

Header Text: c4591001

Visit: COHORT_SELECTION

Form: COHORT_SELECTION

Form Version: 10-Oct-2020 16:01

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1066

Site Name: (1066) Solaris Clinical Research

Subject No: 10661350

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:05

[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	06 OCT 2020
2.	Select appropriate response - What cohort does the subject belong to?	STAGE 3 COHORTS

Header Text: c4591001

Visit: COHORT_SELECTION

Form: MAIN INFORMED CONSENT

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1066

Site Name: (1066) Solaris Clinical Research

Subject No: 10661350

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:05

[eCRF Audit Trail History](#)

Informed Consent

1.	Consent Was:	OBTAINED Date Written Consent Obtained Oct/19/2020
----	--------------	--

Header Text: c4591001

Visit: COHORT_SELECTION

Form: DEMOGRAPHY

Form Version: 15-Sep-2020 21:54

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1066

Site Name: (1066) Solaris Clinical Research

Subject No: 10661350

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:05

[eCRF Audit Trail History](#)

Demography

1.	Subject ID	[10661350]
2.	Birth Date:	(b) (6)/1962
3.	Sex:	MALE
4.	Ethnicity:	NOT HISPANIC OR LATINO(A) OR OF SPANISH ORIGIN
5.	Race: (Check X all that apply):	WHITE
6.	Racial Designation:	

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:02

Site No: 1066

Subject No: 10661350

Generated By: (b) (4)

Form: DATE OF VISIT

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1066) Solaris Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:05

[eCRF Audit Trail History](#)

Date of Visit		
1.	Date of Visit	Oct/19/2020
2.	Erroneous Visit	

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 10-Oct-2020 16:00

Site No: 1066

Subject No: 10661350

Generated By: (b) (4)

Form: INCLUSION/EXCLUSION CRITERIA

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1066) Solaris Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:05

[Form Comments](#)

Inclusion Criteria Not Met

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

Exclusion Criteria Met

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

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: DISPOSITION - SCREENING

Form Version: 15-Sep-2020 21:52

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1066

Site Name: (1066) Solaris Clinical Research

Subject No: 10661350

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:05

[eCRF Audit Trail History](#)

Disposition - Screening

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

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1066

Subject No: 10661350

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1066) Solaris Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:05

[eCRF Audit Trail History](#)

Medical History Details

1.a	Line/MH Number:	[1]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[GERD]
	Start Date:	UNK/UNK/2000
	Ongoing:	YES
1.b	Line/MH Number:	[2]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[anxiety]
	Start Date:	UNK/UNK/1990
	Ongoing:	YES
1.c	Line/MH Number:	[3]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[hypertension]
	Start Date:	UNK/UNK/2000
	Ongoing:	YES
1.d	Line/MH Number:	[4]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[hyponatremia]
	Start Date:	UNK/UNK/2015
	Ongoing:	YES

090177e196ae30eb\Final\Final On: 01-Apr-2021 04:19 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1066

Subject No: 10661350

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1066) Solaris Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:05

1.e	Line/MH Number:	[5]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[insomnia]
	Start Date:	UNK/UNK/2000
	Ongoing:	YES
1.f	Line/MH Number:	[6]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[history of seizure]
	Start Date:	UNK/UNK/2015
	Ongoing:	NO End Date: UNK/UNK/2015
1.g	Line/MH Number:	[7]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[spinal stenosis]
	Start Date:	UNK/UNK/2012
	Ongoing:	NO End Date: UNK/UNK/2012
1.h	Line/MH Number:	[8]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[history of alcohol abuse]
	Start Date:	UNK/UNK/2018
	Ongoing:	NO End Date: UNK/UNK/2018

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Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1066

Subject No: 10661350

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1066) Solaris Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:05

1.i	Line/MH Number:	[9]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[L4-L5 laminotomy with diskectomy]
	Start Date:	UNK/UNK/2012
	Ongoing:	NO End Date: UNK/UNK/2012
1.j	Line/MH Number:	[10]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[morphine allergy]
	Start Date:	UNK/UNK/1985
	Ongoing:	YES
1.k	Line/MH Number:	[11]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[sulfa allergy]
	Start Date:	UNK/UNK/1980
	Ongoing:	YES
1.l	Line/MH Number:	[12]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[cardiomyopathy]
	Start Date:	Mar/UNK/2018
	Ongoing:	YES

090177e196ae30eb\Final\Final On: 01-Apr-2021 04:19 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1066

Subject No: 10661350

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1066) Solaris Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:05

1 m	Line/MH Number:	[13]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[myocardial infarction]
	Start Date:	Mar/UNK/2018
	Ongoing:	NO End Date: Mar/UNK/2018

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 15-Sep-2020 21:57

Site No: 1066

Subject No: 10661350

Generated By: (b) (4)

Form: HIV STATUS

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1066) Solaris Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:05

[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: 10-Oct-2020 16:04

Site No: 1066

Subject No: 10661350

Generated By: (b) (4)

Form: VITAL SIGNS - BASELINE

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1066) Solaris Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:05

[eCRF Audit Trail History](#)

Vital Signs

1.	Date:	Oct/19/2020
2.	Weight:	[185.3]
3.	Unit:	LB
4.	Height:	[72.0]
5.	Unit:	in
6.	Body Mass Index:	[25.1]

Vital Signs Details

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

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Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1066

Subject No: 10661350

Generated By: (b) (4)

Form: RANDOMIZATION

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1066) Solaris Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:05

[eCRF Audit Trail History](#)

Disposition

1.	Randomization Date :	Oct/19/2020
2.	Randomization Number:	[270819]
3.	Randomization Group:	[]

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1066

Site Name: (1066) Solaris Clinical Research

Subject No: 10661350

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:05

[eCRF Audit Trail History](#)

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	SERUM
3.	Sample Collected?	YES Date of Collection: Oct/19/2020
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[]

Aliquot

Please enter barcode for each aliquot.

5.a	Sample ID	[BR6T8S]
5.b	Sample ID	[BS5DV6]
5.c	Sample ID	[BS5DV7]

090177e196ae30eb\Final\Final On: 01-Apr-2021 04:19 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1066

Subject No: 10661350

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1066) Solaris Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:05

[eCRF Audit Trail History](#)

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Oct/19/2020
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[]

Aliquot

Please enter barcode for each aliquot.

5.a	Sample ID	[BR6T7X]
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090177e196ae30eb\Final\Final On: 01-Apr-2021 04:19 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:04

Site No: 1066

Subject No: 10661350

Generated By: (b) (4)

Form: VACCINATION

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1066) Solaris Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:05

[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/19/2020 13:32
5.	Anatomical Location:	DELTOID MUSCLE
6.	Body Side:	RIGHT
7.	Route:	INTRAMUSCULAR
8.	Actual Dose:	[]
9.	Unit:	
10.	Timeframe Subject Was Observed	THE PROTOCOL SPECIFIED OBSERVATION PERIOD
11.	Was the subject observed for at least the protocol specified observation period after investigational product administration?	YES

090177e196ae30eb\Final\Final On: 01-Apr-2021 04:19 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 06-Jul-2020 21:53

Site No: 1066

Subject No: 10661350

Generated By: (b) (4)

Form: REACTOGENICITY DIARY

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1066) Solaris Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:05

[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: 1066

Subject No: 10661350

Generated By: (b) (4)

Form: DATE OF VISIT

Form Status: Not Started

Site Name: (1066) Solaris Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:05

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 20-Feb-2021 02:16

Site No: 1066

Subject No: 10661350

Generated By: (b) (4)

Form: VITAL SIGNS - TEMP

Form Status: Not Started

Site Name: (1066) Solaris Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:05

Vital Signs

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

Vital Signs Details

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

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:03

Site No: 1066

Subject No: 10661350

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB

Form Status: Not Started

Site Name: (1066) Solaris Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:05

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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090177e196ae30eb\Final\Final On: 01-Apr-2021 04:19 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 10-Dec-2020 02:26

Site No: 1066

Subject No: 10661350

Generated By: (b) (4)

Form: VACCINATION

Form Status: Not Started

Site Name: (1066) Solaris Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:05

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?	

090177e196ae30eb\Final\Final On: 01-Apr-2021 04:19 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 1066

Subject No: 10661350

Generated By: (b) (4)

Form: DATE OF VISIT

Form Status: Not Started

Site Name: (1066) Solaris Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:05

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1066

Site Name: (1066) Solaris Clinical Research

Subject No: 10661350

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:05

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	[]
----	-----------	-----

090177e196ae30eb\Final\Final On: 01-Apr-2021 04:19 (GMT)

Header Text: c4591001

Visit: V4_MONTH6_L

Form Version: 22-Apr-2020 21:02

Site No: 1066

Subject No: 10661350

Generated By: (b) (4)

Form: DATE OF VISIT

Form Status: Not Started

Site Name: (1066) Solaris Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:05

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

Header Text: c4591001

Visit: V4_MONTH6_L

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1066

Site Name: (1066) Solaris Clinical Research

Subject No: 10661350

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:05

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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090177e196ae30eb\Final\Final On: 01-Apr-2021 04:19 (GMT)

Header Text: c4591001

Visit: V5_MONTH12_L

Form Version: 22-Apr-2020 21:02

Site No: 1066

Subject No: 10661350

Generated By: (b) (4)

Form: DATE OF VISIT

Form Status: Not Started

Site Name: (1066) Solaris Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:05

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

Header Text: c4591001

Visit: V5_MONTH12_L

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1066

Site Name: (1066) Solaris Clinical Research

Subject No: 10661350

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:05

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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090177e196ae30eb\Final\Final On: 01-Apr-2021 04:19 (GMT)

Header Text: c4591001

Visit: V6_MONTH24_L

Form Version: 22-Apr-2020 21:02

Site No: 1066

Subject No: 10661350

Generated By: (b) (4)

Form: DATE OF VISIT

Form Status: Not Started

Site Name: (1066) Solaris Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:05

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

Header Text: c4591001

Visit: V6_MONTH24_L

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1066

Site Name: (1066) Solaris Clinical Research

Subject No: 10661350

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:05

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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090177e196ae30eb\Final\Final On: 01-Apr-2021 04:19 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL - New Unscheduled **Form:** DATE OF VISIT - ILLNESS ONSET Visit

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1066

Site Name: (1066) Solaris Clinical Research

Subject No: 10661350

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:05

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

Form Version: 20-Feb-2021 02:17

Form Status: Not Started

Site No: 1066

Site Name: (1066) Solaris Clinical Research

Subject No: 10661350

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:05

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:	[]
----	------------------------	-----

090177e196ae30eb\Final\Final On: 01-Apr-2021 04:19 (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: 1066

Site Name: (1066) Solaris Clinical Research

Subject No: 10661350

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:05

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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090177e196ae30eb\Final\Final On: 01-Apr-2021 04:19 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL - New Unscheduled **Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB Visit

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1066

Site Name: (1066) Solaris Clinical Research

Subject No: 10661350

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:05

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	[]
----	-----------	-----

090177e196ae30eb\Final\Final On: 01-Apr-2021 04:19 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL - New Unscheduled **Form:** HEALTH CARE UTILIZATION
Visit

Form Version: 20-Feb-2021 02:19

Form Status: Not Started

Site No: 1066

Site Name: (1066) Solaris Clinical Research

Subject No: 10661350

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:05

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?	
----	--	--

090177e196ae30eb\Final\Final On: 01-Apr-2021 04:19 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL - New Unscheduled **Form:** ILLNESS DETAILS
Visit

Form Version: 06-Jul-2020 21:52

Form Status: Not Started

Site No: 1066

Site Name: (1066) Solaris Clinical Research

Subject No: 10661350

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:05

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: 1066

Site Name: (1066) Solaris Clinical Research

Subject No: 10661350

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:05

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 Version: 22-Apr-2020 21:03

Site No: 1066

Subject No: 10661350

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING -
IMMUNOGENICITY

Form Status: Not Started

Site Name: (1066) Solaris Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:05

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	[]
----	-----------	-----

090177e196ae30eb\Final\Final On: 01-Apr-2021 04:19 (GMT)

Header Text: c4591001

Visit: POT_COVID_REPEAT_SWAB - New **Form:** DATE OF VISIT - REPEAT SWAB
Unscheduled Visit

Form Version: 10-Oct-2020 15:57

Form Status: Not Started

Site No: 1066

Site Name: (1066) Solaris Clinical Research

Subject No: 10661350

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:05

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

Form Version: 10-Oct-2020 15:57

Form Status: Not Started

Site No: 1066

Site Name: (1066) Solaris Clinical Research

Subject No: 10661350

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:05

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	[]
----	-----------	-----

090177e196ae30eb\Final\Final On: 01-Apr-2021 04:19 (GMT)

Header Text: c4591001

Visit: Logs

Form: ADVERSE EVENT REPORT

Form Version: 22-Apr-2020 21:02

Site No: 1066

Site Name: (1066) Solaris Clinical Research

Subject No: 10661350

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:05

#	Category	AE Identifier	Adverse Event	Start Date	Is the Adverse Event Still Ongoing	Form Instance
1.	ADVERSE EVENT	1	myocardial infarction	Nov/3/2020 UNK:UNK	NO End Date Time: Nov/3/2020 UNK:UNK	Repeating Pages

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1066

Subject No: 10661350

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Frozen, Verified

Site Name: (1066) Solaris Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:05

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

Adverse Event Report

1.	Category:	ADVERSE EVENT
2.	AE ID:	[1]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[myocardial infarction]
4.	Start Date Time:	Nov/3/2020 UNK:UNK
5.	Is the adverse event still ongoing?	NO End Date Time: Nov/3/2020 UNK:UNK
6.	Toxicity Grade:	4
7.	Is the adverse event serious? If Yes, NOTIFY PFIZER IMMEDIATELY. Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).	YES Is this serious event associated with congenital anomaly or birth defect? NO Did this serious event result in death? YES Did this serious event require or prolong hospitalization? NO 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

090177e196ae30eb\Final\Final On: 01-Apr-2021 04:19 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1066

Subject No: 10661350

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Frozen, Verified

Site Name: (1066) Solaris Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:05

8.	Is this adverse event the result of a study Medication Error? If Yes, record the type of medication error on the Medication Error Log.	NO
9.	Is this event related to study treatment:	NOT RELATED If Not Related to study treatment(s), this event is due to: OTHER If Other, specify: [disease progression]
10.	Latest Action Taken with Study Treatment:	DRUG WITHDRAWN
11.	Was a Concomitant Medication given?	NO
12.	Was a Non-Drug Treatment given?	NO
13.	What was the outcome of this adverse event?:	FATAL
14.	Did the adverse event cause the subject to be discontinued from the study?	YES
15.	Serious Adverse Event Number: For Pfizer Use Only	[2020446214]

090177e196ae30eb\Final\Final On: 01-Apr-2021 04:19 (GMT)

Header Text: c4591001

Visit: Logs

Form: MEDICATION ERROR

Form Version: 17-Jul-2020 21:54

Site No: 1066

Site Name: (1066) Solaris Clinical Research

Subject No: 10661350

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:05

#	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: 1066

Subject No: 10661350

Generated By: (b) (4)

Form: MEDICATION ERROR

Form Status: Not Started

Site Name: (1066) Solaris Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:05

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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	[]

090177e196ae30eb\Final\Final On: 01-Apr-2021 04:19 (GMT)

Header Text: c4591001

Visit: Logs

Form: CONCOMITANT MEDICATIONS - NON STUDY
VACCINATIONS

Form Version: 22-Apr-2020 21:03

Site No: 1066

Site Name: (1066) Solaris Clinical Research

Subject No: 10661350

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:05

#	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: 1066

Site Name: (1066) Solaris Clinical Research

Subject No: 10661350

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:05

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Concomitant Medications

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

Header Text: c4591001

Visit: Logs

Form: CONCOMITANT MEDICATIONS - PROHIBITED

Form Version: 22-Apr-2020 21:03

Site No: 1066

Site Name: (1066) Solaris Clinical Research

Subject No: 10661350

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:05

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

090177e196ae30eb\Final\Final On: 01-Apr-2021 04:19 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1066

Subject No: 10661350

Generated By: (b) (4)

Form: CONCOMITANT MEDICATIONS - PROHIBITED

Form Status: Not Started

Site Name: (1066) Solaris Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:05

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Concomitant Medications

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

090177e196ae30eb\Final\Final On: 01-Apr-2021 04:19 (GMT)

Header Text: c4591001

Visit: Logs

Form: RADIATION TREATMENT

Form Version: 22-Apr-2020 21:02

Site No: 1066

Site Name: (1066) Solaris Clinical Research

Subject No: 10661350

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:05

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

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1066

Subject No: 10661350

Generated By: (b) (4)

Form: RADIATION TREATMENT

Form Status: Not Started

Site Name: (1066) Solaris Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:05

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Radiation Treatment

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

Header Text: c4591001

Visit: Logs

Form: TRANSFUSIONS

Form Version: 22-Apr-2020 21:03

Site No: 1066

Site Name: (1066) Solaris Clinical Research

Subject No: 10661350

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:05

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

090177e196ae30eb\Final\Final On: 01-Apr-2021 04:19 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1066

Subject No: 10661350

Generated By: (b) (4)

Form: TRANSFUSIONS

Form Status: Not Started

Site Name: (1066) Solaris Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:05

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

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: 1066

Site Name: (1066) Solaris Clinical Research

Subject No: 10661350

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:05

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: 1066

Site Name: (1066) Solaris Clinical Research

Subject No: 10661350

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:05

Unplanned Assessments

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

Header Text: c4591001

Visit: Unplanned Vaccination - Unscheduled **Form:** DATE OF VISIT

Form Version: 22-Apr-2020 21:02 **Form Status:** Not Started

Site No: 1066 **Site Name:** (1066) Solaris Clinical Research

Subject No: 10661350 **Subject Initials:** ---

Generated By: (b) (4) **Generated Time (GMT):** 29-Mar-2021 10:05

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: 1066

Site Name: (1066) Solaris Clinical Research

Subject No: 10661350

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:05

Vital Signs

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

Vital Signs Details

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

Header Text: c4591001

Visit: Unplanned Vaccination - Unscheduled **Form:** VACCINATION

Form Version: 10-Dec-2020 02:26 **Form Status:** Not Started

Site No: 1066

Site Name: (1066) Solaris Clinical Research

Subject No: 10661350

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:05

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?	

090177e196ae30eb\Final\Final On: 01-Apr-2021 04:19 (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: 1066 **Site Name:** (1066) Solaris Clinical Research

Subject No: 10661350 **Subject Initials:** ---

Generated By: (b) (4) **Generated Time (GMT):** 29-Mar-2021 10:05

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: 1066 **Site Name:** (1066) Solaris Clinical Research

Subject No: 10661350 **Subject Initials:** ---

Generated By: (b) (4) **Generated Time (GMT):** 29-Mar-2021 10:05

Contact Outcome

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

Header Text: c4591001

Visit: V201_SURVEIL_CONSENT -
Unscheduled

Form: DATE OF VISIT

Form Version: 22-Apr-2020 21:02

Form Status: Not Started

Site No: 1066

Site Name: (1066) Solaris Clinical Research

Subject No: 10661350

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:05

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

Header Text: c4591001

Visit: V201_SURVEIL_CONSENT -
Unscheduled

Form: INFORMED CONSENT - ASYMPTOMATIC
SURVEILLANCE

Form Version: 14-Jan-2021 02:29

Form Status: Not Started

Site No: 1066

Site Name: (1066) Solaris Clinical Research

Subject No: 10661350

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:05

Informed Consent - Asymptomatic Surveillance

1.	Consent Was:	
----	--------------	--

Header Text: c4591001

Visit: V201_SURVEIL_CONSENT -
Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1066

Subject No: 10661350

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING -
IMMUNOGENICITY

Form Status: Not Started

Site Name: (1066) Solaris Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:05

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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090177e196ae30eb\Final\Final On: 01-Apr-2021 04:19 (GMT)

Header Text: c4591001

Visit: V201_SURVEIL_CONSENT -
Unscheduled

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1066

Site Name: (1066) Solaris Clinical Research

Subject No: 10661350

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:05

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	[]
----	-----------	-----

090177e196ae30eb\Final\Final On: 01-Apr-2021 04:19 (GMT)

Header Text: c4591001

Visit: End of Treatment - Unscheduled

Form: DISPOSITION - TREATMENT

Form Version: 15-Sep-2020 21:55

Form Status: Data Complete, Frozen, Verified

Site No: 1066

Site Name: (1066) Solaris Clinical Research

Subject No: 10661350

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:05

[eCRF Audit Trail History](#)

Disposition - Treatment

1.	Date of Completion/Discontinuation /Death :	Nov/3/2020
2.	Phase of Disposition:	VACCINATION
3.	Status:	DEATH
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: 1066

Site Name: (1066) Solaris Clinical Research

Subject No: 10661350

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:05

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

Date of Visit

1.	Date of Visit	Not Applicable _____ //	Comments
2.	Erroneous Visit	Not Applicable _____	Comments

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: 1066

Site Name: (1066) Solaris Clinical Research

Subject No: 10661350

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:05

[Form Comments](#)

[eCRF Audit Trail History](#)

Further Vaccination Confirmation

1.	Select appropriate response - Is participant willing to return for Vaccination 3?	Not Applicable	Comments
----	---	----------------	--------------------------

Header Text: c4591001

Visit: Follow-Up - Unscheduled

Form Version: 15-Sep-2020 21:53

Site No: 1066

Subject No: 10661350

Generated By: (b) (4)

Form: DISPOSITION - FOLLOW-UP

Form Status: Data Complete, Frozen, Verified

Site Name: (1066) Solaris Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:05

[eCRF Audit Trail History](#)

Disposition - Follow-Up

1.	Date of Completion/Discontinuation /Death :	Nov/3/2020
2.	Phase of Disposition:	FOLLOW-UP
3.	Status:	DEATH
4.	Specify Status:	[]

Header Text: c4591001

Visit: Disposition - Unscheduled

Form: TREATMENT UNBLINDED

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1066

Site Name: (1066) Solaris Clinical Research

Subject No: 10661350

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:05

Treatment Unblinded

1.	Date Treatment Unblinded :	//
2.	Primary Reason for Unblinding:	

Header Text: c4591001

Visit: Disposition - Unscheduled

Form: WITHDRAWAL OF CONSENT

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1066

Site Name: (1066) Solaris Clinical Research

Subject No: 10661350

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:05

Withdrawal Of Consent

1.	Withdrawal of Consent Date :	//
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Header Text: c4591001

Visit: Disposition - Unscheduled

Form: DEATH DETAILS CODED

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1066

Site Name: (1066) Solaris Clinical Research

Subject No: 10661350

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:05

[eCRF Audit Trail History](#)

Death Details

1.	Date of Collection / Notification of Death:	Nov/10/2020
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Cause of Death

2.a	Cause of Death Status:	PRIMARY CAUSE OF DEATH
	Cause of Death:	[myocardial infarction]

Header Text: c4591001

Visit: Subject Status - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1066

Subject No: 10661350

Generated By: (b) (4)

Form: SUBJECT STATUS

Form Status: Data Complete, Verified

Site Name: (1066) Solaris Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:05

[eCRF Audit Trail History](#)

Subject Status

1.	Subject Status	DISCONTINUED
2.	Subject Status Date	Nov/3/2020

Header Text: c4591001

Visit: Investigator Signature - Unscheduled

Form: CASEBOOK SIGNATURE FORM

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Verified

Site No: 1066

Site Name: (1066) Solaris Clinical Research

Subject No: 10661350

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:05

[eCRF Audit Trail History](#)

Casebook Signature Form

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

Header Text: c4591001

Visit: Investigator Signature - Unscheduled

Form: CASEBOOK SIGNATURE FORM

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Verified

Site No: 1066

Site Name: (1066) Solaris Clinical Research

Subject No: 10661350

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:05

[Audit Trail](#)

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

- CRF_Sign
- CRF_Sign_1

Name	Signature Meaning	Date	Type	Action
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Header Text: c4591001
Visit: V1_DAY1_VAX1_L
Form Version: 10-Oct-2020 16:00
Site No: 1066
Subject No: 10661350
Generated By: (b) (4)

Form: INCLUSION/EXCLUSION CRITERIA - Comments
Form Status: Data Complete, Locked, Frozen, Verified
Site Name: (1066) Solaris Clinical Research
Subject Initials: ---
Generated Time (GMT): 29-Mar-2021 10:05

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Item	Date	User	Comment
Form	Oct-19-2020 15:43:38 (UTC-07:00) Mountain Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

Header Text: c4591001

Visit: Potential ReVax Initial Contact -
Unscheduled

Form: DATE OF VISIT - Comments

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen, Verified

Site No: 1066

Site Name: (1066) Solaris Clinical Research

Subject No: 10661350

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:05

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Item	Date	User	Comment
Form	Mar-09-2021 08:24:44 (UTC-07:00) Mountain Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

Header Text: c4591001

Visit: Potential ReVax Initial Contact

Form Version: 22-Apr-2020 21:02

Site No: 1066

Subject No: 10661350

Generated By: (b) (4)

Form: DATE OF VISIT - Comments

Form Status: Data Complete, Frozen, Verified

Site Name: (1066) Solaris Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:05

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Item	Date	User	Comment
1	Mar-09-2021 08:24:44 (UTC-07:00) Mountain Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

Header Text: c4591001

Visit: Potential ReVax Initial Contact

Form Version: 22-Apr-2020 21:02

Site No: 1066

Subject No: 10661350

Generated By: (b) (4)

Form: DATE OF VISIT - Comments

Form Status: Data Complete, Frozen, Verified

Site Name: (1066) Solaris Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:05

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Item	Date	User	Comment
2	Mar-09-2021 08:24:44 (UTC-07:00) Mountain Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

Header Text: c4591001

Visit: Potential ReVax Initial Contact -
Unscheduled

Form: FURTHER VACCINATION CONFIRMATION - Comments

Form Version: 10-Dec-2020 02:25

Form Status: Data Complete, Frozen

Site No: 1066

Site Name: (1066) Solaris Clinical Research

Subject No: 10661350

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:05

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Item	Date	User	Comment
Form	Mar-09-2021 08:25:02 (UTC-07:00) Mountain Time (US & Canada)	(b) (4), (b) (6) [REDACTED]	Not Applicable

Header Text: c4591001

Visit: Potential ReVax Initial Contact

Form Version: 10-Dec-2020 02:25

Site No: 1066

Subject No: 10661350

Generated By: (b) (4)

Form: FURTHER VACCINATION CONFIRMATION - Comments

Form Status: Data Complete, Frozen

Site Name: (1066) Solaris Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:05

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Item	Date	User	Comment
1	Mar-09-2021 08:25:02 (UTC-07:00) Mountain 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, Verified

Site No: 1066

Site Name: (1066) Solaris Clinical Research

Subject No: 10661350

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:05

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

- CRF_Sign
- CRF_Sign_1

Name	Signature Meaning	Date	Type	Action
(b) (6)	N/A	Mar-09-2021 08:24:44 (UTC-07:00) Mountain Time (US & Canada)		Edit - All signatures invalidated

Affidavit:

N/A

David Butuk	Approved	Jan-26-2021 20:36:38 (UTC-07:00) Mountain Time (US & Canada)	BOOK	Signed
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Affidavit:

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

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

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

Header Text: c4591001

Visit: COHORT_SELECTION

Form: COHORT SELECTION - eCRF Audit Trail History

Form Version: 10-Oct-2020 16:01

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1066

Site Name: (1066) Solaris Clinical Research

Subject No: 10661350

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:05

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1. Select appropriate response - Protocol version

Date	Location	User	Value	Reason
Oct-19-2020 15:42:53 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 06 OCT 2020	Initial Entry

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

Date	Location	User	Value	Reason
Oct-19-2020 15:42:53 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: STAGE 3 COHORTS	Initial Entry

090177e196ae30eb\Final\Final On: 01-Apr-2021 04:19 (GMT)

Header Text: c4591001

Visit: COHORT_SELECTION

Form: MAIN INFORMED CONSENT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1066

Site Name: (1066) Solaris Clinical Research

Subject No: 10661350

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:05

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I. Consent Was:

Date	Location	User	Value	Reason
Oct-19-2020 15:43:05 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: OBTAINED Date Written Consent Obtai ned Oct/19/2020	Initial Entry

Header Text: c4591001

Visit: COHORT_SELECTION

Form: DEMOGRAPHY - eCRF Audit Trail History

Form Version: 15-Sep-2020 21:54

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1066

Site Name: (1066) Solaris Clinical Research

Subject No: 10661350

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:05

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1. Subject ID

Date	Location	User	Value	Reason
Oct-19-2020 15:42:46 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 10661350	Item copied from previous form

2. Birth Date:

Date	Location	User	Value	Reason
Oct-19-2020 15:42:41 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: (b) (6)/1962	Enrollment Entry

3. Sex:

Date	Location	User	Value	Reason
Oct-19-2020 15:43:16 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: MALE	Initial Entry

4. Ethnicity:

Date	Location	User	Value	Reason
Oct-19-2020 15:43:16 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NOT HISPANIC OR LATIN O(A) OR OF SPANISH ORIGIN	Initial Entry

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

Date	Location	User	Value	Reason
Oct-19-2020 15:43:16 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: WHITE	Initial Entry

090177e196ae30eb\Final\Final On: 01-Apr-2021 04:19 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:02

Site No: 1066

Subject No: 10661350

Generated By: (b) (4)

Form: DATE OF VISIT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1066) Solaris Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:05

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I. Date of Visit

Date	Location	User	Value	Reason
Oct-19-2020 15:43:30 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Oct/19/2020	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 15-Sep-2020 21:52

Site No: 1066

Subject No: 10661350

Generated By: (b) (4)

Form: DISPOSITION - SCREENING - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1066) Solaris Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:05

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1. Date of Completion/Discontinuation/Death

Date	Location	User	Value	Reason
Oct-19-2020 15:43:50 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Oct/19/2020	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Oct-19-2020 15:43:50 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SCREENING	Initial Entry

3. Status:

Date	Location	User	Value	Reason
Oct-19-2020 15:43:50 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: COMPLETED	Initial Entry

090177e196ae30eb\Final\Final On: 01-Apr-2021 04:19 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1066

Subject No: 10661350

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1066) Solaris Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:05

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I.a

Date	Location	User	Value	Reason
Oct-19-2020 15:44:14 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: Medical History GERD Term: Start Date: UNK/UNK/ 2000 Ongoing: YES	Initial Entry

I.a Line/MH Number:

Date	Location	User	Value	Reason
Oct-19-2020 15:44:14 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 1	Initial Entry

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

Date	Location	User	Value	Reason
Oct-19-2020 15:44:14 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: GERD	Initial Entry

I.a Start Date:

Date	Location	User	Value	Reason
Oct-19-2020 15:44:14 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNK/UNK/2000	Initial Entry

I.a Ongoing:

Date	Location	User	Value	Reason
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090177e196ae30eb\Final\Final On: 01-Apr-2021 04:19 (GMT)

Header Text: c4591001
Visit: V1_DAY1_VAX1_L
Form Version: 22-Apr-2020 21:03
Site No: 1066
Subject No: 10661350
Generated By: (b) (4)
Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History
Form Status: Data Complete, Locked, Frozen, Verified
Site Name: (1066) Solaris Clinical Research
Subject Initials: ---
Generated Time (GMT): 29-Mar-2021 10:05

Oct-19-2020 15:44:14 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry
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I.b

Date	Location	User	Value	Reason
Oct-19-2020 15:44:32 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Numbe 2 r: Medical History anxiety Term: Start Date: UNK/UNK/ 1990 Ongoing: YES	Initial Entry

090177e196ae30eb\Final\Final On: 01-Apr-2021 04:19 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1066

Subject No: 10661350

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1066) Solaris Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:05

1.b Line/MH Number:

Date	Location	User	Value	Reason
Oct-19-2020 15:44:32 (UTC-07:00) Mountain 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
Oct-19-2020 15:44:32 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: anxiety	Initial Entry

1.b Start Date:

Date	Location	User	Value	Reason
Oct-19-2020 15:44:32 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNK/UNK/1990	Initial Entry

1.b Ongoing:

Date	Location	User	Value	Reason
Oct-19-2020 15:44:32 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

1.c

Date	Location	User	Value	Reason
Oct-19-2020 15:44:44 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Numbe 3 r: Medical History hypertension Term: Start Date: UNK/UNK/ 2000 Ongoing: YES	Initial Entry

090177e196ae30eb\Final\Final On: 01-Apr-2021 04:19 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1066

Subject No: 10661350

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1066) Solaris Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:05

I.c Line/MH Number:

Date	Location	User	Value	Reason
Oct-19-2020 15:44:44 (UTC-07:00) Mountain 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
Oct-19-2020 15:44:44 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: hypertension	Initial Entry

I.c Start Date:

Date	Location	User	Value	Reason
Oct-19-2020 15:44:44 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNK/UNK/2000	Initial Entry

I.c Ongoing:

Date	Location	User	Value	Reason
Oct-19-2020 15:44:44 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

I.d

Date	Location	User	Value	Reason
Oct-19-2020 15:44:59 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Numbe 4 r: Medical History hyponatremi Term: a Start Date: UNK/UNK/ 2015 Ongoing: YES	Initial Entry

090177e196ae30eb\Final\Final On: 01-Apr-2021 04:19 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1066

Subject No: 10661350

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1066) Solaris Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:05

1.d Line/MH Number:

Date	Location	User	Value	Reason
Oct-19-2020 15:44:59 (UTC-07:00) Mountain 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
Oct-19-2020 15:44:59 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: hyponatremia	Initial Entry

1.d Start Date:

Date	Location	User	Value	Reason
Oct-19-2020 15:44:59 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNK/UNK/2015	Initial Entry

1.d Ongoing:

Date	Location	User	Value	Reason
Oct-19-2020 15:44:59 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

1.e

Date	Location	User	Value	Reason
Oct-19-2020 15:45:10 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Numbe 5 r: Medical History insomnia Term: Start Date: UNK/UNK/ 2000 Ongoing: YES	Initial Entry

090177e196ae30eb\Final\Final On: 01-Apr-2021 04:19 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1066

Subject No: 10661350

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1066) Solaris Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:05

I.e Line/MH Number:

Date	Location	User	Value	Reason
Oct-19-2020 15:45:10 (UTC-07:00) Mountain 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
Oct-19-2020 15:45:10 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: insomnia	Initial Entry

I.e Start Date:

Date	Location	User	Value	Reason
Oct-19-2020 15:45:10 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNK/UNK/2000	Initial Entry

I.e Ongoing:

Date	Location	User	Value	Reason
Oct-19-2020 15:45:10 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

I.f

Date	Location	User	Value	Reason
Oct-19-2020 15:45:28 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Num 6 ber: Medical Histor history of seiz y Term: ure Start Date: UNK/UNK/20 15	Initial Entry

090177e196ae30eb\Final\Final On: 01-Apr-2021 04:19 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1066

Subject No: 10661350

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1066) Solaris Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:05

			Ongoing:	NO	
				End Date:	
				UNK/UNK	
				/2015	

1.f Line/MH Number:

Date	Location	User	Value	Reason
Oct-19-2020 15:45:28 (UTC-07:00) Mountain 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
Oct-19-2020 15:45:28 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: history of seizure	Initial Entry

1.f Start Date:

Date	Location	User	Value	Reason
Oct-19-2020 15:45:28 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNK/UNK/2015	Initial Entry

1.f Ongoing:

Date	Location	User	Value	Reason
Oct-19-2020 15:45:28 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO End Date: UNK/UNK/2015	Initial Entry

1.g

Date	Location	User	Value	Reason
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090177e196ae30eb\Final\Final On: 01-Apr-2021 04:19 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1066

Subject No: 10661350

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1066) Solaris Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:05

Oct-19-2020 15:45:44 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Num 7 ber: Medical Histor spinal stenosis y Term: Start Date: UNK/UNK/20 12 Ongoing: NO End Date: UNK/UNK /2012	Initial Entry
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090177e196ae30eb\Final\Final On: 01-Apr-2021 04:19 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1066

Subject No: 10661350

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1066) Solaris Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:05

I.g Line/MH Number:

Date	Location	User	Value	Reason
Oct-19-2020 15:45:44 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 7	Initial Entry

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

Date	Location	User	Value	Reason
Oct-19-2020 15:45:44 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: spinal stenosis	Initial Entry

I.g Start Date:

Date	Location	User	Value	Reason
Oct-19-2020 15:45:44 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNK/UNK/2012	Initial Entry

I.g Ongoing:

Date	Location	User	Value	Reason
Oct-19-2020 15:45:44 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO End Date: UNK/UNK/2012	Initial Entry

I.h

Date	Location	User	Value	Reason
Oct-19-2020 15:45:59 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Nu 8 mber: Medical Histo history of alcoh ry Term: ol abuse Start Date: UNK/UNK/201 8	Initial Entry

090177e196ae30eb\Final\Final On: 01-Apr-2021 04:19 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1066

Subject No: 10661350

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1066) Solaris Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:05

			Ongoing: NO End Date: UNK/UNK/ 2018	
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1.h Line/MH Number:

Date	Location	User	Value	Reason
Oct-19-2020 15:45:59 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 8	Initial Entry

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

Date	Location	User	Value	Reason
Oct-19-2020 15:45:59 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: history of alcohol abuse	Initial Entry

1.h Start Date:

Date	Location	User	Value	Reason
Oct-19-2020 15:45:59 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNK/UNK/2018	Initial Entry

1.h Ongoing:

Date	Location	User	Value	Reason
Oct-19-2020 15:45:59 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO End Date: UNK/UNK/2018	Initial Entry

1.i

Date	Location	User	Value	Reason
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090177e196ae30eb\Final\Final On: 01-Apr-2021 04:19 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1066

Subject No: 10661350

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1066) Solaris Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:05

Oct-19-2020 15:46:42 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH N 9 umber: Medical Hi L4-L5 laminotomy story Term with diskectomy : Start Date: UNK/UNK/2012 Ongoing: NO End Date: UNK/UNK/201 2	Initial Entry
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090177e196ae30eb\Final\Final On: 01-Apr-2021 04:19 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1066

Subject No: 10661350

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1066) Solaris Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:05

1.i Line/MH Number:

Date	Location	User	Value	Reason
Oct-19-2020 15:46:42 (UTC-07:00) Mountain 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
Oct-19-2020 15:46:42 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: L4-L5 laminotomy with discectomy	Initial Entry

1.i Start Date:

Date	Location	User	Value	Reason
Oct-19-2020 15:46:42 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNK/UNK/2012	Initial Entry

1.i Ongoing:

Date	Location	User	Value	Reason
Oct-19-2020 15:46:42 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO End Date: UNK/UNK/2012	Initial Entry

1.j

Date	Location	User	Value	Reason
Oct-19-2020 15:47:00 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 10 r: Medical History Term: morphine allergy Start Date: UNK/UNK/1985	Initial Entry

090177e196ae30eb\Final\Final On: 01-Apr-2021 04:19 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1066

Subject No: 10661350

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1066) Solaris Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:05

			Ongoing:	YES	
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1.j Line/MH Number:

Date	Location	User	Value	Reason
Oct-19-2020 15:47:00 (UTC-07:00) Mountain 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
Oct-19-2020 15:47:00 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: morphine allergy	Initial Entry

1.j Start Date:

Date	Location	User	Value	Reason
Oct-19-2020 15:47:00 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNK/UNK/1985	Initial Entry

1.j Ongoing:

Date	Location	User	Value	Reason
Oct-19-2020 15:47:00 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

090177e196ae30eb\Final\Final On: 01-Apr-2021 04:19 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1066

Subject No: 10661350

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1066) Solaris Clinical Research

Subject Initials: ---

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<i>I.k</i>				
Date	Location	User	Value	Reason
Oct-19-2020 15:47:13 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 11 Medical History Term: sulfa allergy Start Date: UNK/UNK/ 1980 Ongoing: YES	Initial Entry

090177e196ae30eb\Final\Final On: 01-Apr-2021 04:19 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1066

Subject No: 10661350

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1066) Solaris Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:05

1.k Line/MH Number:

Date	Location	User	Value	Reason
Oct-19-2020 15:47:13 (UTC-07:00) Mountain 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
Oct-19-2020 15:47:13 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: sulfa allergy	Initial Entry

1.k Start Date:

Date	Location	User	Value	Reason
Oct-19-2020 15:47:13 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNK/UNK/1980	Initial Entry

1.k Ongoing:

Date	Location	User	Value	Reason
Nov-12-2020 12:59:15 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Hayley Wyper (b) (4)	Query 1: Closed	Response satisfies query
Nov-12-2020 12:52:47 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Changed data per query
Nov-11-2020 21:55:49 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	CLINQUERY: MH update to be completed for cardiovascular history in line with

090177e196ae30eb\Final\Final On: 01-Apr-2021 04:19 (GMT)

Header Text: c4591001
Visit: V1_DAY1_VAX1_L
Form Version: 22-Apr-2020 21:03
Site No: 1066
Subject No: 10661350
Generated By: (b) (4)
Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History
Form Status: Data Complete, Locked, Frozen, Verified
Site Name: (1066) Solaris Clinical Research
Subject Initials: ---
Generated Time (GMT): 29-Mar-2021 10:05

				AE of MI
Nov-11-2020 16:39:41 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Hayley Wyper (b) (4)	Query 1: Candidate	CLINQUERY: MH update to be completed for cardiovascular history in line with AE of MI
Oct-19-2020 15:47:13 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

1.1

Date	Location	User	Value	Reason
Nov-12-2020 12:51:59 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 12 r: Medical History: cardiomyopathy Term: athy Start Date: Mar/UNK/2018 Ongoing: YES	Initial Entry

090177e196ae30eb\Final\Final On: 01-Apr-2021 04:19 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1066

Subject No: 10661350

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1066) Solaris Clinical Research

Subject Initials: ---

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1.1 Line/MH Number:

Date	Location	User	Value	Reason
Nov-12-2020 12:51:59 (UTC-07:00) Mountain 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
Nov-12-2020 12:51:59 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: cardiomyopathy	Initial Entry

1.1 Start Date:

Date	Location	User	Value	Reason
Nov-12-2020 12:51:59 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Mar/UNK/2018	Initial Entry

1.1 Ongoing:

Date	Location	User	Value	Reason
Nov-12-2020 12:51:59 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

1.m

Date	Location	User	Value	Reason
Nov-12-2020 12:52:35 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Num 13 ber: Medical History Term: myocardial infarction Start Date: Mar/UNK/2018	Initial Entry

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Header Text: c4591001

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Form Version: 22-Apr-2020 21:03

Site No: 1066

Subject No: 10661350

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1066) Solaris Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:05

			Ongoing: NO	
			End Date:	
			Mar/UNK/2018	

1.m Line/MH Number:

Date	Location	User	Value	Reason
Nov-12-2020 12:52:35 (UTC-07:00) Mountain 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
Nov-12-2020 12:52:35 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: myocardial infarction	Initial Entry

1.m Start Date:

Date	Location	User	Value	Reason
Nov-12-2020 12:52:35 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Mar/UNK/2018	Initial Entry

1.m Ongoing:

Date	Location	User	Value	Reason
Nov-12-2020 12:52:35 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO End Date: Mar/UNK/2018	Initial Entry

090177e196ae30eb\Final\Final On: 01-Apr-2021 04:19 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 15-Sep-2020 21:57

Site No: 1066

Subject No: 10661350

Generated By: (b) (4)

Form: HIV STATUS - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1066) Solaris Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:05

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1. Select appropriate response - What is the subject HIV status?

Date	Location	User	Value	Reason
Oct-19-2020 15:47:36 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: The subject is NOT known to be HIV POSITIVE	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: VITAL SIGNS - BASELINE - eCRF Audit Trail History

Form Version: 10-Oct-2020 16:04

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1066

Site Name: (1066) Solaris Clinical Research

Subject No: 10661350

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:05

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1. Date:

Date	Location	User	Value	Reason
Oct-19-2020 15:47:58 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Oct/19/2020	Initial Entry

2. Weight:

Date	Location	User	Value	Reason
Oct-19-2020 15:47:58 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 185.3	Initial Entry

3. Unit:

Date	Location	User	Value	Reason
Oct-19-2020 15:47:58 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: LB	Initial Entry

4. Height:

Date	Location	User	Value	Reason
Oct-19-2020 15:47:58 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 72.0	Initial Entry

5. Unit:

Date	Location	User	Value	Reason
Oct-19-2020 15:47:58 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: in	Initial Entry

6. Body Mass Index:

Date	Location	User	Value	Reason
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090177e196ae30eb\Final\Final On: 01-Apr-2021 04:19 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 10-Oct-2020 16:04

Site No: 1066

Subject No: 10661350

Generated By: (b) (4)

Form: VITAL SIGNS - BASELINE - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1066) Solaris Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:05

Oct-19-2020 15:47:58 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 25.1	Initial Entry
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7.a

Date	Location	User	Value	Reason
Oct-19-2020 15:47:58 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Record Identifi 1 er:: Temperature: 98.8 Temperature U F nit: Temperature L ORAL CA ocation:: VITY	Initial Entry

7.a Record Identifier:

Date	Location	User	Value	Reason
Oct-19-2020 15:47:58 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 1	Initial Entry

7.a Temperature:

Date	Location	User	Value	Reason
Oct-19-2020 15:47:58 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 98.8	Initial Entry

7.a Unit:

Date	Location	User	Value	Reason
Oct-19-2020 15:47:58 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: F	Initial Entry

7.a Temperature Location:

Date	Location	User	Value	Reason
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090177e196ae30eb\Final\Final On: 01-Apr-2021 04:19 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 10-Oct-2020 16:04

Site No: 1066

Subject No: 10661350

Generated By: (b) (4)

Form: VITAL SIGNS - BASELINE - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1066) Solaris Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:05

Oct-19-2020 15:47:58 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: ORAL CAVITY	Initial Entry
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Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1066

Subject No: 10661350

Generated By: (b) (4)

Form: RANDOMIZATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1066) Solaris Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:05

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1. Randomization Date :

Date	Location	User	Value	Reason
Oct-19-2020 15:48:12 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Oct/19/2020	Initial Entry

2. Randomization Number:

Date	Location	User	Value	Reason
Oct-19-2020 15:48:12 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 270819	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: 1066

Site Name: (1066) Solaris Clinical Research

Subject No: 10661350

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:05

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1. Data Origin

Date	Location	User	Value	Reason
Oct-19-2020 15:48:21 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Oct-19-2020 15:48:21 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SERUM	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Oct-19-2020 15:50:12 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Oct-19-2020 15:48:21 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Oct-19-2020 15:48:21 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Collection: Oct/19/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
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090177e196ae30eb\Final\Final On: 01-Apr-2021 04:19 (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: 1066

Site Name: (1066) Solaris Clinical Research

Subject No: 10661350

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:05

Oct-19-2020 15:50:12 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BR6T8S	Initial Entry
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5.a Sample ID

Date	Location	User	Value	Reason
Oct-19-2020 15:50:12 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BR6T8S	Initial Entry

5.b

Date	Location	User	Value	Reason
Nov-12-2020 17:50:13 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BS5DV6	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Nov-12-2020 17:50:13 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BS5DV6	Initial Entry

5.c

Date	Location	User	Value	Reason
Nov-12-2020 17:50:23 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BS5DV7	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Nov-12-2020 17:50:23 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BS5DV7	Initial Entry

090177e196ae30eb\Final\Final On: 01-Apr-2021 04:19 (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: 1066

Site Name: (1066) Solaris Clinical Research

Subject No: 10661350

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:05

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1. Data Origin

Date	Location	User	Value	Reason
Oct-19-2020 15:48:32 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Oct-19-2020 15:48:32 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: NASAL_SWAB	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Oct-19-2020 15:49:53 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Oct-19-2020 15:48:32 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Oct-19-2020 15:48:32 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Collection: Oct/19/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
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090177e196ae30eb\Final\Final On: 01-Apr-2021 04:19 (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: 1066

Site Name: (1066) Solaris Clinical Research

Subject No: 10661350

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:05

Oct-19-2020 15:49:53 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BR6T7X	Initial Entry
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5.a Sample ID

Date	Location	User	Value	Reason
Oct-19-2020 15:49:53 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BR6T7X	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:04

Site No: 1066

Subject No: 10661350

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1066) Solaris Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:05

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1. Was there a temporary delay of vaccination?

Date	Location	User	Value	Reason
Oct-19-2020 15:49:05 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2. Treatment Name

Date	Location	User	Value	Reason
Oct-19-2020 15:49:05 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: BLINDED THERAPY	Initial Entry

3. Formulation:

Date	Location	User	Value	Reason
Oct-19-2020 15:49:05 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INJECTION	Initial Entry

4. Dose Date Time:

Date	Location	User	Value	Reason
Oct-19-2020 15:49:05 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Oct/19/2020 13:32	Initial Entry

5. Anatomical Location:

Date	Location	User	Value	Reason
Oct-19-2020 15:49:05 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: DELTOID MUSCLE	Initial Entry

6. Body Side:

Date	Location	User	Value	Reason
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090177e196ae30eb\Final\Final On: 01-Apr-2021 04:19 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:04

Site No: 1066

Subject No: 10661350

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1066) Solaris Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:05

Oct-19-2020 15:49:05 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: RIGHT	Initial Entry
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7. Route:

Date	Location	User	Value	Reason
Oct-19-2020 15:49:05 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INTRAMUSCULAR	Initial Entry

10. Timeframe Subject Was Observed

Date	Location	User	Value	Reason
Oct-19-2020 15:49:05 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: THE PROTOCOL SPECIFIED OBSERVATION PERIOD	Initial Entry

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

Date	Location	User	Value	Reason
Oct-19-2020 15:49:05 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

090177e196ae30eb\Final\Final On: 01-Apr-2021 04:19 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 06-Jul-2020 21:53

Site No: 1066

Subject No: 10661350

Generated By: (b) (4)

Form: REACTOGENICITY DIARY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1066) Solaris Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:05

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1. Select appropriate response - Reactogenicity diary collection

Date	Location	User	Value	Reason
Oct-19-2020 15:49:33 (UTC-07:00) Mountain 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: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - Audit Trail

Form Version: 22-Apr-2020 21:02

Form Status:

Site No: 1066

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Subject No: 10661350

Subject Initials: ---

Generated By: (b) (4)

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Date	Location	User	Value	Reason
Nov-10-2020 13:41:02 (UTC-07:00) Mountain 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: 1066

Subject No: 10661350

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1066) Solaris Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:05

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1. Category:

Date	Location	User	Value	Reason
Nov-10-2020 13:41:02 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: ADVERSE EVENT	Initial Entry

2. AE ID:

Date	Location	User	Value	Reason
Nov-10-2020 13:41:02 (UTC-07:00) Mountain 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
Mar-08-2021 14:45:56 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Clo sed	Query closed; will follow for requested clinical course information.
Mar-08-2021 12:14:13 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: An swere d	FU re-faxed
Mar-05-2021 20:28:00 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Rei ssued: Open ed	Clinical - Followup: no SAE update yet; please submit the information (no death cert received; spouse

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Header Text: c4591001

Visit: Logs - Unscheduled

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Site No: 1066

Subject No: 10661350

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1066) Solaris Clinical Research

Subject Initials: ---

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				reported the cause of death to site) as a SAE Safety update
Feb-24-2021 14:29:15 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Answered	SAE safety updated will be submitted to Pfizer safety with this information
Feb-22-2021 20:47:56 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Reissued: Opened	CLINICAL Thank you; please submit this information (no death cert received; spouse reported the cause of death to site) as a SAE Safety update
Feb-20-2021 11:51:23 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Answered	reported by subject spouse. death certificate not provided to site
Feb-19-2021 00:29:00 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Opened	Clinical - Please clarify in SAE safety update who specified cause of death (for death at home), ie primary MD or Med

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Header Text: c4591001

Visit: Logs - Unscheduled

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Site No: 1066

Subject No: 10661350

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1066) Solaris Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:05

				Examiner. Please confirm cause of death on Death certificate.
Feb-18-2021 10:15:22 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Candidate	Clinical - Please clarify in SAE safety update who specified cause of death (for death at home), ie primary MD or Med Examiner. Please confirm cause of death on Death certificate.
Nov-15-2020 07:42:08 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	the MI reported in Med hx is a prior MI; occurred in 2018
Nov-14-2020 09:26:57 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	PFE SDQ PROD (b) (4)	Query 1: Opened	The AE myocardial infarction was reported but is also listed in Medical History. Please clarify if this is a worsening of the baseline condition, and if so, please

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Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1066

Subject No: 10661350

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1066) Solaris Clinical Research

Subject Initials: ---

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				consider adding "worsening" to the AE term. AE as baseline conditions should only be reported as AEs if they worsen. (b) (4)
Nov-10-2020 13:41:02 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: myocardial infarction	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason
Nov-10-2020 13:41:02 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Nov/3/2020 UNK:UNK	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Nov-10-2020 13:41:02 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO End Date Time: Nov/3/2020 UNK:UNK	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
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Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

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Form Status: Data Complete, Frozen, Verified

Site No: 1066

Site Name: (1066) Solaris Clinical Research

Subject No: 10661350

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:05

Nov-10-2020 13:41:02 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 4	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
Nov-12-2020 11:15:14 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Nov-10-2020 13:41:45 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Closed	Close Auto Query
Nov-10-2020 13:41:45 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Is this serious event associa ted with congenital anomal y or birth defect? NO Did this serious event resul t in death? YES Did this serious event requi re or prolong hospitalizatio n? NO Did this serious event resul	Transcription Error

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Subject No: 10661350

Generated By: (b) (4)

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Form Status: Data Complete, Frozen, Verified

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			<p>t 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>	
Nov-10-2020 13:41:02 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Opened	Is this adverse event serious?' is reported 'Yes', but at least one seriousness criteria is missing. Please review and update as appropriate.
Nov-10-2020 13:41:02 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	For AE myocardial infarction: Response to "Is the adverse event serious?" is 'Yes' but "Serious Adverse Event Number" is blank.
Nov-10-2020 13:41:02 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<p>Data Entry:</p> <p>YES</p> <p>Did this serious event result in death?</p> <p>YES</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.

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Subject No: 10661350

Generated By: (b) (4)

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Form Status: Data Complete, Frozen, Verified

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Date	Location	User	Value	Reason
Nov-10-2020 13:41:02 (UTC-07:00) Mountain 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
Nov-12-2020 12:59:02 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Hayley Wyper (b) (4)	Query 2: Closed	Response satisfies query
Nov-12-2020 12:53:04 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Answered	Changed data per query
Nov-12-2020 03:41:43 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Hayley Wyper (b) (4)	Query 2: Reissued:Opened	CLINQUERY: to confirm, the MH page is now unfrozen and can be updated
Nov-11-2020 19:29:51 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Nov-11-2020 16:37:41 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Answered	please unfreeze MH form to update data
Nov-11-2020 16:36:15 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Hayley Wyper (b) (4)	Query 2: Opened	CLINQUERY: Please review the MH entries for this subject and clarify if updates are needed to capture the prior cardiovascular history. Page can be unlocked if updates

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Header Text: c4591001**Visit:** Logs - Unscheduled**Form Version:** 22-Apr-2020 21:02**Site No:** 1066**Subject No:** 10661350**Generated By:** (b) (4)**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History**Form Status:** Data Complete, Frozen, Verified**Site Name:** (1066) Solaris Clinical Research**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 10:05

				needed
Nov-11-2020 15:31:32 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Changed Information
Nov-11-2020 15:31:32 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry: NOT RELATED If Not Related to study treatment(s), this event is due to: OTHER <i>If Other, specify:</i> disease progression	Changed Information
Nov-11-2020 14:14:29 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Query 1: Opened	CLINICAL - Event relationship is reported as UNKNOWN; however, SAE report states it was due to 'progression of underlying disease' in this subject with Past Med H of MI & cardiomyopathy. Please review, and update as appropriate.
Nov-10-2020 13:43:21 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry: NOT RELATED If Not Related to study treatment(s), this event is due to: OTHER <i>If Other, specify:</i>	Transcription Error

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

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Form Status: Data Complete, Frozen, Verified

Site No: 1066

Site Name: (1066) Solaris Clinical Research

Subject No: 10661350

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:05

			unknown	
Nov-10-2020 13:41:02 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NOT RELATED	Initial Entry

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Nov-16-2020 08:28:59 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Closed	Acceptable discrepancy per Clinical review
Nov-14-2020 08:26:29 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Reissued:Can didate	pending Clinical review
Nov-13-2020 06:48:42 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Answered	changed data per query. "CLINQUERY: Please review this entry - since event was fatal prior to V2 the status for this question can also be reported as Drug Withdrawn to link to the EOT page"
Nov-13-2020 01:37:09 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Opened	SAE RECON:AER#2020446214 ,action taken was reported as DRUG WITHDRAWN in AE CRF while NOT APPLICABLE in Safety database.Please confirm. If safety update is required, please submit a follow up form
Nov-11-2020 16:36:41	ACV0PFEINFP6000	Hayley Wyper (b) (4)	Query 1: Closed	Response satisfies query

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Header Text: c4591001**Visit:** Logs - Unscheduled**Form Version:** 22-Apr-2020 21:02**Site No:** 1066**Subject No:** 10661350**Generated By:** (b) (4)**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History**Form Status:** Data Complete, Frozen, Verified**Site Name:** (1066) Solaris Clinical Research**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 10:05

(UTC-07:00) Mountain Time (US & Canada)				
Nov-11-2020 16:35:38 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Changed Information
Nov-11-2020 16:35:38 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: DRUG WITHDRAW N	Changed Information
Nov-11-2020 16:32:31 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Hayley Wyper (b) (4)	Query 1: Opened	CLINQUERY: Please review this entry - since event was fatal prior to V2 the status for this question can also be reported as Drug Withdrawn to link to the EOT page
Nov-10-2020 13:41:02 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NOT APPLICABLE	Initial Entry

II. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
Nov-10-2020 13:41:02 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Nov-10-2020 13:41:02 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

Header Text: c4591001

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Site No: 1066

Subject No: 10661350

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1066) Solaris Clinical Research

Subject Initials: ---

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

Date	Location	User	Value	Reason
Nov-11-2020 19:29:00 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Nov-11-2020 15:35:57 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Closed	Close Auto Query
Nov-11-2020 15:31:47 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Opened	Response to "What was the outcome of this adverse event?" is 'Fatal' but Date of Collection / Notification of Death on the Death Details form is not completed. Please review and update as appropriate.
Nov-11-2020 15:31:47 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Transcription Error
Nov-11-2020 15:31:47 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: FATAL	Transcription Error

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Header Text: c4591001

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Form Status: Data Complete, Frozen, Verified

Site Name: (1066) Solaris Clinical Research

Subject Initials: ---

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

Date	Location	User	Value	Reason
Nov-11-2020 14:12:33 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	CLINICAL AE report for this Event of MI states 'Recovered'; however, SAE report states this was a fatal event. Please review, and update as appropriate
Nov-10-2020 13:41:02 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: RECOVERED/RESOLVED	Initial Entry

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

Date	Location	User	Value	Reason
Nov-11-2020 16:33:24 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Hayley Wyper (b) (4)	Query 1: Closed	fatal event, disposition pages completed.
Nov-11-2020 15:37:36 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Changed data per query
Nov-11-2020 10:23:49 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Hayley Wyper (b) (4)	Query 1: Opened	CLINQUERY: Event is reported to have led to end of study, but not end of treatment. Please review this entry and the question 'Last action taken with

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Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen, Verified

Site No: 1066

Site Name: (1066) Solaris Clinical Research

Subject No: 10661350

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:05

				study Rx' and confirm for EOT/FUP status updates
Nov-10-2020 13:41:02 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

15. Serious Adverse Event Number: For Pfizer Use Only

Date	Location	User	Value	Reason
Nov-12-2020 11:15:14 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 2020446214	Initial Entry

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Header Text: c4591001

Visit: End of Treatment - Unscheduled

Form: DISPOSITION - TREATMENT - eCRF Audit Trail History

Form Version: 15-Sep-2020 21:55

Form Status: Data Complete, Frozen, Verified

Site No: 1066

Site Name: (1066) Solaris Clinical Research

Subject No: 10661350

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:05

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1. Date of Completion/Discontinuation/Death :

Date	Location	User	Value	Reason
Nov-11-2020 15:36:40 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Nov/3/2020	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Nov-11-2020 15:36:40 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: VACCINATION	Initial Entry

3. Status:

Date	Location	User	Value	Reason
Nov-11-2020 15:36:40 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: DEATH	Initial Entry

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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: 1066

Site Name: (1066) Solaris Clinical Research

Subject No: 10661350

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:05

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1. Date of Visit

Date	Location	User	Value	Reason
Mar-09-2021 08:24:44 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

2. Erroneous Visit

Date	Location	User	Value	Reason
Mar-09-2021 08:24:44 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

090177e196ae30eb\Final\Final On: 01-Apr-2021 04:19 (GMT)

Header Text: c4591001

Visit: Potential ReVax Initial Contact -
Unscheduled

Form Version: 10-Dec-2020 02:25

Site No: 1066

Subject No: 10661350

Generated By: (b) (4)

Form: FURTHER VACCINATION CONFIRMATION - eCRF Audit
Trail History

Form Status: Data Complete, Frozen

Site Name: (1066) Solaris Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:05

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

Date	Location	User	Value	Reason
Mar-09-2021 08:25:02 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

Header Text: c4591001

Visit: Follow-Up - Unscheduled

Form: DISPOSITION - FOLLOW-UP - eCRF Audit Trail History

Form Version: 15-Sep-2020 21:53

Form Status: Data Complete, Frozen, Verified

Site No: 1066

Site Name: (1066) Solaris Clinical Research

Subject No: 10661350

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:05

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1. Date of Completion/Discontinuation/Death :

Date	Location	User	Value	Reason
Nov-11-2020 15:37:21 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Nov/3/2020	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Nov-11-2020 15:37:21 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: FOLLOW-UP	Initial Entry

3. Status:

Date	Location	User	Value	Reason
Nov-11-2020 15:37:21 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: DEATH	Initial Entry

090177e196ae30eb\Final\Final On: 01-Apr-2021 04:19 (GMT)

Header Text: c4591001

Visit: Disposition - Unscheduled

Form: DEATH DETAILS CODED - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1066

Site Name: (1066) Solaris Clinical Research

Subject No: 10661350

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:05

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I. Date of Collection / Notification of Death:

Date	Location	User	Value	Reason
Nov-11-2020 23:17:34 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	As per site confirmation on date of notification
Nov-11-2020 16:16:33 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	site was not notified of death until 10-NOV-2020
Nov-11-2020 15:37:21 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	Date of Collection / Notification of Death is greater than the Date of Completion/Discontinuation /Death on the Disposition form 03/Nov/2020. Please review and update as appropriate
Nov-11-2020 15:35:57 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Nov/10/2020	Initial Entry

2.a

Date	Location	User	Value	Reason
Nov-11-2020 15:36:22 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Cause of Death Status: PRIMARY CAUSE OF DEATH : H Cause of Death: myocardial infarction	Initial Entry

Header Text: c4591001

Visit: Disposition - Unscheduled

Form: DEATH DETAILS CODED - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1066

Site Name: (1066) Solaris Clinical Research

Subject No: 10661350

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:05

2.a Cause of Death Status:

Date	Location	User	Value	Reason
Nov-11-2020 15:36:22 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: PRIMARY CAUSE OF DEATH	Initial Entry

2.a Cause of Death:

Date	Location	User	Value	Reason
Nov-11-2020 15:36:22 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: myocardial infarction	Initial Entry

Header Text: c4591001

Visit: Subject Status - Unscheduled

Form: SUBJECT STATUS - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Verified

Site No: 1066

Site Name: (1066) Solaris Clinical Research

Subject No: 10661350

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:05

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1. Subject Status

Date	Location	User	Value	Reason
Nov-11-2020 15:37:21 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: DISCONTINUED	Initial Entry
Nov-11-2020 15:36:40 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: DISCONTINUED	Initial Entry
Oct-19-2020 15:48:12 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: ENROLLED/RANDOMIZED	Initial Entry
Oct-19-2020 15:43:50 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SCREENED	Initial Entry

2. Subject Status Date

Date	Location	User	Value	Reason
Nov-11-2020 15:37:21 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Nov/3/2020	Initial Entry
Nov-11-2020 15:36:40 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Nov/3/2020	Initial Entry
Oct-19-2020 15:48:12 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Oct/19/2020	Initial Entry
Oct-19-2020 15:43:50 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Oct/19/2020	Initial Entry

090177e196ae30eb\Final\Final On: 01-Apr-2021 04:19 (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, Verified

Site No: 1066

Site Name: (1066) Solaris Clinical Research

Subject No: 10661350

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:05

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I. Casebook Signature

Date	Location	User	Value	Reason
Oct-23-2020 07:50:53 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Click Here to Enable	Initial Entry