UNK/2016	Initial Entry

090177e196ae3da4\Final\Final On: 01-Apr-2021 04:40 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1117

Subject No: 11171146

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.h Line/MH Number:

Date	Location	User	Value	Reason
Sep-28-2020 14:10:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 8	Initial Entry

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

Date	Location	User	Value	Reason
Sep-28-2020 14:10:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BONE SPUR, SHOULDER, RIG HT	Initial Entry

I.h Start Date:

Date	Location	User	Value	Reason
Sep-28-2020 14:10:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNK/UNK/2016	Initial Entry

I.h Ongoing:

Date	Location	User	Value	Reason
Sep-28-2020 14:10:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO End Date: UNK/UNK/2016	Initial Entry

I.i

Date	Location	User	Value	Reason
Sep-28-2020 14:10:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH 9 Number: Medical History Term: BONE SPUR REMOV AL, SHOULDER, RIG HT Start Date UNK/UNK/2016 :	Initial Entry

090177e196ae3da4\Final\Final On: 01-Apr-2021 04:40 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1117

Subject No: 11171146

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

			Ongoing: NO End Date: UNK/UNK/2016
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1.i Line/MH Number:

Date	Location	User	Value	Reason
Sep-28-2020 14:10:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 9	Initial Entry

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

Date	Location	User	Value	Reason
Sep-28-2020 14:10:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BONE SPUR REMOVAL, SHOULDER, RIGHT	Initial Entry

1.i Start Date:

Date	Location	User	Value	Reason
Sep-28-2020 14:10:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNK/UNK/2016	Initial Entry

1.i Ongoing:

Date	Location	User	Value	Reason
Sep-28-2020 14:10:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO End Date: UNK/UNK/2016	Initial Entry

1.j

Date	Location	User	Value	Reason
Sep-28-2020 14:11:04 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 10 Medical History Term: IRREGULAR HEART BEAT	Initial Entry

090177e196ae3da4\Final\Final On: 01-Apr-2021 04:40 (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: 11171146

Subject Initials: ---

Generated By: (b) (4)

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

			Start Date: UNK/UNK/2018	
			Ongoing: YES	

1.j Line/MH Number:

Date	Location	User	Value	Reason
Sep-28-2020 14:11:04 (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
Sep-28-2020 14:11:04 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: IRREGULAR HEART BEAT	Initial Entry

1.j Start Date:

Date	Location	User	Value	Reason
Sep-28-2020 14:11:04 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNK/UNK/2018	Initial Entry

1.j Ongoing:

Date	Location	User	Value	Reason
Sep-28-2020 14:11:04 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

090177e196ae3da4\Final\Final On: 01-Apr-2021 04:40 (GMT)

Header Text: c4591001

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Subject No: 11171146

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1.k

Date	Location	User	Value	Reason
Sep-28-2020 14:12:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH N 11 umber: Medical His HEARING IMPAIR tory Term: MENT, BILATERA L Start Date: UNK/UNK/2012 Ongoing: YES	Initial Entry

1.k Line/MH Number:

Date	Location	User	Value	Reason
Sep-28-2020 14:12:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 11	Initial Entry

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

Date	Location	User	Value	Reason
Sep-28-2020 14:12:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: HEARING IMPAIRMENT, BILA TERAL	Initial Entry

1.k Start Date:

Date	Location	User	Value	Reason
Sep-28-2020 14:12:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNK/UNK/2012	Initial Entry

1.k Ongoing:

Date	Location	User	Value	Reason
Sep-28-2020 14:12:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

1.l

090177e196ae3da4\Final\Final On: 01-Apr-2021 04:40 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1117

Subject No: 11171146

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

Date	Location	User	Value	Reason
Sep-28-2020 14:13:24 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH N 12 umber: Medical His VISION IMPAIRM tory Term: ENT, BILATERAL Start Date: UNK/UNK/1990 Ongoing: YES	Initial Entry

1.1 Line/MH Number:

Date	Location	User	Value	Reason
Sep-28-2020 14:13:24 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 12	Initial Entry

1.1 Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:

Date	Location	User	Value	Reason
Sep-28-2020 14:13:24 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: VISION IMPAIRMENT, BILATE RAL	Initial Entry

1.1 Start Date:

Date	Location	User	Value	Reason
Sep-28-2020 14:13:24 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNK/UNK/1990	Initial Entry

1.1 Ongoing:

Date	Location	User	Value	Reason
Sep-28-2020 14:13:24 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

1.m

Date	Location	User	Value	Reason
Sep-28-2020 14:13:49 (UTC-06:00) Central	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry:	Initial Entry

090177e196ae3da4\Final\Final On: 01-Apr-2021 04:40 (GMT)

Header Text: c4591001

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Site No: 1117

Subject No: 11171146

Generated By: (b) (4)

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Form Status: Data Complete, Frozen, Verified

Site Name: (1117) Sundance Clinical Research

Subject Initials: ---

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

Time (US & Canada)			Line/MH Number: 13 Medical History Term: PEPTIC ULCERS Start Date: UNK/UNK/2015 Ongoing: NO End Date: UNK/UNK/2017
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1.m Line/MH Number:

Date	Location	User	Value	Reason
Sep-28-2020 14:13:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 13	Initial Entry

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

Date	Location	User	Value	Reason
Sep-28-2020 14:13:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: PEPTIC ULCERS	Initial Entry

1.m Start Date:

Date	Location	User	Value	Reason
Sep-28-2020 14:13:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNK/UNK/2015	Initial Entry

1.m Ongoing:

Date	Location	User	Value	Reason
Sep-28-2020 14:13:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO End Date: UNK/UNK/2017	Initial Entry

1.n

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Header Text: c4591001

Visit: V1_DAY1_VAX1_L

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Site No: 1117

Subject No: 11171146

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

Date	Location	User	Value	Reason
Sep-28-2020 14:14:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH 14 Number: Medical History T NEUROPATHY, LOW ER EXTREMITY, BIL erm: ATERAL Start Date UNK/UNK/2015 : Ongoing: YES	Initial Entry

1.n Line/MH Number:

Date	Location	User	Value	Reason
Sep-28-2020 14:14:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 14	Initial Entry

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

Date	Location	User	Value	Reason
Sep-28-2020 14:14:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NEUROPATHY, LOWER EXTR EMITY, BILATERAL	Initial Entry

1.n Start Date:

Date	Location	User	Value	Reason
Sep-28-2020 14:14:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNK/UNK/2015	Initial Entry

1.n Ongoing:

Date	Location	User	Value	Reason
Sep-28-2020 14:14:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

1.o

Date	Location	User	Value	Reason
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090177e196ae3da4\Final\Final On: 01-Apr-2021 04:40 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1117

Subject No: 11171146

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

Sep-28-2020 14:15:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH N umber: 15 Medical History Term: OSTEOARTHRITIS, HIP, BILATERAL Start Date: UNK/UNK/2015 Ongoing: YES	Initial Entry
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1.o Line/MH Number:

Date	Location	User	Value	Reason
Sep-28-2020 14:15:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 15	Initial Entry

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

Date	Location	User	Value	Reason
Sep-28-2020 14:15:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: OSTEOARTHRITIS, HIP, BILATERAL	Initial Entry

1.o Start Date:

Date	Location	User	Value	Reason
Sep-28-2020 14:15:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNK/UNK/2015	Initial Entry

1.o Ongoing:

Date	Location	User	Value	Reason
Sep-28-2020 14:15:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

1.p

Date	Location	User	Value	Reason
Sep-28-2020 14:15:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH N umber: 16	Initial Entry

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Header Text: c4591001

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Site No: 1117

Subject No: 11171146

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

			Medical History Term OSTEOARTHRITIS, THUMB, BILATERAL Start Date: UNK/UNK/2015 Ongoing: YES
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1.p Line/MH Number:

Date	Location	User	Value	Reason
Sep-28-2020 14:15:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 16	Initial Entry

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

Date	Location	User	Value	Reason
Sep-28-2020 14:15:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: OSTEOARTHRITIS, THUMB, BILATERAL	Initial Entry

1.p Start Date:

Date	Location	User	Value	Reason
Sep-28-2020 14:15:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNK/UNK/2015	Initial Entry

1.p Ongoing:

Date	Location	User	Value	Reason
Sep-28-2020 14:15:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

1.q

Date	Location	User	Value	Reason
Sep-28-2020 14:16:23 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 17 Medical History Term: CELLULITIS, ANKLE, RIGHT	Initial Entry

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Header Text: c4591001

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Site No: 1117

Subject No: 11171146

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: Jan/31/2019 Ongoing: NO End Date: Feb/9/2019
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1.q Line/MH Number:

Date	Location	User	Value	Reason
Sep-28-2020 14:16:23 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 17	Initial Entry

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

Date	Location	User	Value	Reason
Sep-28-2020 14:16:23 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: CELLULITIS, ANKLE, RIGHT	Initial Entry

1.q Start Date:

Date	Location	User	Value	Reason
Sep-28-2020 14:16:23 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Jan/31/2019	Initial Entry

1.q Ongoing:

Date	Location	User	Value	Reason
Sep-28-2020 14:16:23 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO End Date: Feb/9/2019	Initial Entry

1.r

Date	Location	User	Value	Reason
Sep-28-2020 14:16:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Num 18 ber:	Initial Entry

090177e196ae3da4\Final\Final On: 01-Apr-2021 04:40 (GMT)

Header Text: c4591001

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Site No: 1117

Subject No: 11171146

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

			Medical History Term: ALLERGY, SEASONAL Start Date: UNK/UNK/1965 Ongoing: YES
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I.r Line/MH Number:

Date	Location	User	Value	Reason
Sep-28-2020 14:16:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 18	Initial Entry

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

Date	Location	User	Value	Reason
Sep-28-2020 14:16:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: ALLERGY, SEASONAL	Initial Entry

I.r Start Date:

Date	Location	User	Value	Reason
Sep-28-2020 14:16:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNK/UNK/1965	Initial Entry

I.r Ongoing:

Date	Location	User	Value	Reason
Sep-28-2020 14:16:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

I.s

Date	Location	User	Value	Reason
Sep-28-2020 14:17:06 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 19 Medical History Term: ALCOHOL USE, 7 DRINKS/WEEK Start Date: UNK/UNK/1968	Initial Entry

090177e196ae3da4\Final\Final On: 01-Apr-2021 04:40 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1117

Subject No: 11171146

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

			Ongoing: YES	
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I.s Line/MH Number:

Date	Location	User	Value	Reason
Sep-28-2020 14:17:06 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 19	Initial Entry

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

Date	Location	User	Value	Reason
Sep-28-2020 14:17:06 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: ALCOHOL USE, 7 DRINKS/WE EK	Initial Entry

I.s Start Date:

Date	Location	User	Value	Reason
Sep-28-2020 14:17:06 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNK/UNK/1968	Initial Entry

I.s Ongoing:

Date	Location	User	Value	Reason
Sep-28-2020 14:17:06 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

I.t

Date	Location	User	Value	Reason
Nov-25-2020 20:35:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH N umber: Medical Hi story Term: OSTEOARTHRITIS, KNEE, BILATERAL Start Date: UNK/UNK/2017 Ongoing: YES	Initial Entry

090177e196ae3da4\Final\Final On: 01-Apr-2021 04:40 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1117

Subject No: 11171146

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.t Line/MH Number:

Date	Location	User	Value	Reason
Nov-25-2020 20:35:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 20	Initial Entry

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

Date	Location	User	Value	Reason
Nov-25-2020 20:35:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: OSTEOARTHRITIS, KNEE, BIL ATERAL	Initial Entry

1.t Start Date:

Date	Location	User	Value	Reason
Nov-25-2020 20:35:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNK/UNK/2017	Initial Entry

1.t Ongoing:

Date	Location	User	Value	Reason
Nov-25-2020 20:35:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

090177e196ae3da4\Final\Final On: 01-Apr-2021 04:40 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1117

Subject No: 11171146

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

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Subject Initials: ---

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

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<i>I.u</i>				
Date	Location	User	Value	Reason
Nov-25-2020 20:35:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH 21 Number: Medical Hi GASTROESOPHAG story Term EAL REFLUX DISE : ASE Start Date: UNK/UNK/2015 Ongoing: YES	Initial Entry
<i>I.u Line/MH Number:</i>				
Date	Location	User	Value	Reason
Nov-25-2020 20:35:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 21	Initial Entry
<i>I.u Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:</i>				
Date	Location	User	Value	Reason
Nov-25-2020 20:35:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: GASTROESOPHAGEAL REFL UX DISEASE	Initial Entry
<i>I.u Start Date:</i>				
Date	Location	User	Value	Reason
Nov-25-2020 20:35:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNK/UNK/2015	Initial Entry
<i>I.u Ongoing:</i>				
Date	Location	User	Value	Reason
Nov-25-2020 20:35:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry
<i>I.v</i>				

090177e196ae3da4\Final\Final On: 01-Apr-2021 04:40 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

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Site No: 1117

Subject No: 11171146

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1117) Sundance Clinical Research

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

Date	Location	User	Value	Reason
Nov-25-2020 20:36:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number 22 : Medical History T VERTIGO erm: Start Date: UNK/UNK/2 015 Ongoing: YES	Initial Entry

1.v Line/MH Number:

Date	Location	User	Value	Reason
Nov-25-2020 20:36:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 22	Initial Entry

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

Date	Location	User	Value	Reason
Nov-25-2020 20:36:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: VERTIGO	Initial Entry

1.v Start Date:

Date	Location	User	Value	Reason
Nov-25-2020 20:36:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNK/UNK/2015	Initial Entry

1.v Ongoing:

Date	Location	User	Value	Reason
Nov-25-2020 20:36:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

1.w

Date	Location	User	Value	Reason
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090177e196ae3da4\Final\Final On: 01-Apr-2021 04:40 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1117

Subject No: 11171146

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: ---

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<p>Mar-02-2021 10:11:40 (UTC-06:00) Central Time (US & Canada)</p>	<p>ACV0PFEINFP6000</p>	<p>(b) (4), (b) (6)</p>	<p>Data Entry: Line/M 23 H Num ber: Medical History DEEP VEIN THROM BOSIS, LOWER EXT Term: REMITY, BILATERA L Start Date: UNK/UNK/2019 Ongoing: NO g: End Date: UNK/UNK/2019</p>	<p>Changed Information</p>
<p>Feb-19-2021 14:48:43 (UTC-06:00) Central Time (US & Canada)</p>	<p>ACV0PFEINFP6000</p>	<p>(b) (4), (b) (6)</p>	<p>Data Entry: Line/M 23 H Num er: Medical History DEEP VEIN THROM BOSIS, LOWER EXT Term: REMITY, BILATERA L Start Date: UNK/UNK/2019 te: Ongoing YES :</p>	<p>Changed Information</p>
<p>Nov-25-2020 20:36:30 (UTC-06:00) Central Time (US & Canada)</p>	<p>ACV0PFEINFP6000</p>	<p>auto calc (autocalc)</p>	<p>Data Entry: Line/MH Nu 23 mber: Medical History DEEP VEIN TH ROMBOSIS ry Term: ROMBOSIS Start Date: UNK/UNK/2019 Ongoing: YES</p>	<p>Initial Entry</p>

090177e196ae3da4\Final\Final On: 01-Apr-2021 04:40 (GMT)

Header Text: c4591001

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Site No: 1117

Subject No: 11171146

Generated By: (b) (4)

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Form Status: Data Complete, Frozen, Verified

Site Name: (1117) Sundance Clinical Research

Subject Initials: ---

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

I.w Line/MH Number:

Date	Location	User	Value	Reason
Nov-25-2020 20:36:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 23	Initial Entry

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

Date	Location	User	Value	Reason
Feb-19-2021 14:48:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: DEEP VEIN THROMBOSIS, LO WER EXTREMITY, BILATERA L	Changed Information
Nov-25-2020 20:36:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: DEEP VEIN THROMBOSIS	Initial Entry

I.w Start Date:

Date	Location	User	Value	Reason
Nov-25-2020 20:36:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNK/UNK/2019	Initial Entry

I.w Ongoing:

Date	Location	User	Value	Reason
Mar-02-2021 10:11:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO End Date: UNK/UNK/2019	Changed Information
Nov-25-2020 20:36:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

I.x

Date	Location	User	Value	Reason
Dec-07-2020 13:00:46 (UTC-06:00) Central	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Line/MH Numb 24	Changed Information

090177e196ae3da4\Final\Final On: 01-Apr-2021 04:40 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

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Site No: 1117

Subject No: 11171146

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

Time (US & Canada)		(b) (4), (b) (6)	er: Medical History ULCERS, GA Term: STRIC Start Date: UNK/UNK/2015 Ongoing: YES	
Nov-25-2020 20:36:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Numbe 24 r: Medical History ULCERS Term: Start Date: UNK/UNK/2015 Ongoing: YES	Initial Entry

090177e196ae3da4\Final\Final On: 01-Apr-2021 04:40 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1117

Subject No: 11171146

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.x Line/MH Number:

Date	Location	User	Value	Reason
Nov-25-2020 20:36:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 24	Initial Entry

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

Date	Location	User	Value	Reason
Dec-07-2020 13:40:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Svitlana Tonkovyd (b) (4)	Query 1: Closed	closed based on site's response
Dec-07-2020 13:00:46 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Changed Information
Dec-07-2020 13:00:46 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: ULCERS, GASTRIC	Changed Information
Nov-26-2020 15:30:06 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Svitlana Tonkovyd (b) (4)	Query 1: Opened	GPD Clin: Please be more specific of the location/organ of the "ulcers". Also please confirm if the "ulcers" are still present/ongoing. Thanks
Nov-25-2020 20:36:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: ULCERS	Initial Entry

1.x Start Date:

Date	Location	User	Value	Reason
Nov-25-2020 20:36:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNK/UNK/2015	Initial Entry

1.x Ongoing:

Date	Location	User	Value	Reason
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090177e196ae3da4\Final\Final On: 01-Apr-2021 04:40 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: GENERAL MEDICAL HISTORY - 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: 11171146

Subject Initials: ---

Generated By: (b) (4)

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

Nov-25-2020 20:36:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry
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<i>I.y</i>				
Date	Location	User	Value	Reason
Nov-25-2020 20:37:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 25 Medical History Term: KIDNEY STONE Start Date: UNK/UNK/2018 Ongoing: NO End Date: UNK/UNK/ 2019	Initial Entry

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Header Text: c4591001

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Site No: 1117

Subject No: 11171146

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.y Line/MH Number:

Date	Location	User	Value	Reason
Nov-25-2020 20:37:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 25	Initial Entry

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

Date	Location	User	Value	Reason
Nov-25-2020 20:37:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: KIDNEY STONE	Initial Entry

1.y Start Date:

Date	Location	User	Value	Reason
Nov-25-2020 20:37:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNK/UNK/2018	Initial Entry

1.y Ongoing:

Date	Location	User	Value	Reason
Nov-25-2020 20:37:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO End Date: UNK/UNK/2019	Initial Entry

1.z

Date	Location	User	Value	Reason
Nov-25-2020 20:37:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number 26 : Medical History T MUSCLE SP erm: ASM Start Date: UNK/UNK/20 10 Ongoing: YES	Initial Entry

090177e196ae3da4\Final\Final On: 01-Apr-2021 04:40 (GMT)

Header Text: c4591001

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Site No: 1117

Subject No: 11171146

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.z Line/MH Number:

Date	Location	User	Value	Reason
Nov-25-2020 20:37:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 26	Initial Entry

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

Date	Location	User	Value	Reason
Nov-25-2020 20:37:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: MUSCLE SPASM	Initial Entry

1.z Start Date:

Date	Location	User	Value	Reason
Nov-25-2020 20:37:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNK/UNK/2010	Initial Entry

1.z Ongoing:

Date	Location	User	Value	Reason
Nov-25-2020 20:37:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

1.aa

Date	Location	User	Value	Reason
Nov-25-2020 20:37:54 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Nu mber: 27 Medical History Term: HYPERCHOLESTEROLEMIA Start Date: UNK/UNK/2015 Ongoing: YES	Initial Entry

090177e196ae3da4\Final\Final On: 01-Apr-2021 04:40 (GMT)

Header Text: c4591001

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Site No: 1117

Subject No: 11171146

Generated By: (b) (4)

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Form Status: Data Complete, Frozen, Verified

Site Name: (1117) Sundance Clinical Research

Subject Initials: ---

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

1.aa Line/MH Number:

Date	Location	User	Value	Reason
Nov-25-2020 20:37:54 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocale)	Data Entry: 27	Initial Entry

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

Date	Location	User	Value	Reason
Nov-25-2020 20:37:54 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: HYPERCHOLESTEROLEMIA	Initial Entry

1.aa Start Date:

Date	Location	User	Value	Reason
Nov-25-2020 20:37:54 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNK/UNK/2015	Initial Entry

1.aa Ongoing:

Date	Location	User	Value	Reason
Nov-25-2020 20:37:54 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

1.ab

Date	Location	User	Value	Reason
Nov-25-2020 20:38:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocale)	Data Entry: Line/MH Num 28 ber: Medical Histo VITAMIN D DEF ry Term: ICIENCY Start Date: UNK/UNK/2017 Ongoing: YES	Initial Entry

090177e196ae3da4\Final\Final On: 01-Apr-2021 04:40 (GMT)

Header Text: c4591001

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Site No: 1117

Subject No: 11171146

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.ab Line/MH Number:

Date	Location	User	Value	Reason
Nov-25-2020 20:38:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 28	Initial Entry

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

Date	Location	User	Value	Reason
Nov-25-2020 20:38:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: VITAMIN D DEFICIENCY	Initial Entry

1.ab Start Date:

Date	Location	User	Value	Reason
Nov-25-2020 20:38:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNK/UNK/2017	Initial Entry

1.ab Ongoing:

Date	Location	User	Value	Reason
Nov-25-2020 20:38:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

1.ac

Date	Location	User	Value	Reason
Feb-19-2021 14:49:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH 29 Number: Medical Hi PULMONARY ART story Term ERIAL HYPERTENS : ION Start Date: Jan/22/2018 Ongoing: YES	Initial Entry

090177e196ae3da4\Final\Final On: 01-Apr-2021 04:40 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

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Site No: 1117

Subject No: 11171146

Generated By: (b) (4)

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I.ac Line/MH Number:

Date	Location	User	Value	Reason
Feb-19-2021 14:49:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 29	Initial Entry

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

Date	Location	User	Value	Reason
Feb-19-2021 14:49:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: PULMONARY ARTERIAL HYP ERTENSION	Initial Entry

I.ac Start Date:

Date	Location	User	Value	Reason
Feb-19-2021 14:49:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Jan/22/2018	Initial Entry

I.ac Ongoing:

Date	Location	User	Value	Reason
Feb-19-2021 14:49:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

I.ad

Date	Location	User	Value	Reason
Feb-19-2021 14:49:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 30 Medical History Term: AORTIC ANEU RYSM Start Date: Jan/22/2018 Ongoing: YES	Initial Entry

090177e196ae3da4\Final\Final On: 01-Apr-2021 04:40 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1117

Subject No: 11171146

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.ad Line/MH Number:

Date	Location	User	Value	Reason
Feb-19-2021 14:49:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 30	Initial Entry

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

Date	Location	User	Value	Reason
Feb-19-2021 14:49:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: AORTIC ANEURYSM	Initial Entry

I.ad Start Date:

Date	Location	User	Value	Reason
Feb-19-2021 14:49:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Jan/22/2018	Initial Entry

I.ad Ongoing:

Date	Location	User	Value	Reason
Feb-19-2021 14:49:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

I.ae

Date	Location	User	Value	Reason
Feb-19-2021 14:50:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH N 31 umber: Medical Hi VENTRICULAR EN story Term LARGEMENT, RIG : HT Start Date: Jan/22/2010 Ongoing: YES	Initial Entry

090177e196ae3da4\Final\Final On: 01-Apr-2021 04:40 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1117

Subject No: 11171146

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.ae Line/MH Number:

Date	Location	User	Value	Reason
Feb-19-2021 14:50:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 31	Initial Entry

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

Date	Location	User	Value	Reason
Feb-19-2021 14:50:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: VENTRICULAR ENLARGEMENT, RIGHT	Initial Entry

I.ae Start Date:

Date	Location	User	Value	Reason
Feb-19-2021 14:50:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Jan/22/2010	Initial Entry

I.ae Ongoing:

Date	Location	User	Value	Reason
Feb-19-2021 14:50:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

I.af

Date	Location	User	Value	Reason
Feb-19-2021 14:50:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 32 Medical History Term: ATHEROSCLEROTIC DISEASE Start Date: Jan/22/2018 Ongoing: YES	Initial Entry

090177e196ae3da4\Final\Final On: 01-Apr-2021 04:40 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1117

Subject No: 11171146

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.af Line/MH Number:

Date	Location	User	Value	Reason
Feb-19-2021 14:50:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 32	Initial Entry

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

Date	Location	User	Value	Reason
Feb-19-2021 14:50:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: ATHEROSCLEROTIC DISEASE	Initial Entry

1.af Start Date:

Date	Location	User	Value	Reason
Feb-19-2021 14:50:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Jan/22/2018	Initial Entry

1.af Ongoing:

Date	Location	User	Value	Reason
Feb-19-2021 14:50:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

1.ag

Date	Location	User	Value	Reason
Feb-19-2021 14:51:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Num 33 ber: Medical Histo CATARACTS, BI ry Term: LATERAL Start Date: Jun/UNK/2020 Ongoing: YES	Initial Entry

090177e196ae3da4\Final\Final On: 01-Apr-2021 04:40 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1117

Subject No: 11171146

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.ag Line/MH Number:

Date	Location	User	Value	Reason
Feb-19-2021 14:51:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 33	Initial Entry

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

Date	Location	User	Value	Reason
Feb-19-2021 14:51:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: CATARACTS, BILATERAL	Initial Entry

I.ag Start Date:

Date	Location	User	Value	Reason
Feb-19-2021 14:51:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Jun/UNK/2020	Initial Entry

I.ag Ongoing:

Date	Location	User	Value	Reason
Feb-19-2021 14:51:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

090177e196ae3da4\Final\Final On: 01-Apr-2021 04:40 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 15-Sep-2020 21:57

Site No: 1117

Subject No: 11171146

Generated By: (b) (4)

Form: HIV STATUS - 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 - What is the subject HIV status?

Date	Location	User	Value	Reason
Sep-28-2020 14:17:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: The subject is NOT known to be H IV POSITIVE	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 15-Sep-2020 21:56

Site No: 1117

Subject No: 11171146

Generated By: (b) (4)

Form: VITAL SIGNS - BASELINE - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1117) Sundance Clinical Research

Subject Initials: ---

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

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1. Date:

Date	Location	User	Value	Reason
Sep-28-2020 14:17:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sep/22/2020	Initial Entry

2. Weight:

Date	Location	User	Value	Reason
Sep-28-2020 14:17:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 166.8	Initial Entry

3. Unit:

Date	Location	User	Value	Reason
Sep-28-2020 14:17:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: LB	Initial Entry

4. Height:

Date	Location	User	Value	Reason
Sep-28-2020 14:17:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 62.4	Initial Entry

5. Unit:

Date	Location	User	Value	Reason
Sep-28-2020 14:17:44 (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
Sep-28-2020 14:17:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 30.1	Initial Entry

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Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 15-Sep-2020 21:56

Site No: 1117

Subject No: 11171146

Generated By: (b) (4)

Form: VITAL SIGNS - BASELINE - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1117) Sundance Clinical Research

Subject Initials: ---

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

7.a

Date	Location	User	Value	Reason
Sep-28-2020 14:17:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Record Identifier:: 1 Temperature: 96.5 Temperature Unit: F Temperature Location:: ORAL CAVITY	Initial Entry

7.a Record Identifier:

Date	Location	User	Value	Reason
Sep-28-2020 14:17:44 (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
Oct-01-2020 06:36:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Sep-30-2020 15:03:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	ORIGINAL ENTRY IS CORRECT PER INVESTIGATOR, TEMPERATURE IS NOT CLINICALLY SIGNIFICANT
Sep-29-2020 06:02:37 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued:Opened	DM: Confirmation on the out of range value as clinically significant or not is expected. Please review and confirm. Thank you.
Sep-28-2020 14:18:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Original value is correct
Sep-28-2020 14:17:44 (UTC-06:00) Central	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	Temperature 96.5 F is outside of Normal

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Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 15-Sep-2020 21:56

Site No: 1117

Subject No: 11171146

Generated By: (b) (4)

Form: VITAL SIGNS - BASELINE - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1117) Sundance Clinical Research

Subject Initials: ---

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

Time (US & Canada)				Range 97 - 99.5 F.
Sep-28-2020 14:17:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 96.5	Initial Entry

7.a Unit:

Date	Location	User	Value	Reason
Sep-28-2020 14:17:44 (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
Sep-28-2020 14:17:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: ORAL CAVITY	Initial Entry

090177e196ae3da4\Final\Final On: 01-Apr-2021 04:40 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

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

Form Version: 15-Sep-2020 21:51

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1117

Site Name: (1117) Sundance Clinical Research

Subject No: 11171146

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
Sep-28-2020 14:17:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: URINALYSIS	Initial Entry

2. Lab Sub-Panel:

Date	Location	User	Value	Reason
Sep-28-2020 14:17:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: PREGNANCY	Initial Entry

3. Collection Date:

Date	Location	User	Value	Reason
Sep-28-2020 14:17:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sep/22/2020	Initial Entry

4. Laboratory Name and Address (Derived)

Date	Location	User	Value	Reason
Sep-28-2020 14:17:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: STUDY SITE	Initial Entry

5. Specimen Type:

Date	Location	User	Value	Reason
Sep-28-2020 14:17:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: URINE	Initial Entry

6.a

Date	Location	User	Value	Reason
Sep-28-2020 14:17:57 (UTC-06:00) Central	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry:	Initial Entry

090177e196ae3da4\Final\Final On: 01-Apr-2021 04:40 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

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

Form Version: 15-Sep-2020 21:51

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1117

Site Name: (1117) Sundance Clinical Research

Subject No: 11171146

Subject Initials: ---

Generated By: (b) (4)

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

Time (US & Canada)			Sponsor-Defined Identifier: 113 Test:: Choriogonadotropin Beta_PX113 Result:: Not Done:: NOT DONE
--------------------	--	--	--

6.a Sponsor ID:

Date	Location	User	Value	Reason
Sep-28-2020 14:17:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 113	Initial Entry

6.a Test:

Date	Location	User	Value	Reason
Sep-28-2020 14:17:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Choriogonadotropin Beta_PX113	Initial Entry

6.a Not Done:

Date	Location	User	Value	Reason
Sep-28-2020 14:17:57 (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: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1117

Subject No: 11171146

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
Sep-28-2020 14:18:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sep/22/2020	Initial Entry

2. Randomization Number:

Date	Location	User	Value	Reason
Sep-28-2020 14:18:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 263521	Initial Entry

090177e196ae3da4\Final\Final On: 01-Apr-2021 04:40 (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: 11171146

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-29-2020 16:52:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Sep-29-2020 16:52:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SERUM	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Sep-29-2020 16:52:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Sep-29-2020 16:52:35 (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.
Sep-29-2020 16:52:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Collection: Sep/22/2020	Initial Entry

4. If no sample was collected or sample was not collected according to protocol, please provide reason:

Date	Location	User	Value	Reason
Oct-06-2020 16:29:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Initial Entry

090177e196ae3da4\Final\Final On: 01-Apr-2021 04:40 (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: 11171146

Subject Initials: ---

Generated By: (b) (4)

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

Oct-06-2020 01:08:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Not required now
Oct-05-2020 08:55:46 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	DM: If sample was collected according to protocol, please do not record any response in this specified field, Thank you.
Sep-29-2020 16:52:42 (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-29-2020 16:52:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BM8YNL	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Sep-29-2020 16:52:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BM8YNL	Initial Entry

5.b

Date	Location	User	Value	Reason
Sep-29-2020 16:53:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BM8YNK	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Sep-29-2020 16:53:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BM8YNK	Initial Entry

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Header Text: c4591001

Visit: V1_DAY1_VAX1_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1117

Site Name: (1117) Sundance Clinical Research

Subject No: 11171146

Subject Initials: ---

Generated By: (b) (4)

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

5.c

Date	Location	User	Value	Reason
Sep-29-2020 16:53:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BM8YNJ	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Sep-29-2020 16:53:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BM8YNJ	Initial Entry

5.d

Date	Location	User	Value	Reason
Sep-29-2020 17:00:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BPRV5C	Initial Entry

5.d Sample ID

Date	Location	User	Value	Reason
Sep-29-2020 17:00:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BPRV5C	Initial Entry

5.e

Date	Location	User	Value	Reason
Sep-29-2020 17:01:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BPRV5D	Initial Entry

5.e Sample ID

Date	Location	User	Value	Reason
Sep-29-2020 17:01:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BPRV5D	Initial Entry

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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: 11171146

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-29-2020 16:49:51 (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-29-2020 16:49:51 (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-29-2020 16:50:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Sep-29-2020 16:49:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Sep-29-2020 16:49:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Collection: Sep/22/2020	Initial Entry

4. If no sample was collected or sample was not collected according to protocol, please provide reason:

Date	Location	User	Value	Reason
Oct-06-2020 16:29:55 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Initial Entry

090177e196ae3da4\Final\Final On: 01-Apr-2021 04:40 (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: 11171146

Subject Initials: ---

Generated By: (b) (4)

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

Oct-06-2020 01:08:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Not required now
Oct-05-2020 08:55:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	DM: If sample was collected according to protocol, please do not record any response in this specified field, Thank you.
Sep-29-2020 16:49:57 (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-29-2020 16:50:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BM8YMW	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Sep-29-2020 16:50:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BM8YMW	Initial Entry

090177e196ae3da4\Final\Final On: 01-Apr-2021 04:40 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:04

Site No: 1117

Subject No: 11171146

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-28-2020 14:18:33 (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-28-2020 14:18:33 (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-28-2020 14:18:33 (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-28-2020 14:18:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sep/22/2020 15:57	Initial Entry

5. Anatomical Location:

Date	Location	User	Value	Reason
Sep-28-2020 14:18:33 (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-28-2020 14:18:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: LEFT	Initial Entry

090177e196ae3da4\Final\Final On: 01-Apr-2021 04:40 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:04

Site No: 1117

Subject No: 11171146

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

7. Route:

Date	Location	User	Value	Reason
Sep-28-2020 14:18:33 (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-28-2020 14:18:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: THE PROTOCOL SPECIFIED OB SERVATION 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-28-2020 14:18:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

090177e196ae3da4\Final\Final On: 01-Apr-2021 04:40 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 06-Jul-2020 21:53

Site No: 1117

Subject No: 11171146

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
Sep-28-2020 14:18:41 (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: 11171146

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-12-2020 16:01:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Oct/12/2020	Initial Entry

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 10-Oct-2020 16:01

Site No: 1117

Subject No: 11171146

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
Oct-12-2020 16:01:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Oct/12/2020	Initial Entry

2.a

Date	Location	User	Value	Reason
Oct-12-2020 16:01:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Record Identifier:: 1 Temperature: 97.4 Temperature Unit: F Temperature Location:: ORAL CAVITY	Initial Entry

2.a Record Identifier:

Date	Location	User	Value	Reason
Oct-12-2020 16:01:50 (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
Oct-12-2020 16:01:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 97.4	Initial Entry

2.a Unit:

Date	Location	User	Value	Reason
Oct-12-2020 16:01:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: F	Initial Entry

2.a Temperature Location:

090177e196ae3da4\Final\Final On: 01-Apr-2021 04:40 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 10-Oct-2020 16:01

Site No: 1117

Subject No: 11171146

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

Date	Location	User	Value	Reason
Oct-12-2020 16:01:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: ORAL CAVITY	Initial Entry

Header Text: c4591001

Visit: V2_VAX2_L

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

Form Version: 15-Sep-2020 21:51

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1117

Site Name: (1117) Sundance Clinical Research

Subject No: 11171146

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
Oct-12-2020 16:02:27 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: URINALYSIS	Initial Entry

2. Lab Sub-Panel:

Date	Location	User	Value	Reason
Oct-12-2020 16:02:27 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: PREGNANCY	Initial Entry

3. Collection Date:

Date	Location	User	Value	Reason
Oct-12-2020 16:02:27 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Oct/12/2020	Initial Entry

4. Laboratory Name and Address (Derived)

Date	Location	User	Value	Reason
Oct-12-2020 16:02:27 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: STUDY SITE	Initial Entry

5. Specimen Type:

Date	Location	User	Value	Reason
Oct-12-2020 16:02:27 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: URINE	Initial Entry

6.a

Date	Location	User	Value	Reason
Oct-12-2020 16:02:27 (UTC-06:00) Central	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry:	Initial Entry

090177e196ae3da4\Final\Final On: 01-Apr-2021 04:40 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

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

Form Version: 15-Sep-2020 21:51

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1117

Site Name: (1117) Sundance Clinical Research

Subject No: 11171146

Subject Initials: ---

Generated By: (b) (4)

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

Time (US & Canada)			Sponsor-Defined Identifier: 113	
			Test:: Choriogonadotropin Beta_PX113	
			Result::	
			Not Done:: NOT DONE	

6.a Sponsor ID:

Date	Location	User	Value	Reason
Oct-12-2020 16:02:27 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 113	Initial Entry

6.a Test:

Date	Location	User	Value	Reason
Oct-12-2020 16:02:27 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Choriogonadotropin Beta_PX113	Initial Entry

6.a Not Done:

Date	Location	User	Value	Reason
Oct-12-2020 16:02:27 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NOT DONE	Initial Entry

090177e196ae3da4\Final\Final On: 01-Apr-2021 04:40 (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: 11171146

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-14-2020 14:59:15 (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 14:59:15 (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
Oct-14-2020 14:59:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Oct-14-2020 14:59:15 (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 14:59:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Collection: Oct/12/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Oct-14-2020 14:59:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BRJ8FV	Initial Entry

090177e196ae3da4\Final\Final On: 01-Apr-2021 04:40 (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: 11171146

Subject Initials: ---

Generated By: (b) (4)

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

5.a Sample ID

Date	Location	User	Value	Reason
Oct-14-2020 14:59:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BRJ8FV	Initial Entry

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1117

Subject No: 11171146

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
Oct-12-2020 16:02:48 (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
Oct-12-2020 16:02:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: BLINDED THERAPY	Initial Entry

3. Formulation:

Date	Location	User	Value	Reason
Oct-12-2020 16:02:48 (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
Oct-12-2020 16:02:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Oct/12/2020 14:13	Initial Entry

5. Anatomical Location:

Date	Location	User	Value	Reason
Oct-12-2020 16:02:48 (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
Oct-12-2020 16:02:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: LEFT	Initial Entry

090177e196ae3da4\Final\Final On: 01-Apr-2021 04:40 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1117

Subject No: 11171146

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

7. Route:

Date	Location	User	Value	Reason
Oct-12-2020 16:02:48 (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
Oct-12-2020 16:02:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: THE PROTOCOL SPECIFIED OB SERVATION PERIOD	Initial Entry

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

Date	Location	User	Value	Reason
Oct-12-2020 16:02:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

090177e196ae3da4\Final\Final On: 01-Apr-2021 04:40 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 1117

Subject No: 11171146

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
Nov-13-2020 15:06:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Nov-13-2020 12:18:06 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Changed data per query
Nov-13-2020 05:11:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	DM: The treatment period is defined as 1st vaccination visit through the 1-month post vaccination visit after the 2nd vaccination. Please complete treatment disposition CRF and update date of EOT to match date of visit at visit 3.
Nov-12-2020 20:11:23 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Nov/12/2020	Initial Entry

090177e196ae3da4\Final\Final On: 01-Apr-2021 04:40 (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: 11171146

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-12-2020 18:20:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Nov-12-2020 18:20:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SERUM	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Nov-12-2020 18:20:17 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Nov-12-2020 18:20:03 (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-12-2020 18:20:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Collection: Nov/12/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Nov-12-2020 18:20:17 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BRSRX2	Initial Entry

090177e196ae3da4\Final\Final On: 01-Apr-2021 04:40 (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: 11171146

Subject Initials: ---

Generated By: (b) (4)

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

5.a Sample ID

Date	Location	User	Value	Reason
Nov-12-2020 18:20:17 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BRSRX2	Initial Entry

5.b

Date	Location	User	Value	Reason
Nov-12-2020 18:20:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BRSRX3	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Nov-12-2020 18:20:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BRSRX3	Initial Entry

5.c

Date	Location	User	Value	Reason
Nov-12-2020 18:22:55 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BM8YTW	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Nov-12-2020 18:22:55 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BM8YTW	Initial Entry

5.d

Date	Location	User	Value	Reason
Nov-12-2020 18:23:04 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BM8YTX	Initial Entry

090177e196ae3da4\Final\Final On: 01-Apr-2021 04:40 (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: 11171146

Subject Initials: ---

Generated By: (b) (4)

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

5.d Sample ID

Date	Location	User	Value	Reason
Nov-12-2020 18:23:04 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BM8YTX	Initial Entry

5.e

Date	Location	User	Value	Reason
Nov-12-2020 18:23:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BM8YTY	Initial Entry

5.e Sample ID

Date	Location	User	Value	Reason
Nov-12-2020 18:23:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BM8YTY	Initial Entry

090177e196ae3da4\Final\Final On: 01-Apr-2021 04:40 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1117

Subject No: 11171146

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-22-2021 21:21:33 (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: 11171146

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - Audit Trail

Form Status:

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Date	Location	User	Value	Reason
Jan-26-2021 16:55:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Deleted	PER MEDICAL RECORD, PER INVESTIGATOR AORTIC ANEURYSM IS NOT WORSENING, IT IS STABLE.
Jan-22-2021 21:23:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

Header Text: c4591001

Visit: Logs - Unscheduled

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Subject No: 11171146

Generated By: (b) (4)

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Date	Location	User	Value	Reason
Jan-22-2021 21:24:03 (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: 11171146

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-26-2021 16:59:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

Header Text: c4591001

Visit: Logs - Unscheduled

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Site No: 1117

Subject No: 11171146

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
Feb-11-2021 16:45:46 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

Header Text: c4591001

Visit: Logs - Unscheduled

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Site No: 1117

Subject No: 11171146

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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1. Category:

Date	Location	User	Value	Reason
Jan-22-2021 21:21:33 (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
Jan-22-2021 21:21:33 (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
Jan-22-2021 21:21:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: PULMONARY EMBOLI	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason
Jan-22-2021 21:21:55 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Closed	Close Auto Query
Jan-22-2021 21:21:55 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Jan-22-2021 21:21:55 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Jan/21/2021 UNK:UNK	Transcription Error
Jan-22-2021 21:21:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Opened	For PULMONARY EMBOLI: Start date 21/Jan/2020 is before V1D1VX1L visit date 22/Sep/2020. Please review and update as

090177e196ae3da4\Final\Final On: 01-Apr-2021 04:40 (GMT)

Header Text: c4591001

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Subject No: 11171146

Generated By: (b) (4)

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Form Status: Data Complete, Frozen, Verified

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				appropriate.
Jan-22-2021 21:21:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	Start date is before Consent Date 22/Sep /2020.
Jan-22-2021 21:21:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Jan/21/2020 UNK:UNK	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Feb-12-2021 10:18:06 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Feb-11-2021 16:33:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	New Information
Feb-11-2021 16:33:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO End Date Time: Jan/23/2021 UNK:UNK	New Information
Feb-04-2021 13:36:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	SAE RECON: AE 2021064848 has a cessation date on 23-JAN-2021 in SDB. Please review and update accordingly or clarify.
Jan-22-2021 21:21:33 (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
Feb-19-2021 03:45:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Svitlana Tonkovyid (b) (4)	Query 1: Closed	closed based on site's response

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Header Text: c4591001**Visit:** Logs - Unscheduled**Form Version:** 22-Apr-2020 21:02**Site No:** 1117**Subject No:** 11171146**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

Feb-18-2021 17:43:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	PER INVESTIGATOR, CONDITION WOULD HAVE GONE UNNOTICED BY PARTICIPANT, SUBJECT WAS ASYMPTOMATIC. SUBJECT HAD NO COMPLICATIONS DURING ANTICOAGULATION AND WAS DISCHARGED W/O INCIDENT. CONDITION WAS INCIDENTAL FINDING ON ROUTINE IMAGING EXAM.
Feb-12-2021 13:49:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Svitlana Tonkovyd (b) (4)	Query 1: Opened	GPD Clin: Can you please confirm severity grade of AE PULMONARY EMBOLI considering it is considered serous. Thanks
Jan-26-2021 16:58:19 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 1	PER INVESTIGATOR, SUBJECT AYSMTOMATIC AND INCIDENTAL FINDING ON IMAGING STUDY.
Jan-22-2021 21:21:33 (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
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Header Text: c4591001

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Subject No: 11171146

Generated By: (b) (4)

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Jan-29-2021 12:05:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 3: Deleted	Close Auto Query
Jan-28-2021 08:38:55 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Closed	Response satisfies query
Jan-26-2021 16:58:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 3: Candidate	For AE PULMONARY EMBOLI: Response to "Is the adverse event serious?" is 'Yes' but "Serious Adverse Event Number" is blank.
Jan-26-2021 16:58:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Is this serious event associated with congenital anomaly or birt h defect? NO Did this serious event result in d eath? NO Did this serious event require or prolong hospitalization? YES Did this serious event result in p ersistent or significant disability /incapacity? NO Is this serious event life threaten ing? NO Other medically important serio us event	Changed Information

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Header Text: c4591001**Visit:** Logs - Unscheduled**Form Version:** 22-Apr-2020 21:02**Site No:** 1117**Subject No:** 11171146**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

			NO	
Jan-26-2021 16:52:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Answered	FAXED ON 22JAN2021, UPDATE FAXED 26JAN2021
Jan-25-2021 07:21:32 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Opened	SAE RECON: PULMONARY EMBOLI(Onset date:21Jan2021) is not reported to Safety database but marked serious on AE CRF. Confirm seriousness and report to Pfizer immediately. If this event is not serious, downgrade the event on AE CRF
Jan-25-2021 07:20:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Deleted	Query can be addressed internally
Jan-22-2021 21:21:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	For AE PULMONARY EMBOLI: Response to "Is the adverse event serious?" is 'Yes' but "Serious Adverse Event Number" is blank.
Jan-22-2021 21:21:33 (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	Initial Entry

Header Text: c4591001

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			<p>Did this serious event require or prolong 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>YES</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
Jan-22-2021 21:21:33 (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-27-2021 07:37:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Jan-26-2021 16:53:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	New Information
Jan-26-2021 16:53:31 (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	New Information

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Subject Initials: ---

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			<i>If Other, specify:</i> CURRENT DVT, PRIOR HX OF DVT	
Jan-25-2021 08:13:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	clinical: pls advise as to basis for assessing AE 1 and 3 as 'related' Did subject have other RF for PE/DVT eg recent prolonged travel, injury, surgery? Thanks
Jan-22-2021 21:21:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: RELATED	Initial Entry

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Jan-22-2021 21:21:33 (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
Jan-22-2021 21:21:33 (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-22-2021 21:21:33 (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
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090177e196ae3da4\Final\Final On: 01-Apr-2021 04:40 (GMT)

Header Text: c4591001**Visit:** Logs - Unscheduled**Form Version:** 22-Apr-2020 21:02**Site No:** 1117**Subject No:** 11171146**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

Feb-12-2021 10:17:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Feb-11-2021 16:34:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Closed	Close Auto Query
Feb-11-2021 16:34:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	New Information
Feb-11-2021 16:34:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: RECOVERED/RESOLVE D	New Information
Feb-11-2021 16:33:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Opened	For AE PULMONARY EMBOLI: Response to "What was the outcome of this adverse event?" is 'Recovering/Resolving' but AE End Date/Time is present.
Feb-04-2021 13:37:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	SAE RECON: AE 2021064848 has reported outcome of "RECOVERED/RESOLVED" in SDB. Please review and update accordingly or clarify.
Jan-22-2021 21:21:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: RECOVERING/RESOLVI NG	Initial Entry

14. Did the adverse event cause the subject to be discontinued from the study?

Date	Location	User	Value	Reason
Jan-22-2021 21:21:33 (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-29-2021 12:05:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 2021064848	Initial Entry

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1. Category:

Date	Location	User	Value	Reason
Jan-22-2021 21:23:00 (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
Jan-22-2021 21:23:00 (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
Jan-22-2021 21:23:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: WORSENING AORTIC ANEUR YSM	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason
Jan-22-2021 21:23:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Jan/21/2021 UNK:UNK	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Jan-22-2021 21:23:00 (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
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*** THIS REPEATING FORM HAS BEEN DELETED ***

Jan-22-2021 21:23:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 2	Initial Entry
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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-22-2021 21:23:00 (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-22-2021 21:23:00 (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-22-2021 21:23:00 (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: PREEXISTING CONDITION	Initial Entry

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
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*** THIS REPEATING FORM HAS BEEN DELETED ***

Jan-22-2021 21:23:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NOT APPLICABLE	Initial Entry
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11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
Jan-22-2021 21:23:00 (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-22-2021 21:23:00 (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-26-2021 22:29:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	data deleted.
Jan-26-2021 16:54:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Changed data per query
Jan-26-2021 05:18:37 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued:Opened	Please provide date which information will be available for data entry.
Jan-25-2021 18:15:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	WE HAVE NOT RECIEVED OR REVIEWED THE MEDICAL RECORDS FROM THE EVENT NOR HAVE WE HAD CONTACT WITH THE PARTICIPANT.

090177e196ae3da4\Final\Final On: 01-Apr-2021 04:40 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

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Site No: 1117

Subject No: 11171146

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Deleted, Frozen, Verified

Site Name: (1117) Sundance Clinical Research

Subject Initials: ---

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

*** THIS REPEATING FORM HAS BEEN DELETED ***

				OUTCOME IS UNKNOWN.
Jan-24-2021 22:30:46 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued:Opened	Response does not satisfy query. Please clarify why outcome is Unknown for AE wich is still ongoing. Or correct.
Jan-22-2021 21:28:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Original value is correct
Jan-22-2021 21:23:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	For AE WORSENING AORTIC ANEURYSM: 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-22-2021 21:23:00 (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-22-2021 21:23:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

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Header Text: c4591001

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Subject No: 11171146

Generated By: (b) (4)

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Form Status: Data Complete, Frozen, Not Complete

Site Name: (1117) Sundance Clinical Research

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1. Category:

Date	Location	User	Value	Reason
Jan-22-2021 21:24:03 (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-22-2021 21:24:03 (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
Mar-02-2021 14:56:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 4: Clo sed	Response satisfies query
Mar-02-2021 10:17:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 4: An swere d	Changed data per query
Mar-01-2021 11:10:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 4: Rei ssued: Opene d	CLINQUERY - Thanks for specifying Right extremity. However, as MH reports DVT in both legs, please confirm the RIGHT side was "Worsening" to qualify as an AE. Update term as applicable.

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Mar-01-2021 09:57:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 4: An swere d	SUBJECT EXPERIENCED THROMBOTIC EVENT IN RIGHT LEG.
Mar-01-2021 00:43:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 4: Op ened	CLINQUERY - MH of DVT BILATERAL Lower Extremities is ONGOING. Per guidelines, a MH condition should not be reported as an AE unless it "Worsens". Please clarify if worsened on RIGHT and update as needed.
Feb-26-2021 14:13:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 4: Ca ndidat e	CLINQUERY - MH of DVT BILATERAL Lower Extremities is ONGOING. Per guidelines, a MH condition should not be reported as an AE unless it "Worsens". Please clarify if worsened on RIGHT and update as needed.
Feb-22-2021 13:47:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Svitlana Tonkovyd (b) (4)	Query 3: Clo sed	Response satisfies query
Feb-19-2021 14:47:46 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 3: An swere d	Changed Information
Feb-19-2021 14:47:46 (UTC-06:00)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry :	Changed Information

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Subject No: 11171146

Generated By: (b) (4)

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Central Time (US & Canada)			DEEP VEIN THR OMB OSIS, LOW ER E XTRE MITY , RIG HT	
Feb-19-2021 03:48:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Svitlana Tonkovyd (b) (4)	Query 3: Rei ssued: Opene d	GPD Clin: Many Tahnks for confirming DVT anatomical location. Can you please add data into the MH eCRF and clarify the anatomical location of the AE "DEEP VEIN THROMBOSIS, MODERATE EVENT". Thank you
Feb-18-2021 17:30:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: An swere d	PER SUBJECT, HAS HISTORY OF DVT IN BOTH LOWER EXTREMITIES.
Feb-12-2021 15:11:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Clo sed	Response satisfies query
Feb-12-2021 13:04:19 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Svitlana Tonkovyd (b) (4)	Query 3: Op ened	GPD Clin: Given ongoing DVT per MH eCRF page, can you please confirm the location of the AE "DEEP VEIN THROMBOSIS, MODERATE EVENT" and clarify

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				if DVT noted on MH has the same location. Thanks
Feb-11-2021 16:38:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	CONFIRMED IN MEDICAL HISTORY. PER INVESTIGATOR, EPISODE IS AN AE AND NEEDS TO BE RECORDED AS SUCH, NOT A DUPLICATE AND SHOULD NOT BE REMOVED.
Feb-01-2021 11:19:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Giselle Castillo (b) (4)	Query 2: Closed	Response satisfies query
Jan-28-2021 12:46:04 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued: Opened	Please confirm if this AE was episodic and ongoing at baseline too? If yes, please ensure tis detail is documented at Medical History CRF, then this AE would be a duplicate and would need to be removed.
Jan-27-2021 15:38:55 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Answered	UPDATED SAE DOCUMENT AND FAXED 27JAN2021
Jan-27-2021 15:06:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	PER INVESTIGATOR, IT IS INAPPROPRIATE TO CLASSIFY THIS CONDITION AS WORSENING. MOST

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				APPROPRIATELY THIS CONDITION WOULD HAVE EPISODES/EVENTS, WHICH IS ALREADY INCLUDED IN THE EVENT DESCRIPTION.
Jan-27-2021 09:23:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Giselle Castillo (b) (4)	Query 2: Op ened	CLINICAL_ As per the request of our Data Monitoring Committee, please include in the FU form whether COVID testing was conducted – yes/no including not available/not performed. If COVID testing was performed, include the results. Thanks
Jan-27-2021 00:45:54 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Rei ssued: Opene d	DM : Thanks for response. Please clarify if this is a worsening of the baseline condition, and if so, please consider adding "worsening" to the AE term. AE as baseline conditions should only be reported as AEs if they worsen.
Jan-26-2021 16:56:16 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: An swere d	New Information
Jan-26-2021 16:56:16 (UTC-06:00)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry :	New Information

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Generated By: (b) (4)

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Central Time (US & Canada)			DEEP VEIN THR OMB OSIS, MOD ERAT E EV ENT	
Jan-26-2021 11:13:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	PFE SDQ PROD (b) (4)	Query 1: Op ened	The AE DEEP VEIN THROMBOSIS was reported but is also listed in Medical History. Please clarify if this is a worsening of the baseline condition, and if so, please consider adding "worsening" to the AE term. AE as baseline conditions should only be reported as AEs if they worsen. (b) (4)
Jan-22-2021 21:24:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry : DEEP VEIN THR OMB OSIS	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason
Jan-22-2021 21:24:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Jan/21/2021 UNK:UNK	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
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Subject No: 11171146

Generated By: (b) (4)

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Feb-12-2021 10:18:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Feb-11-2021 16:35:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	New Information
Feb-11-2021 16:35:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO End Date Time: Jan/23/2021 UNK:UNK	New Information
Feb-04-2021 13:37:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	SAE RECON: AE 2021064848 has a cessation date on 23-JAN-2021 in SDB. Please review and update accordingly or clarify.
Jan-22-2021 21:24:03 (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-22-2021 21:24:03 (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-25-2021 03:14:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query

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Subject No: 11171146

Generated By: (b) (4)

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Jan-22-2021 21:24:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	For AE DEEP VEIN THROMBOSIS: Response to "Is the adverse event serious?" is 'Yes' but "Serious Adverse Event Number" is blank.
Jan-22-2021 21:24:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<p>Data Entry: 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 prolong 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

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
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Site No: 1117

Subject No: 11171146

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Not Complete

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

Jan-22-2021 21:24:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry
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9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Jan-27-2021 12:59:04 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Svitlana Tonkovyd (b) (4)	Query 1: Closed	Response satisfies query
Jan-26-2021 16:57:19 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Changed Information
Jan-26-2021 16:57:19 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NOT RELATED If Not Related to study treatmen t(s), this event is due to: OTHER <i>If Other, specify:</i> PRIOR HISTORY OF DV T	Changed Information
Jan-25-2021 13:42:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Svitlana Tonkovyd (b) (4)	Query 1: Opened	GPD CLIN: The causality of event is deemed related to study treatment; however, the event of DEEP VEIN THROMBOSIS started prior to participant's screening as reported on MH eCRF. Please review and consider updating causality as applicable, or clarify.
Jan-22-2021 21:24:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: RELATED	Initial Entry

10. Latest Action Taken with Study Treatment:

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Date	Location	User	Value	Reason
Jan-22-2021 21:24:03 (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-22-2021 21:24:03 (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-22-2021 21:24:03 (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
Feb-12-2021 10:18:55 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Feb-11-2021 16:34:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	New Information
Feb-11-2021 16:34:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: RECOVERED/RESOLVED	New Information
Jan-28-2021 07:10:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	SAE RECON:AER#2021064848,outcome was reported as Recovered/Resolved to Safety DB however, recorded as RECOVERING/RESOLVING on

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				AE CRF. Please confirm correct outcome. If safety update is required, please submit a follow-up form.
Jan-26-2021 17:00:32 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: RECOVERING/RES OLVING	Changed Information

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Subject No: 11171146

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Subject Initials: ---

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13. What was the outcome of this adverse event?:

Date	Location	User	Value	Reason
Jan-22-2021 21:24:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NOT RECOVERED/NOT RESO LVED	Initial Entry

14. Did the adverse event cause the subject to be discontinued from the study?

Date	Location	User	Value	Reason
Jan-22-2021 21:24:03 (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 03:14:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 2021064848	Initial Entry

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Subject Initials: ---

Generated By: (b) (4)

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1. Category:

Date	Location	User	Value	Reason
Jan-26-2021 16:59:50 (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-26-2021 16:59:50 (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
Jan-26-2021 16:59:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: HIATAL HERNIA	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason
Jan-26-2021 16:59:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Jan/21/2021 UNK:UNK	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Jan-26-2021 16:59:50 (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-26-2021 16:59:50 (UTC-06:00) Central	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 1	Initial Entry

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Time (US & Canada)

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

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-26-2021 16:59:50 (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-26-2021 16:59:50 (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-26-2021 16:59:50 (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: ETIOLOGY UNKNOWN	Initial Entry

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Jan-26-2021 16:59:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NOT APPLICABLE	Initial Entry

090177e196ae3da4\Final\Final On: 01-Apr-2021 04:40 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1117

Subject No: 11171146

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

11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
Jan-26-2021 16:59:50 (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-26-2021 16:59:50 (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-26-2021 16:59:50 (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-26-2021 16:59:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

090177e196ae3da4\Final\Final On: 01-Apr-2021 04:40 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen

Site No: 1117

Site Name: (1117) Sundance Clinical Research

Subject No: 11171146

Subject Initials: ---

Generated By: (b) (4)

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

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1. Category:

Date	Location	User	Value	Reason
Feb-11-2021 16:45:46 (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
Feb-11-2021 16:45:46 (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
Feb-11-2021 16:45:46 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: CATARACTS, WORSENING CO NDITION	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason
Feb-11-2021 16:45:46 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Feb/3/2021 UNK:UNK	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Feb-11-2021 16:45:46 (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
Feb-11-2021 16:45:46 (UTC-06:00) Central	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 1	Initial Entry

090177e196ae3da4\Final\Final On: 01-Apr-2021 04:40 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1117

Subject No: 11171146

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

Time (US & Canada)

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

7. Is the adverse event serious?

If Yes, NOTIFY PFIZER IMMEDIATELY.

Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).

Date	Location	User	Value	Reason
Feb-11-2021 16:45:46 (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
Feb-11-2021 16:45:46 (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
Feb-19-2021 15:01:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Feb-19-2021 14:51:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	UPDATED MEDHX
Feb-16-2021 09:25:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	clinical: pls update MedHx CRF to reflect 'pre-existing condition' if it predates enrollment. Thanks
Feb-11-2021 16:45:46 (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

090177e196ae3da4\Final\Final On: 01-Apr-2021 04:40 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1117

Subject No: 11171146

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

			OTHER	
			<i>If Other, specify:</i>	
			PRE EXISTING CONDIT ON	

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Feb-11-2021 16:45:46 (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
Feb-11-2021 16:45:46 (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
Feb-11-2021 16:45:46 (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
Feb-11-2021 16:45:46 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NOT RECOVERED/NOT RESOL VED	Initial Entry

14. Did the adverse event cause the subject to be discontinued from the study?

Date	Location	User	Value	Reason
Feb-11-2021 16:45:46 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

090177e196ae3da4\Final\Final On: 01-Apr-2021 04:40 (GMT)

Header Text: c4591001

Visit: End of Treatment - Unscheduled

Form Version: 15-Sep-2020 21:55

Site No: 1117

Subject No: 11171146

Generated By: (b) (4)

Form: DISPOSITION - TREATMENT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1117) Sundance Clinical Research

Subject Initials: ---

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

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1. Date of Completion/Discontinuation/Death :

Date	Location	User	Value	Reason
Nov-13-2020 12:17:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Nov/12/2020	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Nov-13-2020 12:17:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: VACCINATION	Initial Entry

3. Status:

Date	Location	User	Value	Reason
Nov-13-2020 12:17:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: COMPLETED	Initial Entry

090177e196ae3da4\Final\Final On: 01-Apr-2021 04:40 (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: 11171146

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-10-2021 10:06:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Feb-08-2021 10:39:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Changed Information
Feb-08-2021 10:39:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Jan/15/2021	Changed Information
Feb-03-2021 11:25:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	Per source, contact with subject was completed on15Jan2021. If confirmed please change data appropriately.
Jan-22-2021 21:18:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Jan/19/2021	Initial Entry

090177e196ae3da4\Final\Final On: 01-Apr-2021 04:40 (GMT)

Header Text: c4591001

Visit: Potential ReVax Initial Contact -
Unscheduled

Form Version: 10-Dec-2020 02:25

Site No: 1117

Subject No: 11171146

Generated By: (b) (4)

Form: FURTHER VACCINATION CONFIRMATION - 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

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

Date	Location	User	Value	Reason
Jan-22-2021 21:19:06 (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 reco mmendations and confirmed to have received only placebo at V accination 1/2	Initial Entry

Header Text: c4591001

Visit: Disposition - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1117

Subject No: 11171146

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

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1. Date Treatment Unblinded :

Date	Location	User	Value	Reason
Feb-10-2021 10:05:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Feb-08-2021 14:03:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Changed Information
Feb-08-2021 14:03:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Jan/19/2021	Changed Information
Feb-03-2021 11:25:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	per source, subject unblinding, form 2, was 19jan2021. If confirmed please change data appropriately.
Jan-22-2021 21:18:37 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Jan/15/2021	Initial Entry

2. Primary Reason for Unblinding:

Date	Location	User	Value	Reason
Jan-22-2021 21:18:37 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: ASSESS ELIGIBILITY FOR AD DITIONAL VACCINATION	Initial Entry

090177e196ae3da4\Final\Final On: 01-Apr-2021 04:40 (GMT)

Header Text: c4591001

Visit: V101_VAX3

Form Version: 22-Apr-2020 21:02

Site No: 1117

Subject No: 11171146

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-25-2021 23:49:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Jan-25-2021 18:13:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Changed data per query
Jan-25-2021 04:44:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	DM: Kindly consider to update missing SWAB PFE and SAMP TRK forms or else clarify. Thank you.
Jan-22-2021 21:19:17 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Jan/19/2021	Initial Entry

090177e196ae3da4\Final\Final On: 01-Apr-2021 04:40 (GMT)

Header Text: c4591001

Visit: V101_VAX3

Form: INFORMED CONSENT - FURTHER VACCINATION - eCRF
Audit Trail History

Form Version: 10-Dec-2020 02:31

Form Status: Data Complete, Frozen, Verified

Site No: 1117

Site Name: (1117) Sundance Clinical Research

Subject No: 11171146

Subject Initials: ---

Generated By: (b) (4)

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

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1. Consent Was:

Date	Location	User	Value	Reason
Jan-22-2021 21:19:23 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: OBTAINED Date Written Consent Obtained Jan/19/2021	Initial Entry

Header Text: c4591001

Visit: V101_VAX3

Form: DISPOSITION - SCREENING FOR FURTHER VACCINATION - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:31

Form Status: Data Complete, Frozen, Verified

Site No: 1117

Site Name: (1117) Sundance Clinical Research

Subject No: 11171146

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-22-2021 21:19:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Jan/19/2021	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Jan-22-2021 21:19:50 (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-22-2021 21:19:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: COMPLETED	Initial Entry

090177e196ae3da4\Final\Final On: 01-Apr-2021 04:40 (GMT)

Header Text: c4591001

Visit: V101_VAX3

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

Form Version: 14-Jan-2021 02:21

Form Status: Data Complete, Frozen, Verified

Site No: 1117

Site Name: (1117) Sundance Clinical Research

Subject No: 11171146

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-22-2021 21:20:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: URINALYSIS	Initial Entry

2. Lab Sub-Panel:

Date	Location	User	Value	Reason
Jan-22-2021 21:20:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: PREGNANCY	Initial Entry

3. Collection Date:

Date	Location	User	Value	Reason
Jan-22-2021 21:20:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Jan/19/2021	Initial Entry

4. Laboratory Name and Address (Derived)

Date	Location	User	Value	Reason
Jan-22-2021 21:20:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: STUDY SITE	Initial Entry

5. Specimen Type:

Date	Location	User	Value	Reason
Jan-22-2021 21:20:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: URINE	Initial Entry

6.a

Date	Location	User	Value	Reason
Jan-22-2021 21:20:00 (UTC-06:00) Central	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry:	Initial Entry

090177e196ae3da4\Final\Final On: 01-Apr-2021 04:40 (GMT)

Header Text: c4591001

Visit: V101_VAX3

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

Form Version: 14-Jan-2021 02:21

Form Status: Data Complete, Frozen, Verified

Site No: 1117

Site Name: (1117) Sundance Clinical Research

Subject No: 11171146

Subject Initials: ---

Generated By: (b) (4)

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

Time (US & Canada)			Sponsor-Defined Identifier: 113 Test:: Choriogonadotropin Beta_PX113 Result:: Not Done:: NOT DONE
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6.a Sponsor ID:

Date	Location	User	Value	Reason
Jan-22-2021 21:20:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 113	Initial Entry

6.a Test:

Date	Location	User	Value	Reason
Jan-22-2021 21:20:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Choriogonadotropin Beta_PX113	Initial Entry

6.a Not Done:

Date	Location	User	Value	Reason
Jan-22-2021 21:20:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NOT DONE	Initial Entry

090177e196ae3da4\Final\Final On: 01-Apr-2021 04:40 (GMT)

Header Text: c4591001

Visit: V101_VAX3

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1117

Site Name: (1117) Sundance Clinical Research

Subject No: 11171146

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-25-2021 13:16:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Jan-25-2021 13:16:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SERUM	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Jan-25-2021 13:16:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Jan-25-2021 13:16:35 (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.
Jan-25-2021 13:16:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Collection: Jan/19/2021	Initial Entry

5.a

Date	Location	User	Value	Reason
Jan-25-2021 13:16:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BRSRHZ	Initial Entry

090177e196ae3da4\Final\Final On: 01-Apr-2021 04:40 (GMT)

Header Text: c4591001

Visit: V101_VAX3

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1117

Site Name: (1117) Sundance Clinical Research

Subject No: 11171146

Subject Initials: ---

Generated By: (b) (4)

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

5.a Sample ID

Date	Location	User	Value	Reason
Jan-25-2021 13:16:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BRSRHZ	Initial Entry

5.b

Date	Location	User	Value	Reason
Jan-25-2021 13:16:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BRSRJ0	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Jan-25-2021 13:16:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BRSRJ0	Initial Entry

5.c

Date	Location	User	Value	Reason
Jan-25-2021 14:51:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BR6RNS	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Jan-25-2021 14:51:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BR6RNS	Initial Entry

5.d

Date	Location	User	Value	Reason
Jan-25-2021 14:51:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BR6RNT	Initial Entry

090177e196ae3da4\Final\Final On: 01-Apr-2021 04:40 (GMT)

Header Text: c4591001

Visit: V101_VAX3

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1117

Site Name: (1117) Sundance Clinical Research

Subject No: 11171146

Subject Initials: ---

Generated By: (b) (4)

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

5.d Sample ID

Date	Location	User	Value	Reason
Jan-25-2021 14:51:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BR6RNT	Initial Entry

5.e

Date	Location	User	Value	Reason
Jan-25-2021 14:51:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BR6RNV	Initial Entry

5.e Sample ID

Date	Location	User	Value	Reason
Jan-25-2021 14:51:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BR6RNV	Initial Entry

090177e196ae3da4\Final\Final On: 01-Apr-2021 04:40 (GMT)

Header Text: c4591001

Visit: V101_VAX3

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1117

Site Name: (1117) Sundance Clinical Research

Subject No: 11171146

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-25-2021 14:31:56 (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-25-2021 14:31:56 (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-25-2021 14:32:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Jan-25-2021 14:31:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Jan-25-2021 14:31:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Collection: Jan/19/2021	Initial Entry

5.a

Date	Location	User	Value	Reason
Jan-25-2021 14:32:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BP58ZY	Initial Entry

090177e196ae3da4\Final\Final On: 01-Apr-2021 04:40 (GMT)

Header Text: c4591001

Visit: V101_VAX3

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1117

Site Name: (1117) Sundance Clinical Research

Subject No: 11171146

Subject Initials: ---

Generated By: (b) (4)

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

5.a Sample ID

Date	Location	User	Value	Reason
Jan-25-2021 14:32:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BP58ZY	Initial Entry

Header Text: c4591001

Visit: V101_VAX3

Form Version: 10-Dec-2020 02:26

Site No: 1117

Subject No: 11171146

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1117) Sundance Clinical Research

Subject Initials: ---

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

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1. Was there a temporary delay of vaccination?

Date	Location	User	Value	Reason
Jan-22-2021 21:20:21 (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
Jan-22-2021 21:20:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: BNT162b2	Initial Entry

3. Formulation:

Date	Location	User	Value	Reason
Jan-22-2021 21:20:21 (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
Jan-22-2021 21:20:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Jan/19/2021 14:55	Initial Entry

5. Anatomical Location:

Date	Location	User	Value	Reason
Jan-22-2021 21:20:21 (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
Jan-22-2021 21:20:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: LEFT	Initial Entry

090177e196ae3da4\Final\Final On: 01-Apr-2021 04:40 (GMT)

Header Text: c4591001

Visit: V101_VAX3

Form Version: 10-Dec-2020 02:26

Site No: 1117

Subject No: 11171146

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1117) Sundance Clinical Research

Subject Initials: ---

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

7. Route:

Date	Location	User	Value	Reason
Jan-22-2021 21:20:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INTRAMUSCULAR	Initial Entry

8. Actual Dose:

Date	Location	User	Value	Reason
Jan-22-2021 21:20:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 30.0	Initial Entry

9. Unit:

Date	Location	User	Value	Reason
Jan-22-2021 21:20:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: ug	Initial Entry

10. Timeframe Subject Was Observed

Date	Location	User	Value	Reason
Jan-22-2021 21:20:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 30 MINUTES	Initial Entry

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

Date	Location	User	Value	Reason
Jan-22-2021 21:20:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

090177e196ae3da4\Final\Final On: 01-Apr-2021 04:40 (GMT)

Header Text: c4591001

Visit: V102_VAX4

Form Version: 22-Apr-2020 21:02

Site No: 1117

Subject No: 11171146

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
Feb-11-2021 16:38:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Feb/9/2021	Initial Entry

Header Text: c4591001

Visit: V102_VAX4

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

Form Version: 14-Jan-2021 02:21

Form Status: Data Complete, Frozen, Verified

Site No: 1117

Site Name: (1117) Sundance Clinical Research

Subject No: 11171146

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
Feb-11-2021 16:38:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: URINALYSIS	Initial Entry

2. Lab Sub-Panel:

Date	Location	User	Value	Reason
Feb-11-2021 16:38:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: PREGNANCY	Initial Entry

3. Collection Date:

Date	Location	User	Value	Reason
Feb-11-2021 16:38:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Feb/9/2021	Initial Entry

4. Laboratory Name and Address (Derived)

Date	Location	User	Value	Reason
Feb-11-2021 16:38:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: STUDY SITE	Initial Entry

5. Specimen Type:

Date	Location	User	Value	Reason
Feb-11-2021 16:38:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: URINE	Initial Entry

6.a

Date	Location	User	Value	Reason
Feb-11-2021 16:38:56 (UTC-06:00) Central	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry:	Initial Entry

090177e196ae3da4\Final\Final On: 01-Apr-2021 04:40 (GMT)

Header Text: c4591001

Visit: V102_VAX4

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

Form Version: 14-Jan-2021 02:21

Form Status: Data Complete, Frozen, Verified

Site No: 1117

Site Name: (1117) Sundance Clinical Research

Subject No: 11171146

Subject Initials: ---

Generated By: (b) (4)

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

Time (US & Canada)			Sponsor-Defined Identifier: 113 Test:: Choriogonadotropin Beta_PX113 Result:: Not Done:: NOT DONE
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6.a Sponsor ID:

Date	Location	User	Value	Reason
Feb-11-2021 16:38:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 113	Initial Entry

6.a Test:

Date	Location	User	Value	Reason
Feb-11-2021 16:38:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Choriogonadotropin Beta_PX113	Initial Entry

6.a Not Done:

Date	Location	User	Value	Reason
Feb-11-2021 16:38:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NOT DONE	Initial Entry

090177e196ae3da4\Final\Final On: 01-Apr-2021 04:40 (GMT)

Header Text: c4591001

Visit: V102_VAX4

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1117

Site Name: (1117) Sundance Clinical Research

Subject No: 11171146

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-12-2021 17:36:25 (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-12-2021 17:36:25 (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
Feb-12-2021 17:36:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Feb-12-2021 17:36:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Feb-12-2021 17:36:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Collection: Feb/9/2021	Initial Entry

5.a

Date	Location	User	Value	Reason
Feb-12-2021 17:36:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BR6RV6	Initial Entry

090177e196ae3da4\Final\Final On: 01-Apr-2021 04:40 (GMT)

Header Text: c4591001

Visit: V102_VAX4

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1117

Site Name: (1117) Sundance Clinical Research

Subject No: 11171146

Subject Initials: ---

Generated By: (b) (4)

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

5.a Sample ID

Date	Location	User	Value	Reason
Feb-12-2021 17:36:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BR6RV6	Initial Entry

Header Text: c4591001

Visit: V102_VAX4

Form Version: 10-Dec-2020 02:26

Site No: 1117

Subject No: 11171146

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1117) Sundance Clinical Research

Subject Initials: ---

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

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1. Was there a temporary delay of vaccination?

Date	Location	User	Value	Reason
Feb-11-2021 16:39:44 (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
Feb-11-2021 16:39:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: BNT162b2	Initial Entry

3. Formulation:

Date	Location	User	Value	Reason
Feb-11-2021 16:39:44 (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
Feb-11-2021 16:39:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Feb/9/2021 14:45	Initial Entry

5. Anatomical Location:

Date	Location	User	Value	Reason
Feb-11-2021 16:39:44 (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
Feb-11-2021 16:39:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: LEFT	Initial Entry

090177e196ae3da4\Final\Final On: 01-Apr-2021 04:40 (GMT)

Header Text: c4591001

Visit: V102_VAX4

Form Version: 10-Dec-2020 02:26

Site No: 1117

Subject No: 11171146

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1117) Sundance Clinical Research

Subject Initials: ---

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

7. Route:

Date	Location	User	Value	Reason
Feb-11-2021 16:39:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> INTRAMUSCULAR	Initial Entry

8. Actual Dose:

Date	Location	User	Value	Reason
Feb-11-2021 16:39:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> 30.0	Initial Entry

9. Unit:

Date	Location	User	Value	Reason
Feb-11-2021 16:39:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> ug	Initial Entry

10. Timeframe Subject Was Observed

Date	Location	User	Value	Reason
Feb-11-2021 16:39:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> 30 MINUTES	Initial Entry

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

Date	Location	User	Value	Reason
Feb-11-2021 16:39:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> YES	Initial Entry

090177e196ae3da4\Final\Final On: 01-Apr-2021 04:40 (GMT)

Header Text: c4591001

Visit: Subject Status - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1117

Subject No: 11171146

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
Nov-13-2020 12:17:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: FOLLOW-UP	Initial Entry
Sep-28-2020 14:18:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: ENROLLED/RANDOMIZED	Initial Entry
Sep-28-2020 14:06:00 (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
Nov-13-2020 12:17:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Nov/12/2020	Initial Entry
Sep-28-2020 14:18:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sep/22/2020	Initial Entry
Sep-28-2020 14:06:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sep/22/2020	Initial Entry

090177e196ae3da4\Final\Final On: 01-Apr-2021 04:40 (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: 11171146

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
Nov-10-2020 17:00:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Click Here to Enable	Initial Entry