

Header Text: c4591001

Visit: COHORT_SELECTION

Form: COHORT SELECTION

Form Version: 15-Sep-2020 21:55

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1152

Site Name: (1152) California Research Foundation

Subject No: 11521497

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

[eCRF Audit Trail History](#)

Cohort Selection

DO NOT USE THE OPTIONS STAGE 1 NONSENTINEL and STAGE 2 from this CRF. As per protocol amendment 5, STAGE 3 option is equivalent to PHASE 2/3.

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

Header Text: c4591001

Visit: COHORT_SELECTION

Form Version: 22-Apr-2020 21:02

Site No: 1152

Subject No: 11521497

Generated By: (b) (4)

Form: MAIN INFORMED CONSENT

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1152) California Research Foundation

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:56

[eCRF Audit Trail History](#)

Informed Consent

1.	Consent Was:	OBTAINED Date Written Consent Obtained Oct/7/2020
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Header Text: c4591001

Visit: COHORT_SELECTION

Form Version: 15-Sep-2020 21:54

Site No: 1152

Subject No: 11521497

Generated By: (b) (4)

Form: DEMOGRAPHY

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1152) California Research Foundation

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:56

[eCRF Audit Trail History](#)

Demography

1.	Subject ID	[11521497]
2.	Birth Date:	(b) (6)/1948
3.	Sex:	MALE
4.	Ethnicity:	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: 1152

Subject No: 11521497

Generated By: (b) (4)

Form: DATE OF VISIT

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1152) California Research Foundation

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:56

eCRF Audit Trail History

Date of Visit

1.	Date of Visit	Oct/7/2020
2.	Erroneous Visit	

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 15-Sep-2020 21:53

Site No: 1152

Subject No: 11521497

Generated By: (b) (4)

Form: INCLUSION/EXCLUSION CRITERIA

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1152) California Research Foundation

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:56

Form Comments

Inclusion Criteria Not Met

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

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

Visit: V1_DAY1_VAX1_L

Form Version: 15-Sep-2020 21:52

Site No: 1152

Subject No: 11521497

Generated By: (b) (4)

Form: DISPOSITION - SCREENING

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1152) California Research Foundation

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:56

[eCRF Audit Trail History](#)

Disposition - Screening

1.	Date of Completion/Discontinuation/Death	Oct/7/2020
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: 1152

Subject No: 11521497

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1152) California Research Foundation

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:56

[eCRF Audit Trail History](#)

Medical History Details

1.a	Line/MH Number:	[1]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[osteoarthritis]
	Start Date:	UNK/UNK/2010
	Ongoing:	YES
1.b	Line/MH Number:	[2]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[nephrolithiasis]
	Start Date:	UNK/UNK/1999
	Ongoing:	NO End Date: UNK/UNK/1999
1.c	Line/MH Number:	[3]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[hypertension]
	Start Date:	UNK/UNK/2018
	Ongoing:	YES
1.d	Line/MH Number:	[4]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Type II diabetes]
	Start Date:	UNK/UNK/2010
	Ongoing:	YES

090177e196ae2fce\Final\Final On: 01-Apr-2021 03:52 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1152

Subject No: 11521497

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1152) California Research Foundation

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:56

1.e	Line/MH Number:	[5]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[prostatism]
	Start Date:	UNK/UNK/2019
	Ongoing:	YES
1.f	Line/MH Number:	[6]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[allergy to celery]
	Start Date:	UNK/UNK/2000
	Ongoing:	YES
1.g	Line/MH Number:	[7]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[allergy to mango]
	Start Date:	UNK/UNK/2000
	Ongoing:	YES
1.h	Line/MH Number:	[8]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[lithotripsy]
	Start Date:	UNK/UNK/1999
	Ongoing:	NO End Date: UNK/UNK/1999
1.i	Line/MH Number:	[9]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[hearing loss]
	Start Date:	UNK/UNK/2010
	Ongoing:	YES

090177e196ae2fce\Final\Final On: 01-Apr-2021 03:52 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 15-Sep-2020 21:57

Site No: 1152

Subject No: 11521497

Generated By: (b) (4)

Form: HIV STATUS

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1152) California Research Foundation

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:56

[eCRF Audit Trail History](#)

HIV Status

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

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 15-Sep-2020 21:56

Site No: 1152

Subject No: 11521497

Generated By: (b) (4)

Form: VITAL SIGNS - BASELINE

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1152) California Research Foundation

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:56

[eCRF Audit Trail History](#)

Vital Signs

1.	Date:	Oct/7/2020
2.	Weight:	[172.2]
3.	Unit:	LB
4.	Height:	[69.5]
5.	Unit:	in
6.	Body Mass Index:	[25.1]

Vital Signs Details

7.a	Record Identifier:	1
	Temperature:	[98.3]
	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: 1152

Subject No: 11521497

Generated By: (b) (4)

Form: RANDOMIZATION

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1152) California Research Foundation

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:56

[eCRF Audit Trail History](#)

Disposition

1.	Randomization Date :	Oct/7/2020
2.	Randomization Number:	[267518]
3.	Randomization Group:	[]

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1152

Subject No: 11521497

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1152) California Research Foundation

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:56

eCRF Audit Trail History

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	SERUM
3.	Sample Collected?	YES Date of Collection: Oct/7/2020
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	[BP0SVN]
5.b	Sample ID	[BP0SVP]
5.c	Sample ID	[BNT3DN]

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Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1152

Subject No: 11521497

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1152) California Research Foundation

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:56

eCRF Audit Trail History

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Oct/7/2020
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	[BP0SLR]
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090177e196ae2fce\Final\Final On: 01-Apr-2021 03:52 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:04

Site No: 1152

Subject No: 11521497

Generated By: (b) (4)

Form: VACCINATION

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1152) California Research Foundation

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:56

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/7/2020 12:52
5.	Anatomical Location:	DELTOID MUSCLE
6.	Body Side:	LEFT
7.	Route:	INTRAMUSCULAR
8.	Actual Dose:	[]
9.	Unit:	
10.	Timeframe Subject Was Observed	THE PROTOCOL SPECIFIED OBSERVATION PERIOD
11.	Was the subject observed for at least the protocol specified observation period after investigational product administration?	YES

090177e196ae2fce\Final\Final On: 01-Apr-2021 03:52 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 06-Jul-2020 21:53

Site No: 1152

Subject No: 11521497

Generated By: (b) (4)

Form: REACTOGENICITY DIARY

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1152) California Research Foundation

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:56

[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: 1152

Subject No: 11521497

Generated By: (b) (4)

Form: DATE OF VISIT

Form Status: Data Complete, Frozen, Verified

Site Name: (1152) California Research Foundation

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:56

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

Date of Visit

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

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 20-Feb-2021 02:16

Site No: 1152

Subject No: 11521497

Generated By: (b) (4)

Form: VITAL SIGNS - TEMP

Form Status: Not Started

Site Name: (1152) California Research Foundation

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:56

Vital Signs

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

Vital Signs Details

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

090177e196ae2fce\Final\Final On: 01-Apr-2021 03:52 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:03

Site No: 1152

Subject No: 11521497

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB

Form Status: Not Started

Site Name: (1152) California Research Foundation

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:56

Electronic Sample Tracking

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

Aliquot

Please enter barcode for each aliquot.

5.	Sample ID	[]
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Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 10-Dec-2020 02:26

Site No: 1152

Subject No: 11521497

Generated By: (b) (4)

Form: VACCINATION

Form Status: Not Started

Site Name: (1152) California Research Foundation

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:56

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?	

090177e196ae2fce\Final\Final On: 01-Apr-2021 03:52 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 1152

Subject No: 11521497

Generated By: (b) (4)

Form: DATE OF VISIT

Form Status: Not Started

Site Name: (1152) California Research Foundation

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:56

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form Version: 22-Apr-2020 21:03

Site No: 1152

Subject No: 11521497

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Status: Not Started

Site Name: (1152) California Research Foundation

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:56

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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090177e196ae2fce\Final\Final On: 01-Apr-2021 03:52 (GMT)

Header Text: c4591001

Visit: V4_MONTH6_L

Form Version: 22-Apr-2020 21:02

Site No: 1152

Subject No: 11521497

Generated By: (b) (4)

Form: DATE OF VISIT

Form Status: Not Started

Site Name: (1152) California Research Foundation

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:56

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

Header Text: c4591001

Visit: V4_MONTH6_L

Form Version: 22-Apr-2020 21:03

Site No: 1152

Subject No: 11521497

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Status: Not Started

Site Name: (1152) California Research Foundation

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:56

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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090177e196ae2fce\Final\Final On: 01-Apr-2021 03:52 (GMT)

Header Text: c4591001

Visit: V5_MONTH12_L

Form Version: 22-Apr-2020 21:02

Site No: 1152

Subject No: 11521497

Generated By: (b) (4)

Form: DATE OF VISIT

Form Status: Not Started

Site Name: (1152) California Research Foundation

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:56

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

Header Text: c4591001

Visit: V5_MONTH12_L

Form Version: 22-Apr-2020 21:03

Site No: 1152

Subject No: 11521497

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Status: Not Started

Site Name: (1152) California Research Foundation

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:56

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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090177e196ae2fce\Final\Final On: 01-Apr-2021 03:52 (GMT)

Header Text: c4591001

Visit: V6_MONTH24_L

Form Version: 22-Apr-2020 21:02

Site No: 1152

Subject No: 11521497

Generated By: (b) (4)

Form: DATE OF VISIT

Form Status: Not Started

Site Name: (1152) California Research Foundation

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:56

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

Header Text: c4591001

Visit: V6_MONTH24_L

Form Version: 22-Apr-2020 21:03

Site No: 1152

Subject No: 11521497

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Status: Not Started

Site Name: (1152) California Research Foundation

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:56

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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090177e196ae2fce\Final\Final On: 01-Apr-2021 03:52 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL - New Unscheduled Visit

Form: DATE OF VISIT - ILLNESS ONSET

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1152

Site Name: (1152) California Research Foundation

Subject No: 11521497

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

COVID-19 Illness Visit

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

Header Text: c4591001

Visit: POT_COVID_ILL - New Unscheduled Visit

Form: SIGNS AND SYMPTOMS OF POTENTIAL COVID-19

Form Version: 20-Feb-2021 02:17

Form Status: Not Started

Site No: 1152

Site Name: (1152) California Research Foundation

Subject No: 11521497

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

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

090177e196ae2fce\Final\Final On: 01-Apr-2021 03:52 (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: 1152

Site Name: (1152) California Research Foundation

Subject No: 11521497

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

Electronic Sample Tracking

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

Aliquot

Please enter barcode for each aliquot.

5.	Sample ID	[]
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Header Text: c4591001

Visit: POT_COVID_ILL - New Unscheduled Visit

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1152

Site Name: (1152) California Research Foundation

Subject No: 11521497

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

Electronic Sample Tracking

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

Aliquot

Please enter barcode for each aliquot.

5.	Sample ID	[]
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Header Text: c4591001

Visit: POT_COVID_ILL - New Unscheduled Visit

Form: HEALTH CARE UTILIZATION

Form Version: 20-Feb-2021 02:19

Form Status: Not Started

Site No: 1152

Site Name: (1152) California Research Foundation

Subject No: 11521497

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

Health Care Utilization

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

Health Care Utilization Other

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

Health Care Utilization

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

Header Text: c4591001

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

Form Version: 06-Jul-2020 21:52 **Form Status:** Not Started

Site No: 1152 **Site Name:** (1152) California Research Foundation

Subject No: 11521497 **Subject Initials:** ---

Generated By: (b) (4) **Generated Time (GMT):** 29-Mar-2021 11:56

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: 1152

Site Name: (1152) California Research Foundation

Subject No: 11521497

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

COVID-19 Illness Visit

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

Header Text: c4591001

Visit: POT_COVID_CONVA - New
Unscheduled Visit

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1152

Site Name: (1152) California Research Foundation

Subject No: 11521497

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

Electronic Sample Tracking

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

Aliquot

Please enter barcode for each aliquot.

5.	Sample ID	[]
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Header Text: c4591001

Visit: POT_COVID_REPEAT_SWAB - New
Unscheduled Visit

Form: DATE OF VISIT - REPEAT SWAB

Form Version: 10-Oct-2020 15:57

Form Status: Not Started

Site No: 1152

Site Name: (1152) California Research Foundation

Subject No: 11521497

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

COVID-19 Repeat Swab

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

Visit: POT_COVID_REPEAT_SWAB - New
Unscheduled Visit

Form: ELECTRONIC SAMPLE TRACKING - REPEAT SWAB

Form Version: 10-Oct-2020 15:57

Form Status: Not Started

Site No: 1152

Site Name: (1152) California Research Foundation

Subject No: 11521497

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

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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090177e196ae2fce\Final\Final On: 01-Apr-2021 03:52 (GMT)

Header Text: c4591001

Visit: Unplanned - New Unscheduled Visit

Form: DATE OF VISIT

Form Version: 22-Apr-2020 21:02

Form Status: Not Started

Site No: 1152

Site Name: (1152) California Research Foundation

Subject No: 11521497

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

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: 1152

Site Name: (1152) California Research Foundation

Subject No: 11521497

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

Unplanned Assessments

1.	Assessments	
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Header Text: c4591001

Visit: Logs

Form: ADVERSE EVENT REPORT

Form Version: 22-Apr-2020 21:02

Site No: 1152

Site Name: (1152) California Research Foundation

Subject No: 11521497

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

#	Category	AE Identifier	Adverse Event	Start Date	Is the Adverse Event Still Ongoing	Form Instance
1.	ADVERSE EVENT	1	vasovagal syncope	Oct/26/2020 U NK:UNK	NO End Date Time: Oct/26/2020 UNK: UNK	Repeating Pages
2. DELETED	ADVERSE EVENT	2	Shigellosis	Oct/26/2020 U NK:UNK	NO End Date Time: Nov/11/2020 UNK: UNK	Repeating Pages
3.	ADVERSE EVENT	3	sepsis related to Shigella infection	Oct/26/2020 U NK:UNK	NO End Date Time: Nov/11/2020 UNK: UNK	Repeating Pages

090177e196ae2fce\Final\Final On: 01-Apr-2021 03:52 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1152

Subject No: 11521497

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Frozen

Site Name: (1152) California Research Foundation

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:56

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[Form Audit Trail](#)

Adverse Event Report

1.	Category:	ADVERSE EVENT	
2.	AE ID:	[1]	
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[vasovagal syncope]	
4.	Start Date Time:	Oct/26/2020 UNK:UNK	
5.	Is the adverse event still ongoing?	NO End Date Time: Oct/26/2020 UNK:UNK	Comments
6.	Toxicity Grade:	3	
7.	Is the adverse event serious? If Yes, NOTIFY PFIZER IMMEDIATELY. Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).	NO	
8.	Is this adverse event the result of a study Medication Error? If Yes, record the type of medication error on the Medication Error Log.	NO	
9.	Is this event related to study treatment:	NOT RELATED If Not Related to study treatment(s), this event is due to: OTHER If Other, specify: [sepsis related to shigella infection]	

090177e196ae2fce\Final\Final On: 01-Apr-2021 03:52 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1152

Subject No: 11521497

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Frozen

Site Name: (1152) California Research Foundation

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:56

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

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1152

Subject No: 11521497

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Deleted

Site Name: (1152) California Research Foundation

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:56

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

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Adverse Event Report

1.	Category:	ADVERSE EVENT
2.	AE ID:	[2]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[Shigellosis]
4.	Start Date Time:	Oct/26/2020 UNK:UNK
5.	Is the adverse event still ongoing?	NO End Date Time: Nov/11/2020 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? YES Did this serious event result in persistent or significant disability/incapacity? NO Is this serious event life threatening? YES Other medically important serious event NO
8.	Is this adverse event the result of a study Medication Error? If Yes, record the type of medication error on the Medication Error Log.	NO

090177e196ae2fce\Final\Final On: 01-Apr-2021 03:52 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1152

Subject No: 11521497

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Deleted

Site Name: (1152) California Research Foundation

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:56

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

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: [Shigella infection]
10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE
11.	Was a Concomitant Medication given?	YES
12.	Was a Non-Drug Treatment given?	NO
13.	What was the outcome of this adverse event?:	FATAL
14.	Did the adverse event cause the subject to be discontinued from the study?	NO
15.	Serious Adverse Event Number: For Pfizer Use Only	[2020437859]

090177e196ae2fce\Final\Final On: 01-Apr-2021 03:52 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1152

Subject No: 11521497

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Frozen

Site Name: (1152) California Research Foundation

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:56

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Adverse Event Report

1.	Category:	ADVERSE EVENT
2.	AE ID:	[3]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[sepsis related to Shigella infection]
4.	Start Date Time:	Oct/26/2020 UNK:UNK
5.	Is the adverse event still ongoing?	NO End Date Time: Nov/11/2020 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? YES Did this serious event result in persistent or significant disability/incapacity? NO Is this serious event life threatening? YES Other medically important serious event NO
8.	Is this adverse event the result of a study Medication Error? If Yes, record the type of medication error on the Medication Error Log.	NO

090177e196ae2fce\Final\Final On: 01-Apr-2021 03:52 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1152

Subject No: 11521497

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Frozen

Site Name: (1152) California Research Foundation

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:56

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: [Shigella infection]
10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE
11.	Was a Concomitant Medication given?	YES
12.	Was a Non-Drug Treatment given?	YES
13.	What was the outcome of this adverse event?:	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	[2020437859]

090177e196ae2fce\Final\Final On: 01-Apr-2021 03:52 (GMT)

Header Text: c4591001

Visit: Logs

Form: MEDICATION ERROR

Form Version: 17-Jul-2020 21:54

Site No: 1152

Site Name: (1152) California Research Foundation

Subject No: 11521497

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

#	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: 1152

Subject No: 11521497

Generated By: (b) (4)

Form: MEDICATION ERROR

Form Status: Not Started

Site Name: (1152) California Research Foundation

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:56

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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	[]

090177e196ae2fce\Final\Final On: 01-Apr-2021 03:52 (GMT)

Header Text: c4591001

Visit: Logs

Form: CONCOMITANT MEDICATIONS - NON STUDY
VACCINATIONS

Form Version: 22-Apr-2020 21:03

Site No: 1152

Site Name: (1152) California Research Foundation

Subject No: 11521497

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

#	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: 1152

Site Name: (1152) California Research Foundation

Subject No: 11521497

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

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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:	//

090177e196ae2fce\Final\Final On: 01-Apr-2021 03:52 (GMT)

Header Text: c4591001

Visit: Logs

Form: CONCOMITANT MEDICATIONS - PROHIBITED

Form Version: 22-Apr-2020 21:03

Site No: 1152

Site Name: (1152) California Research Foundation

Subject No: 11521497

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

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

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1152

Subject No: 11521497

Generated By: (b) (4)

Form: CONCOMITANT MEDICATIONS - PROHIBITED

Form Status: Not Started

Site Name: (1152) California Research Foundation

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:56

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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?	

090177e196ae2fce\Final\Final On: 01-Apr-2021 03:52 (GMT)

Header Text: c4591001

Visit: Logs

Form: RADIATION TREATMENT

Form Version: 22-Apr-2020 21:02

Site No: 1152

Site Name: (1152) California Research Foundation

Subject No: 11521497

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

#	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: 1152

Subject No: 11521497

Generated By: (b) (4)

Form: RADIATION TREATMENT

Form Status: Not Started

Site Name: (1152) California Research Foundation

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:56

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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: 1152

Site Name: (1152) California Research Foundation

Subject No: 11521497

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

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

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1152

Subject No: 11521497

Generated By: (b) (4)

Form: TRANSFUSIONS

Form Status: Not Started

Site Name: (1152) California Research Foundation

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:56

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

Header Text: c4591001

Visit: End of Treatment - Unscheduled

Form: DISPOSITION - TREATMENT

Form Version: 15-Sep-2020 21:55

Form Status: Data Complete, Queries, Verified

Site No: 1152

Site Name: (1152) California Research Foundation

Subject No: 11521497

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

[eCRF Audit Trail History](#)

Disposition - Treatment

1.	Date of Completion/Discontinuation/Death :	Nov/6/2020
2.	Phase of Disposition:	VACCINATION
3.	Status:	ADVERSE EVENT
4.	Specify Status:	[]

Header Text: c4591001

Visit: Unplanned Vaccination - Unscheduled

Form: DATE OF VISIT

Form Version: 22-Apr-2020 21:02

Form Status: Not Started

Site No: 1152

Site Name: (1152) California Research Foundation

Subject No: 11521497

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

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: 1152

Site Name: (1152) California Research Foundation

Subject No: 11521497

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

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: 1152

Site Name: (1152) California Research Foundation

Subject No: 11521497

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

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?	

090177e196ae2fce\Final\Final On: 01-Apr-2021 03:52 (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: 1152

Site Name: (1152) California Research Foundation

Subject No: 11521497

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

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: 1152

Site Name: (1152) California Research Foundation

Subject No: 11521497

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

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: 1152

Site Name: (1152) California Research Foundation

Subject No: 11521497

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

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: 1152

Site Name: (1152) California Research Foundation

Subject No: 11521497

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

Informed Consent - Asymptomatic Surveillance

1.	Consent Was:	
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Header Text: c4591001

Visit: V201_SURVEIL_CONSENT -
Unscheduled

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1152

Site Name: (1152) California Research Foundation

Subject No: 11521497

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

Electronic Sample Tracking

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

Aliquot

Please enter barcode for each aliquot.

5.	Sample ID	[]
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Header Text: c4591001

Visit: V201_SURVEIL_CONSENT -
Unscheduled

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1152

Site Name: (1152) California Research Foundation

Subject No: 11521497

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

Electronic Sample Tracking

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

Aliquot

Please enter barcode for each aliquot.

5.	Sample ID	[]
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Header Text: c4591001

Visit: Follow-Up - Unscheduled

Form Version: 15-Sep-2020 21:53

Site No: 1152

Subject No: 11521497

Generated By: (b) (4)

Form: DISPOSITION - FOLLOW-UP

Form Status: Data Complete, Frozen, Verified

Site Name: (1152) California Research Foundation

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:56

[eCRF Audit Trail History](#)

Disposition - Follow-Up

1.	Date of Completion/Discontinuation/Death :	Nov/11/2020
2.	Phase of Disposition:	FOLLOW-UP
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: Not Started

Site No: 1152

Site Name: (1152) California Research Foundation

Subject No: 11521497

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

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

Header Text: c4591001

Visit: Potential ReVax Initial Contact -
Unscheduled

Form: FURTHER VACCINATION CONFIRMATION

Form Version: 10-Dec-2020 02:25

Form Status: Not Started

Site No: 1152

Site Name: (1152) California Research Foundation

Subject No: 11521497

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

Further Vaccination Confirmation

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

Header Text: c4591001

Visit: Disposition - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1152

Subject No: 11521497

Generated By: (b) (4)

Form: TREATMENT UNBLINDED

Form Status: Not Started

Site Name: (1152) California Research Foundation

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:56

Treatment Unblinded

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

Header Text: c4591001

Visit: Disposition - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1152

Subject No: 11521497

Generated By: (b) (4)

Form: WITHDRAWAL OF CONSENT

Form Status: Not Started

Site Name: (1152) California Research Foundation

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:56

Withdrawal Of Consent

1.	Withdrawal of Consent Date :	//
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090177e196ae2fce\Final\Final On: 01-Apr-2021 03:52 (GMT)

Header Text: c4591001

Visit: Disposition - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1152

Subject No: 11521497

Generated By: (b) (4)

Form: DEATH DETAILS CODED

Form Status: Data Complete, Frozen, Verified

Site Name: (1152) California Research Foundation

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:56

[eCRF Audit Trail History](#)

Death Details

1.	Date of Collection / Notification of Death:	Nov/11/2020
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Cause of Death

2.a	Cause of Death Status:	PRIMARY CAUSE OF DEATH
	Cause of Death:	[SEPSIS RELATED TO SHIGELLA INFECTION]

Header Text: c4591001

Visit: Subject Status - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1152

Subject No: 11521497

Generated By: (b) (4)

Form: SUBJECT STATUS

Form Status: Data Complete, Verified

Site Name: (1152) California Research Foundation

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:56

[eCRF Audit Trail History](#)

Subject Status

1.	Subject Status	DISCONTINUED
2.	Subject Status Date	Nov/11/2020

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: 1152

Site Name: (1152) California Research Foundation

Subject No: 11521497

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

[eCRF Audit Trail History](#)

Casebook Signature Form

1.	Casebook Signature	Click Here to Enable
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Header Text: c4591001

Visit: Investigator Signature - Unscheduled

Form: CASEBOOK SIGNATURE FORM

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Verified

Site No: 1152

Site Name: (1152) California Research Foundation

Subject No: 11521497

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

[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: 15-Sep-2020 21:53

Site No: 1152

Subject No: 11521497

Generated By: (b) (4)

Form: INCLUSION/EXCLUSION CRITERIA - Comments

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1152) California Research Foundation

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:56

[Back to Form](#)

Item	Date	User	Comment
Form	Oct-07-2020 16:41:31 (UTC-08:00) Pacific Time (US & Canada)	(b)(4),(b)(6)	Not Applicable

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 1152

Subject No: 11521497

Generated By: (b) (4)

Form: DATE OF VISIT - Comments

Form Status: Data Complete, Frozen, Verified

Site Name: (1152) California Research Foundation

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:56

[Back to Form](#)

Item	Date	User	Comment
Form	Mar-04-2021 07:51:24 (UTC-08:00) Pacific Time (US & Canada)	(b)(4),(b)(6)	SUBJECT EXPIRED. Not Done

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 1152

Subject No: 11521497

Generated By: (b) (4)

Form: DATE OF VISIT - Comments

Form Status: Data Complete, Frozen, Verified

Site Name: (1152) California Research Foundation

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:56

[Back to Form](#)

Item	Date	User	Comment
1	Mar-04-2021 07:51:24 (UTC-08:00) Pacific Time (US & Canada)	(b)(4),(b)(6)	SUBJECT EXPIRED.
			Not Done

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 1152

Subject No: 11521497

Generated By: (b) (4)

Form: DATE OF VISIT - Comments

Form Status: Data Complete, Frozen, Verified

Site Name: (1152) California Research Foundation

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:56

[Back to Form](#)

Item	Date	User	Comment
2	Mar-04-2021 07:51:24 (UTC-08:00) Pacific Time (US & Canada)	(b)(4),(b)(6)	SUBJECT EXPIRED.
			Not Done

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1152

Subject No: 11521497

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - Comments

Form Status: Data Complete, Frozen

Site Name: (1152) California Research Foundation

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:56

[Back to Form](#)

Item	Date	User	Comment
5	Nov-18-2020 11:24:09 (UTC-08:00) Pacific Time (US & Canada)	(b)(4),(b)(6)	
5	Nov-16-2020 08:50:11 (UTC-08:00) Pacific Time (US & Canada)	(b)(4),(b)(6)	Unknown

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: 1152

Site Name: (1152) California Research Foundation

Subject No: 11521497

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

[Back to Form](#)

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	Feb-15-2021 09:11:43 (UTC-08:00) Pacific Time (US & Canada)		Edit - All signatures invalidated

Affidavit:

N/A

Donald Brandon	Approved	Jan-21-2021 11:31:21 (UTC-08:00) Pacific Time (US & Canada)	BOOK	Signed
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Affidavit:

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

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

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

(b) (6)	N/A	Dec-07-2020 07:20:04 (UTC-08:00) Pacific Time (US & Canada)		Edit - All signatures invalidated
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Affidavit:

N/A

Donald Brandon	Approved	Nov-24-2020 20:19:46 (UTC-08:00) Pacific Time (US & Canada)	BOOK	Signed
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Affidavit:

By my dated signature below, I, DonaldBrandon, 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.

090177e196ae2fce\Final\Final On: 01-Apr-2021 03:52 (GMT)

Header Text: c4591001**Visit:** Investigator Signature - Unscheduled**Form:** CASEBOOK SIGNATURE FORM - Signature History**Form Version:** 22-Apr-2020 21:04**Form Status:** Data Complete, Verified**Site No:** 1152**Site Name:** (1152) California Research Foundation**Subject No:** 11521497**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 11:56

(b) (6)	N/A	Nov-18-2020 11:24:09 (UTC-08:00) Pacific Time (US & Canada)		Edit - All signatures invalidated
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Affidavit:

N/A

Donald Brandon	Approved	Nov-16-2020 12:29:18 (UTC-08:00) Pacific Time (US & Canada)	BOOK	Signed
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Affidavit:

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

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

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

(b) (6)	N/A	Nov-16-2020 05:48:23 (UTC-08:00) Pacific Time (US & Canada)		Edit - All signatures invalidated
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Affidavit:

N/A

Donald Brandon	Approved	Nov-13-2020 10:00:44 (UTC-08:00) Pacific Time (US & Canada)	BOOK	Signed
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Affidavit:

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

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

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

(b) (6)	N/A	Nov-12-2020 13:48:15 (UTC-08:00) Pacific Time (US & Canada)		Edit - All signatures invalidated
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Affidavit:

N/A

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: 1152

Site Name: (1152) California Research Foundation

Subject No: 11521497

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

Donald Brandon	Approved	Nov-10-2020 18:10:28 (UTC-08:00) Pacific Time (US & Canada)	BOOK	Signed
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Affidavit:

By my dated signature below, I, DonaldBrandon, 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.

090177e196ae2fce\Final\Final On: 01-Apr-2021 03:52 (GMT)

Header Text: c4591001

Visit: COHORT_SELECTION

Form Version: 15-Sep-2020 21:55

Site No: 1152

Subject No: 11521497

Generated By: (b) (4)

Form: COHORT_SELECTION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1152) California Research Foundation

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:56

[Back to Form](#)

1. Select appropriate response - Protocol version

Date	Location	User	Value	Reason
Oct-07-2020 16:40:31 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: 08 SEP 2020	Initial Entry

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

Date	Location	User	Value	Reason
Oct-07-2020 16:40:31 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: STAGE 3 COHORTS	Initial Entry

Header Text: c4591001

Visit: COHORT_SELECTION

Form Version: 22-Apr-2020 21:02

Site No: 1152

Subject No: 11521497

Generated By: (b) (4)

Form: MAIN INFORMED CONSENT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1152) California Research Foundation

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:56

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I. Consent Was:

Date	Location	User	Value	Reason
Oct-07-2020 16:40:42 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: OBTAINED Date Written Consent Obtained Oct/7/2020	Initial Entry

Header Text: c4591001**Visit:** COHORT_SELECTION**Form Version:** 15-Sep-2020 21:54**Site No:** 1152**Subject No:** 11521497**Generated By:** (b) (4)**Form:** DEMOGRAPHY - eCRF Audit Trail History**Form Status:** Data Complete, Locked, Frozen, Verified**Site Name:** (1152) California Research Foundation**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 11:56[Back to Form](#)**1. Subject ID**

Date	Location	User	Value	Reason
Nov-13-2020 03:21:24 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b)(6)	Query 1: Closed	Response satisfies query
Nov-12-2020 14:32:49 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Query 1: Answered	AE had been entered
Nov-09-2020 03:35:34 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b)(6)	Query 1: Opened	SAE RECON:AER#2020437859 faint(onset date:26Oct2020)was reported as serious in Safety database but missing in AE CRF. Please confirm and update CRF. If safety update is required, submit a follow-up SAE Form.
Oct-07-2020 16:40:20 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 11521497	Item copied from previous form

2. Birth Date:

Date	Location	User	Value	Reason
Oct-07-2020 16:39:24 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: (b) (6)/1948	Enrollment Entry

3. Sex:

Date	Location	User	Value	Reason
Oct-07-2020 16:40:56 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: MALE	Initial Entry

4. Ethnicity:

Date	Location	User	Value	Reason
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Header Text: c4591001

Visit: COHORT_SELECTION

Form Version: 15-Sep-2020 21:54

Site No: 1152

Subject No: 11521497

Generated By: (b) (4)

Form: DEMOGRAPHY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1152) California Research Foundation

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:56

Oct-07-2020 16:40:56 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: HISPANIC OR LATINO(A) OR OF SPANISH ORIGIN	Initial Entry
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5. Race: (Check X all that apply):

Date	Location	User	Value	Reason
Oct-07-2020 16:40:56 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: WHITE	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:02

Site No: 1152

Subject No: 11521497

Generated By: (b) (4)

Form: DATE OF VISIT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1152) California Research Foundation

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:56

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1. Date of Visit

Date	Location	User	Value	Reason
Oct-07-2020 16:41:16 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: Oct/7/2020	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 15-Sep-2020 21:52

Site No: 1152

Subject No: 11521497

Generated By: (b) (4)

Form: DISPOSITION - SCREENING - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1152) California Research Foundation

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:56

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1. Date of Completion/Discontinuation/Death

Date	Location	User	Value	Reason
Oct-07-2020 16:41:48 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: Oct/7/2020	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Oct-07-2020 16:41:48 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SCREENING	Initial Entry

3. Status:

Date	Location	User	Value	Reason
Oct-07-2020 16:41:48 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: COMPLETED	Initial Entry

090177e196ae2fce\Final\Final On: 01-Apr-2021 03:52 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1152

Subject No: 11521497

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1152) California Research Foundation

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:56

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I.a

Date	Location	User	Value	Reason
Oct-07-2020 16:42:14 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number 1 : Medical History T osteoarthritis erm: Start Date: UNK/UNK/2 010 Ongoing: YES	Initial Entry

I.a Line/MH Number:

Date	Location	User	Value	Reason
Oct-07-2020 16:42:14 (UTC-08:00) Pacific 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-07-2020 16:42:14 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: osteoarthritis	Initial Entry

I.a Start Date:

Date	Location	User	Value	Reason
Oct-07-2020 16:42:14 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: UNK/UNK/2010	Initial Entry

I.a Ongoing:

Date	Location	User	Value	Reason
Oct-07-2020 16:42:14 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: YES	Initial Entry

090177e196ae2fce\Final\Final On: 01-Apr-2021 03:52 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1152

Subject No: 11521497

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1152) California Research Foundation

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:56

I.b

Date	Location	User	Value	Reason
Oct-07-2020 16:42:45 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocale)	Data Entry: Line/MH Number: Medical History: nephrolithiasis Term: Start Date: UNK/UNK/1999 Ongoing: NO End Date: UNK/UNK/ 1999	Initial Entry

090177e196ae2fce\Final\Final On: 01-Apr-2021 03:52 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1152

Subject No: 11521497

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1152) California Research Foundation

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:56

I.b Line/MH Number:

Date	Location	User	Value	Reason
Oct-07-2020 16:42:45 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 2	Initial Entry

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

Date	Location	User	Value	Reason
Oct-07-2020 16:42:45 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: nephrolithiasis	Initial Entry

I.b Start Date:

Date	Location	User	Value	Reason
Oct-07-2020 16:42:45 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: UNK/UNK/1999	Initial Entry

I.b Ongoing:

Date	Location	User	Value	Reason
Oct-07-2020 16:42:45 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: NO End Date: UNK/UNK/1999	Initial Entry

I.c

Date	Location	User	Value	Reason
Oct-07-2020 16:43:03 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number 3 : Medical History T hypertension erm: Start Date: UNK/UNK/2 018 Ongoing: YES	Initial Entry

090177e196ae2fce\Final\Final On: 01-Apr-2021 03:52 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1152

Subject No: 11521497

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1152) California Research Foundation

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:56

I.c Line/MH Number:

Date	Location	User	Value	Reason
Oct-07-2020 16:43:03 (UTC-08:00) Pacific 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-07-2020 16:43:03 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: hypertension	Initial Entry

I.c Start Date:

Date	Location	User	Value	Reason
Oct-07-2020 16:43:03 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: UNK/UNK/2018	Initial Entry

I.c Ongoing:

Date	Location	User	Value	Reason
Oct-07-2020 16:43:03 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: YES	Initial Entry

I.d

Date	Location	User	Value	Reason
Oct-07-2020 16:43:35 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number 4 : Medical History T Type II diabet erm: es Start Date: UNK/UNK/2 010 Ongoing: YES	Initial Entry

090177e196ae2fce\Final\Final On: 01-Apr-2021 03:52 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1152

Subject No: 11521497

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1152) California Research Foundation

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:56

I.d Line/MH Number:

Date	Location	User	Value	Reason
Oct-07-2020 16:43:35 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 4	Initial Entry

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

Date	Location	User	Value	Reason
Oct-07-2020 16:43:35 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: Type II diabetes	Initial Entry

I.d Start Date:

Date	Location	User	Value	Reason
Oct-07-2020 16:43:35 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: UNK/UNK/2010	Initial Entry

I.d Ongoing:

Date	Location	User	Value	Reason
Oct-07-2020 16:43:35 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: YES	Initial Entry

I.e

Date	Location	User	Value	Reason
Oct-07-2020 16:44:26 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number 5 : Medical History T prostatism erm: Start Date: UNK/UNK/2 019 Ongoing: YES	Initial Entry

090177e196ae2fce\Final\Final On: 01-Apr-2021 03:52 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1152

Subject No: 11521497

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1152) California Research Foundation

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:56

I.e Line/MH Number:

Date	Location	User	Value	Reason
Oct-07-2020 16:44:26 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> 5	Initial Entry

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

Date	Location	User	Value	Reason
Oct-07-2020 16:44:26 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	<u>Data Entry:</u> prostatism	Initial Entry

I.e Start Date:

Date	Location	User	Value	Reason
Oct-07-2020 16:44:26 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	<u>Data Entry:</u> UNK/UNK/2019	Initial Entry

I.e Ongoing:

Date	Location	User	Value	Reason
Oct-07-2020 16:44:26 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	<u>Data Entry:</u> YES	Initial Entry

I.f

Date	Location	User	Value	Reason
Oct-07-2020 16:44:53 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> Line/MH Number 6 : Medical History T allergy to cel erm: ery Start Date: UNK/UNK/2 000 Ongoing: YES	Initial Entry

090177e196ae2fce\Final\Final On: 01-Apr-2021 03:52 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1152

Subject No: 11521497

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1152) California Research Foundation

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:56

1.f Line/MH Number:

Date	Location	User	Value	Reason
Oct-07-2020 16:44:53 (UTC-08:00) Pacific 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-07-2020 16:44:53 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: allergy to celery	Initial Entry

1.f Start Date:

Date	Location	User	Value	Reason
Oct-07-2020 16:44:53 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: UNK/UNK/2000	Initial Entry

1.f Ongoing:

Date	Location	User	Value	Reason
Oct-07-2020 16:44:53 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: YES	Initial Entry

1.g

Date	Location	User	Value	Reason
Oct-07-2020 16:45:11 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number 7 : Medical History T allergy to ma erm: ngo Start Date: UNK/UNK/2 000 Ongoing: YES	Initial Entry

090177e196ae2fce\Final\Final On: 01-Apr-2021 03:52 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1152

Subject No: 11521497

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1152) California Research Foundation

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:56

I.g Line/MH Number:

Date	Location	User	Value	Reason
Oct-07-2020 16:45:11 (UTC-08:00) Pacific 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-07-2020 16:45:11 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: allergy to mango	Initial Entry

I.g Start Date:

Date	Location	User	Value	Reason
Oct-07-2020 16:45:11 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: UNK/UNK/2000	Initial Entry

I.g Ongoing:

Date	Location	User	Value	Reason
Oct-07-2020 16:45:11 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: YES	Initial Entry

I.h

Date	Location	User	Value	Reason
Oct-07-2020 16:45:57 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: r: Medical History lithotripsy Term: Start Date: UNK/UNK/199 9	Initial Entry

090177e196ae2fce\Final\Final On: 01-Apr-2021 03:52 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1152

Subject No: 11521497

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1152) California Research Foundation

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:56

			Ongoing:	NO End Date: UNK/UNK/ 1999
--	--	--	----------	---

1.h Line/MH Number:

Date	Location	User	Value	Reason
Oct-07-2020 16:45:57 (UTC-08:00) Pacific 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-07-2020 16:45:57 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: lithotripsy	Initial Entry

1.h Start Date:

Date	Location	User	Value	Reason
Oct-07-2020 16:45:57 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: UNK/UNK/1999	Initial Entry

1.h Ongoing:

Date	Location	User	Value	Reason
Oct-07-2020 16:45:57 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: NO End Date: UNK/UNK/1999	Initial Entry

1.i

Date	Location	User	Value	Reason
Oct-08-2020 07:45:31 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number 9 :	Initial Entry

090177e196ae2fce\Final\Final On: 01-Apr-2021 03:52 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1152

Subject No: 11521497

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1152) California Research Foundation

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:56

			Medical History T hearing loss erm:	
			Start Date: UNK/UNK/2010	
			Ongoing: YES	

1.i Line/MH Number:

Date	Location	User	Value	Reason
Oct-08-2020 07:45:31 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> 9	Initial Entry

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

Date	Location	User	Value	Reason
Oct-08-2020 07:45:31 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	<u>Data Entry:</u> hearing loss	Initial Entry

1.i Start Date:

Date	Location	User	Value	Reason
Oct-08-2020 07:45:31 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	<u>Data Entry:</u> UNK/UNK/2010	Initial Entry

1.i Ongoing:

Date	Location	User	Value	Reason
Oct-08-2020 07:45:31 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	<u>Data Entry:</u> YES	Initial Entry

090177e196ae2fce\Final\Final On: 01-Apr-2021 03:52 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 15-Sep-2020 21:57

Site No: 1152

Subject No: 11521497

Generated By: (b) (4)

Form: HIV STATUS - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1152) California Research Foundation

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:56

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

Date	Location	User	Value	Reason
Oct-07-2020 16:46:31 (UTC-08:00) Pacific 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 Version: 15-Sep-2020 21:56

Site No: 1152

Subject No: 11521497

Generated By: (b) (4)

Form: VITAL SIGNS - BASELINE - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1152) California Research Foundation

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:56

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1. Date:

Date	Location	User	Value	Reason
Oct-07-2020 17:27:47 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: Oct/7/2020	Initial Entry

2. Weight:

Date	Location	User	Value	Reason
Oct-07-2020 17:27:47 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: 172.2	Initial Entry

3. Unit:

Date	Location	User	Value	Reason
Oct-07-2020 17:27:47 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: LB	Initial Entry

4. Height:

Date	Location	User	Value	Reason
Oct-07-2020 17:27:47 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: 69.5	Initial Entry

5. Unit:

Date	Location	User	Value	Reason
Oct-07-2020 17:27:47 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: in	Initial Entry

6. Body Mass Index:

Date	Location	User	Value	Reason
Oct-07-2020 17:27:47 (UTC-08:00) Pacific	ACV0PFEINFP6000	auto calc (autocale)	Data Entry: 25.1	Initial Entry

090177e196ae2fce\Final\Final On: 01-Apr-2021 03:52 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 15-Sep-2020 21:56

Site No: 1152

Subject No: 11521497

Generated By: (b) (4)

Form: VITAL SIGNS - BASELINE - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1152) California Research Foundation

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:56

Time (US & Canada)

7.a

Date	Location	User	Value	Reason
Oct-07-2020 17:27:47 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: Record Identifier: 1 : Temperature: 98.3 Temperature Unit F : Temperature Loc ORAL CAV ation:: ITY	Initial Entry

7.a Record Identifier:

Date	Location	User	Value	Reason
Oct-07-2020 17:27:47 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: 1	Initial Entry

7.a Temperature:

Date	Location	User	Value	Reason
Oct-07-2020 17:27:47 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: 98.3	Initial Entry

7.a Unit:

Date	Location	User	Value	Reason
Oct-07-2020 17:27:47 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: F	Initial Entry

7.a Temperature Location:

Date	Location	User	Value	Reason
Oct-07-2020 17:27:47 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: ORAL CAVITY	Initial Entry

090177e196ae2fce\Final\Final On: 01-Apr-2021 03:52 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1152

Subject No: 11521497

Generated By: (b) (4)

Form: RANDOMIZATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1152) California Research Foundation

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:56

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1. Randomization Date :

Date	Location	User	Value	Reason
Oct-07-2020 17:28:07 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: Oct/7/2020	Initial Entry

2. Randomization Number:

Date	Location	User	Value	Reason
Oct-07-2020 17:28:07 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: 267518	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1152

Site Name: (1152) California Research Foundation

Subject No: 11521497

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

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1. Data Origin

Date	Location	User	Value	Reason
Oct-07-2020 17:28:16 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Oct-07-2020 17:28:16 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SERUM	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Oct-07-2020 21:28:22 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Oct-07-2020 17:28:16 (UTC-08:00) Pacific 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-07-2020 17:28:16 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: YES Date of Collection: Oct/7/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Oct-07-2020 21:28:22 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: Sample ID: BPOSVN	Initial Entry

090177e196ae2fce\Final\Final On: 01-Apr-2021 03:52 (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: 1152

Site Name: (1152) California Research Foundation

Subject No: 11521497

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

5.a Sample ID

Date	Location	User	Value	Reason
Oct-07-2020 21:28:22 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	<u>Data Entry:</u> BP0SVN	Initial Entry

5.b

Date	Location	User	Value	Reason
Oct-07-2020 21:28:31 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	<u>Data Entry:</u> Sample ID: BP0SVP	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Oct-07-2020 21:28:31 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	<u>Data Entry:</u> BP0SVP	Initial Entry

5.c

Date	Location	User	Value	Reason
Oct-07-2020 21:28:42 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	<u>Data Entry:</u> Sample ID: BNT3DN	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Oct-07-2020 21:28:42 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	<u>Data Entry:</u> BNT3DN	Initial Entry

090177e196ae2fce\Final\Final On: 01-Apr-2021 03:52 (GMT)

Header Text: c4591001**Visit:** V1_DAY1_VAX1_L**Form Version:** 22-Apr-2020 21:03**Site No:** 1152**Subject No:** 11521497**Generated By:** (b) (4)**Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB - eCRF
Audit Trail History**Form Status:** Data Complete, Locked, Frozen, Verified**Site Name:** (1152) California Research Foundation**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 11:56[Back to Form](#)**1. Data Origin**

Date	Location	User	Value	Reason
Oct-07-2020 17:28:27 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Oct-07-2020 17:28:27 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: NASAL_SWAB	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Oct-07-2020 21:28:57 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Oct-07-2020 17:28:27 (UTC-08:00) Pacific 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-07-2020 17:28:27 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: YES Date of Collection: Oct/7/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Oct-07-2020 21:28:57 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: Sample ID: BPOS LR	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1152

Site Name: (1152) California Research Foundation

Subject No: 11521497

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

5.a Sample ID

Date	Location	User	Value	Reason
Oct-07-2020 21:28:57 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: BPOSLR	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:04

Site No: 1152

Subject No: 11521497

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1152) California Research Foundation

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:56

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1. Was there a temporary delay of vaccination?

Date	Location	User	Value	Reason
Oct-07-2020 17:28:52 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: NO	Initial Entry

2. Treatment Name

Date	Location	User	Value	Reason
Oct-07-2020 17:28:52 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: BLINDED THERAPY	Initial Entry

3. Formulation:

Date	Location	User	Value	Reason
Oct-07-2020 17:28:52 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INJECTION	Initial Entry

4. Dose Date Time:

Date	Location	User	Value	Reason
Oct-07-2020 17:28:52 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: Oct/7/2020 12:52	Initial Entry

5. Anatomical Location:

Date	Location	User	Value	Reason
Oct-07-2020 17:28:52 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: DELTOID MUSCLE	Initial Entry

6. Body Side:

Date	Location	User	Value	Reason
Oct-07-2020 17:28:52 (UTC-08:00) Pacific	ACV0PFEINFP6000	(b) (6)	Data Entry: LEFT	Initial Entry

090177e196ae2fce\Final\Final On: 01-Apr-2021 03:52 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:04

Site No: 1152

Subject No: 11521497

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1152) California Research Foundation

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:56

Time (US & Canada)

(b) (4)

7. Route:

Date	Location	User	Value	Reason
Oct-07-2020 17:28:52 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INTRAMUSCULAR	Initial Entry

10. Timeframe Subject Was Observed

Date	Location	User	Value	Reason
Oct-07-2020 17:28:52 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: THE PROTOCOL SPECIFIED O BSERVATION 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-07-2020 17:28:52 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: YES	Initial Entry

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Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 06-Jul-2020 21:53

Site No: 1152

Subject No: 11521497

Generated By: (b) (4)

Form: REACTOGENICITY DIARY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1152) California Research Foundation

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:56

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1. Select appropriate response - Reactogenicity diary collection

Date	Location	User	Value	Reason
Oct-07-2020 17:29:02 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: NO - REACTOGENICITY E-DI ARY NOT COLLECTED FOR T HIS SUBJECT	Initial Entry

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 1152

Subject No: 11521497

Generated By: (b) (4)

Form: DATE OF VISIT - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1152) California Research Foundation

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:56

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1. Date of Visit

Date	Location	User	Value	Reason
Mar-04-2021 07:51:24 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: Not Done	Initial Entry

2. Erroneous Visit

Date	Location	User	Value	Reason
Mar-04-2021 07:51:24 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: Not Done	Initial Entry

090177e196ae2fce\Final\Final On: 01-Apr-2021 03:52 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1152

Subject No: 11521497

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - Audit Trail

Form Status:

Site Name: (1152) California Research Foundation

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:56

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Date	Location	User	Value	Reason
Nov-12-2020 13:48:15 (UTC-08:00) Pacific 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: 1152

Subject No: 11521497

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - Audit Trail

Form Status:

Site Name: (1152) California Research Foundation

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:56

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

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Date	Location	User	Value	Reason
Jan-08-2021 05:43:05 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Form Deleted	Duplicate, per query.
Dec-29-2020 11:36:45 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Form Created	

090177e196ae2fce\Final\Final On: 01-Apr-2021 03:52 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1152

Subject No: 11521497

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - Audit Trail

Form Status:

Site Name: (1152) California Research Foundation

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:56

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Date	Location	User	Value	Reason
Dec-29-2020 11:39:15 (UTC-08:00) Pacific 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: 1152

Subject No: 11521497

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Frozen

Site Name: (1152) California Research Foundation

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:56

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1. Category:

Date	Location	User	Value	Reason
Nov-12-2020 13:48:15 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: ADVERSE EVENT	Initial Entry

2. AE ID:

Date	Location	User	Value	Reason
Nov-12-2020 13:48:15 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 1	Initial Entry

3. Adverse Event:

(If possible specify diagnosis, not individual symptoms)

Date	Location	User	Value	Reason
Jan-19-2021 05:19:49 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b)(6)	Query 2: Closed	Response satisfies query
Jan-18-2021 15:17:52 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Query 2: Answered	Answer remains the same. Records do not indicate a specific reason for the vasovagal syncope.
Jan-15-2021 05:17:49 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b)(6)	Query 2: Reissued:Opened	clinical: query was to confirm dx was vasovagal syncope rather than a hypotensive event due to sepsis. Thanks
Jan-15-2021 04:42:13 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Query 2: Answered	Correct as far as we can tell. Not sure why this is queried.
Jan-13-2021 07:22:25 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b)(6)	Query 2: Opened	clinical: pls confirm AE term is correct since causality is

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				listed as sepsis. Thanks
Nov-16-2020 08:48:00 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: vasovagal syncope	Changed Information
Nov-14-2020 12:54:23 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Giselle Castillo (b) (4)	Query 1: Closed	Appreciate the prompt response. Thank you.
Nov-13-2020 16:06:10 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Query 1: Answered	No other information is available at this time. We will continue to diligently attempt to get more information and provide it to you as we get it.
Nov-13-2020 11:14:56 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Giselle Castillo (b) (4)	Query 1: Opened	Per case narrative, the subject was in the intensive care unit (ICU). However, cause of hospitalization was unknown. Please provide, with a FU report, final diagnosis and discharge summary if available. Thank you
Nov-12-2020 13:48:15 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b) (6)	Data Entry: Fainting	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason
Nov-12-2020 13:48:15 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b) (6)	Data Entry: Oct/26/2020 UNK:UNK	Initial Entry

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5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Nov-18-2020 11:24:38 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: NO End Date Time: Oct/26/2020 UNK:UNK	Initial Entry
Nov-18-2020 11:24:09 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry:	Initial Entry
Nov-16-2020 08:50:11 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: Unknown	Initial Entry
Nov-16-2020 08:49:58 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry:	Changed Information
Nov-12-2020 13:48:15 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b) (6)	Data Entry: YES	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
Jan-11-2021 17:08:05 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Quan Jason Gong (b) (4)	Query 1: Closed	Response satisfies query
Jan-11-2021 15:23:39 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Transcription Error
Jan-11-2021 15:23:39 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: 3	Transcription Error
Jan-11-2021 06:15:17 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Quan Jason Gong (b) (4)	Query 1: Opened	GPDClin: Please clarify the grade. If G4 life-threatening, it met SAE criteria and SAE for this term should be reported. If not

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				considered a SAE, a lower grade, e.g., G3, should be assigned.
Nov-18-2020 11:24:55 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: 4	Changed Information
Nov-12-2020 13:48:15 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b) (6)	Data Entry: 3	Initial Entry

7. Is the adverse event serious?

If Yes, NOTIFY PFIZER IMMEDIATELY.

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

Date	Location	User	Value	Reason
Jan-10-2021 23:28:37 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 5: Deleted	Close Auto Query
Jan-10-2021 23:00:41 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b)(6)	Query 3: Closed	Response satisfies query
Jan-08-2021 05:45:16 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 4: Closed	Close Auto Query
Jan-08-2021 05:44:35 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 5: Candidate	For AE vasovagal syncope: Response to "Is the adverse event serious?" is 'No' but "Serious Adverse Event Number" is present.
Jan-08-2021 05:44:35 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 4: Opened	For AE vasovagal syncope: Response to "Is the adverse event serious?" is "No" but "What was the outcome of this adverse event?" is 'Fatal'.

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Jan-08-2021 05:44:35 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 3: Answered	This was a symptom of the actual SAE, per PI.
Jan-08-2021 05:44:35 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: NO	This was a symptom of the actual SAE, per PI.
Jan-08-2021 03:46:32 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b)(6)	Query 3: Reissued:Opened	SAE RECON: Form is not frozen. please updated accordingly
Jan-05-2021 13:42:51 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Query 3: Answered	PI says this was due to the shigellosis and thus not an SAE in itself. Please unfreeze this line and I will make the change. Thank you.
Jan-05-2021 05:27:12 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b)(6)	Query 3: Reissued:Opened	SAE RECON 1: Please submit a follow up AEM form to clarify with Pfizer Safety that VASOVAGAL SYNCOPE is still a valid SAE.
Jan-04-2021 07:51:03 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Query 3: Answered	This was the reason the subject was hospitalized. Doesn't that make it an SAE?
Jan-04-2021 02:42:00 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b)(6)	Query 3: Opened	SAE RECON: AER#2020437859,vasovagal syncope event is no longer listed in Safety database but recorded as serious in AE CRF.Please confirm event seriousness.If event is not serious, please downgrade in AE CRF.
Nov-18-2020 11:25:34 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: YES Is this serious event asso ciated with congenital an omaly or birth defect? NO	New Information

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			<p>Did this serious event result in death?</p> <p>YES</p> <p>Did this serious event require or prolong hospitalization?</p> <p>YES</p> <p>Did this serious event result in persistent or significant disability/incapacity?</p> <p>NO</p> <p>Is this serious event life threatening?</p> <p>YES</p> <p>Other medically important serious event</p> <p>NO</p>	
Nov-13-2020 03:22:58 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Nov-12-2020 13:49:00 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Closed	Close Auto Query
Nov-12-2020 13:49:00 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b)(6)	Data Entry: YES Is this serious event associated with congenital anomaly or birth defect? NO	New Information

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			<p>Did this serious event result in death?</p> <p>NO</p> <p>Did this serious event require or prolong hospitalization?</p> <p>YES</p> <p>Did this serious event result in persistent or significant disability/incapacity?</p> <p>NO</p> <p>Is this serious event life threatening?</p> <p>YES</p> <p>Other medically important serious event</p> <p>NO</p>	
Nov-12-2020 13:48:15 (UTC-08:00) Pacific 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-12-2020 13:48:15 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	For AE Fainting: Response to "Is the adverse event serious?" is 'Yes' but "Serious Adverse Event Number" is blank.
Nov-12-2020 13:48:15 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b)(6)	Data Entry: YES	Initial Entry
			Is this serious event associated with congenital anomaly or birth defect?	

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			NO	
			Did this serious event result in death?	
			NO	
			Did this serious event require or prolong hospitalization?	
			YES	
			Is this serious event life threatening?	
			YES	
			Other medically important serious event	
			NO	

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

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

Date	Location	User	Value	Reason
Nov-12-2020 13:48:15 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b)(6)	Data Entry: NO	Initial Entry

9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Jan-11-2021 17:08:37 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Quan Jason Gong (b) (4)	Query 1: Closed	Response satisfies query
Jan-11-2021 15:26:43 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Changed Information
Jan-11-2021 15:26:43 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: NOT RELATED If Not Related to study treatment(s), this event is due to:	Changed Information

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			OTHER <i>If Other, specify:</i> sepsis related to shigella i nfection	
Jan-11-2021 06:18:25 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Quan Jason Gong (b) (4)	Query 1: Opened	GPDClin: Please clarify if this was related to the SAE of Sepsis, e.g., a symptom of it. If yes, please make the corresponding change.
Nov-12-2020 13:48:15 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b) (6)	Data Entry: NOT RELATED If Not Related to study treatme nt(s), this event is due to: OTHER <i>If Other, specify:</i> Unknown	Initial Entry

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Dec-09-2020 02:28:50 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b)(6)	Query 1: Closed	Response satisfies query

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10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Dec-07-2020 07:20:04 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Subject expired, so second vaccination is Not Applicable.
Dec-07-2020 07:20:04 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: NOT APPLICABLE	Subject expired, so second vaccination is Not Applicable.
Dec-07-2020 02:50:43 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b)(6)	Query 1: Reissued:Op ened	form is unfrozen. if correct action taken is not applicable. please update accordingly.
Dec-04-2020 06:31:00 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Query 1: Answered	I am unable to change this to match the safety database because this page is frozen.
Dec-04-2020 04:29:37 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b)(6)	Query 1: Opened	SAE RECON:AER#2020437859,action taken was updated to DRUG WITHDRAWN in AE CRF while NOT APPLICABLE in Safety database.Please confirm correct action taken. If safety update is required, please submit a follow up form
Nov-16-2020 09:04:04 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: DRUG WITHDRAW N	Subject will receive no more study vaccine.
Nov-12-2020 13:48:15 (UTC-08:00) Pacific	ACV0PFEINFP6000	(b)(4),(b) (6)	Data Entry: NOT APPLICABLE	Initial Entry

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11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
Jan-11-2021 17:08:55 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Quan Jason Gong (b) (4)	Query 1: Closed	Response satisfies query
Jan-11-2021 15:27:12 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Changed Information
Jan-11-2021 15:27:12 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: NO	Changed Information
Jan-11-2021 06:21:23 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Quan Jason Gong (b) (4)	Query 1: Opened	GPDClin: Please clarify what medication was given for this AE?
Nov-12-2020 13:48:15 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b)(6)	Data Entry: YES	Initial Entry

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Jan-11-2021 17:09:10 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Quan Jason Gong (b) (4)	Query 1: Closed	Response satisfies query
Jan-11-2021 15:27:32 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Changed Information
Jan-11-2021 15:27:32 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: NO	Changed Information
Jan-11-2021 06:19:28 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Quan Jason Gong (b) (4)	Query 1: Opened	GPDClin: Please clarify what non-drug treatment was given for this

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				AE.
Nov-12-2020 13:48:15 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b)(6)	Data Entry: YES	Initial Entry

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

Date	Location	User	Value	Reason
Jan-08-2021 05:45:16 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b)(6)	Data Entry: RECOVERED/RE SOLVED	Changed Information
Nov-24-2020 06:41:05 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Giselle Castillo (b) (4)	Query 6: Closed	Thank you.
Nov-23-2020 07:22:18 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b)(6)	Query 6: Answered	We have already submitted all the information we have. We do not have access to records. We do not know reason for ICU admission, or even if ICU admission actually occurred. The subject died in the hospital.
Nov-20-2020 14:59:10 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Giselle Castillo (b) (4)	Query 6: Reissued: Opened	Kindly provide information on hospital course, including work-up, imaging, and treatment received in a FU report. Please clarify reason for ICU admission and if the subject died during hospitalization. Thank you
Nov-19-2020 15:08:09 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b)(6)	Query 6: Answered	We don't have those either. We will submit the information when are able to obtain it. It will likely be at least 8 weeks.
Nov-19-2020 15:00:54 (UTC-08:00) Pacific Time (US	ACV0PFEINFP6000	Giselle Castillo (b) (4)	Query 6: Opened	Death event has been recorded on CRF. However, we do not have the cause of death or a death certificate. Kindly submit a FU report with this

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& Canada)				information. Thank you.
Nov-18-2020 11:26:58 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 5: Closed	Close Auto Query
Nov-18-2020 11:25:59 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 5: 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-18-2020 11:25:59 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 4: Closed	Close Auto Query
Nov-18-2020 11:25:59 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b)(6)	Data Entry: FATAL	New Information
Nov-18-2020 11:24:38 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 4: Opened	For AE vasovagal syncope: Response to "What was the outcome of this adverse event?" is 'Unknown' but End Date/Time is provided or "Is the adverse event still ongoing?" is marked "Yes".
Nov-16-2020 12:33:25 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Query 2: Closed	Response satisfies query
Nov-16-2020 08:49:58 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 3: Closed	Close Auto Query
Nov-16-2020 08:48:00	ACV0PFEINFP6000	auto query (autoquery)	Query 3: Opened	For AE vasovagal syncope: Response to "What was the outcome

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(UTC-08:00) Pacific Time (US & Canada)				of this adverse event?" is 'Unknown' but End Date/Time is provided or "Is the adverse event still ongoing?" is marked "Yes".
Nov-16-2020 06:00:11 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b)(6)	Query 1: Closed	Response satisfies query
Nov-16-2020 05:51:12 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b)(6)	Query 2: Answered	Well, the answer certainly cannot be "No", so it HAS to be "Yes". Unknown is not a choice in that field.
Nov-16-2020 05:48:23 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Opened	For AE Fainting: Response to "What was the outcome of this adverse event?" is 'Unknown' but End Date/Time is provided or "Is the adverse event still ongoing?" is marked "Yes".
Nov-16-2020 05:48:23 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Changed Information
Nov-16-2020 05:48:23 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b)(6)	Data Entry: UNKNOWN	Changed Information
Nov-14-2020 05:52:13 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b)(6)	Query 1: Opened	SAE RECON:AER#2020437859,outcome was reported as UNKNOWN to Safety DB however, recorded as NOT RECOVERED/NOT RESOLVED on AE CRF. Please confirm correct outcome. If safety update is required, please submit a follow-up form.
Nov-12-2020 13:48:15	ACV0PFEINFP6000	(b) (6)	Data Entry: NOT RECOVERE	Initial Entry

090177e196ae2fce\Final\Final On: 01-Apr-2021 03:52 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen

Site No: 1152

Site Name: (1152) California Research Foundation

Subject No: 11521497

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

(UTC-08:00) Pacific Time (US & Canada)		(b) (4)	D/NOT RESOLVE D
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14. Did the adverse event cause the subject to be discontinued from the study?

Date	Location	User	Value	Reason
Dec-02-2020 04:38:15 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Hayley Wyper (b) (4)	Query 1: Deleted	hold - review cause of death and AE entries
Dec-02-2020 04:29:42 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Hayley Wyper (b) (4)	Query 1: Candidate	CLINQUERY: Field indicates the fatal event of vasovagal syncope 26Oct20 was not the cause of study end. However, FUP tab indicates death as reason for end of study, dated 11Nov20. Please review if this field should be updated to match FUP; clarify dates
Nov-12-2020 13:48:15 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: NO	Initial Entry

15. Serious Adverse Event Number: For Pfizer Use Only

Date	Location	User	Value	Reason
Jan-10-2021 23:28:37 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b)(6)	Data Entry:	downgraded to non serious
Nov-13-2020 03:22:58 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b)(6)	Data Entry: 2020437859	Initial Entry

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Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Deleted

Site No: 1152

Site Name: (1152) California Research Foundation

Subject No: 11521497

Subject Initials: ---

Generated By: (b) (4)

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

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1. Category:

Date	Location	User	Value	Reason
Dec-29-2020 11:36:45 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: ADVERSE EVENT	Initial Entry

2. AE ID:

Date	Location	User	Value	Reason
Dec-29-2020 11:36:45 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 2	Initial Entry

3. Adverse Event:

(If possible specify diagnosis, not individual symptoms)

Date	Location	User	Value	Reason
Jan-10-2021 23:04:26 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b)(6)	Query 1: Closed	event inactivated in Inform
Jan-08-2021 05:42:25 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Query 1: Answered	OK.
Jan-08-2021 01:12:15 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b)(6)	Query 1: Opened	SAE RECON:AER#2020437859, Shigellosis was recorded as a separate event. Please confirm if this is a singular event of shigella sepsis and AE#2 is duplicate of adverse event 3.
Dec-29-2020 11:36:45 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: Shigellosis	Initial Entry

4. Start Date Time:

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Site No: 1152

Subject No: 11521497

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

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

Date	Location	User	Value	Reason
Dec-29-2020 11:36:45 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: Oct/26/2020 UNK:UNK	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Dec-29-2020 11:36:45 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: NO End Date Time: Nov/11/2020 UNK:UNK	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
Dec-29-2020 11:36:45 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: 4	Initial Entry

7. Is the adverse event serious?

If Yes, NOTIFY PFIZER IMMEDIATELY.

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

Date	Location	User	Value	Reason
Jan-04-2021 00:58:43 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b)(6)	Query 2: Closed	Response satisfies query
Jan-02-2021 03:09:38 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b)(6)	Query 2: Opened	SAE RECON:Shigellosis(Onset date:26Oct2020) is not reported to Safety database but marked serious on AE CRF. Confirm seriousness and report to Pfizer

Header Text: c4591001

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Form Version: 22-Apr-2020 21:02

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Subject No: 11521497

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Deleted

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

				immediately. If this event is not serious, downgrade the event on AE CRF
Jan-02-2021 03:08:03 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b)(6)	Query 1: Deleted	Query can be addressed internally
Dec-29-2020 11:36:45 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	For AE Shigellosis: Response to "Is the adverse event serious?" is 'Yes' but "Serious Adverse Event Number" is blank.
Dec-29-2020 11:36:45 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: YES Is this serious event associ- ated with congenital anom- aly or birth defect? NO Did this serious event resul- t in death? YES Did this serious event requ- ire or prolong hospitalizati- on? YES Did this serious event resul- t in persistent or significan- t disability/incapacity? NO Is this serious event life thr- eatening? YES Other medically important serious event	Initial Entry

090177e196ae2fce\Final\Final On: 01-Apr-2021 03:52 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

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Site Name: (1152) California Research Foundation

Subject No: 11521497

Subject Initials: ---

Generated By: (b) (4)

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

			NO	
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8. Is this adverse event the result of a study Medication Error?

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

Date	Location	User	Value	Reason
Dec-29-2020 11:36:45 (UTC-08:00) Pacific 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
Dec-29-2020 11:36:45 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: NOT RELATED If Not Related to study treatment(s), this event is due to: OTHER If Other, specify: Shigella infection	Initial Entry

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Dec-29-2020 11:36:45 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: NOT APPLICABLE	Initial Entry

11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
Dec-29-2020 11:36:45 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: YES	Initial Entry

12. Was a Non-Drug Treatment given?

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

Dec-29-2020 11:36:45 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: NO	Initial Entry
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13. What was the outcome of this adverse event?:

Date	Location	User	Value	Reason
Dec-29-2020 11:36:45 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: FATAL	Initial Entry

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

Date	Location	User	Value	Reason
Dec-29-2020 11:44:00 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: NO	I know this will be queried, even though this IS a reason the subject discontinued from the study . . .
Dec-29-2020 11:36:45 (UTC-08:00) Pacific 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
Jan-04-2021 00:58:12 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b)(6)	Data Entry: 2020437859	Initial Entry

090177e196ae2fce\Final\Final On: 01-Apr-2021 03:52 (GMT)

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Subject Initials: ---

Generated By: (b) (4)

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1. Category:

Date	Location	User	Value	Reason
Dec-29-2020 11:39:15 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: ADVERSE EVENT	Initial Entry

2. AE ID:

Date	Location	User	Value	Reason
Dec-29-2020 11:39:15 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 3	Initial Entry

3. Adverse Event:

(If possible specify diagnosis, not individual symptoms)

Date	Location	User	Value	Reason
Dec-29-2020 11:39:15 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: sepsis related to Shigella infectio n	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason
Dec-29-2020 11:39:15 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: Oct/26/2020 UNK:UNK	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Feb-16-2021 15:11:06 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b)(6)	Query 1: Closed	Response satisfies query
Feb-15-2021 09:11:43 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	OK
Feb-15-2021 09:11:43	ACV0PFEINFP6000	(b) (6)	Data Entry:	OK

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(UTC-08:00) Pacific Time (US & Canada)		(b) (4)	NO End Date Time: Nov/11/2020 UNK:UNK	
Feb-15-2021 01:33:07 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b)(6)	Query 1: Opened	CLINQUERY: please clarify if the stop date for sepsis related to Shigella infection should be reported as 11Nov2020 for consistency with the date of death.
Feb-12-2021 13:28:54 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b)(6)	Query 1: Candidate	CLINQUERY: please clarify if the stop date for sepsis related to Shigella infection should be reported as 11Nov2020 for consistency with the date of death.
Dec-29-2020 11:39:15 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b)(6)	Data Entry: NO End Date Time: Nov/10/2020 UNK:UNK	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
Dec-29-2020 11:39:33 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: 4	Initial Entry

7. Is the adverse event serious?

If Yes, NOTIFY PFIZER IMMEDIATELY.

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

Date	Location	User	Value	Reason
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Header Text: c4591001

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Jan-04-2021 01:06:46 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b)(6)	Query 2: Closed	event entered in SDB
Jan-02-2021 03:11:52 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b)(6)	Query 2: Opened	SAE RECON:sepsis related to Shigella infection(Onset date:26Oct2020) is not reported to Safety database but marked serious on AE CRF. Confirm seriousness and report to Pfizer immediately. If this event is not serious, downgrade the event on AE CRF
Jan-02-2021 03:10:07 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b)(6)	Query 1: Deleted	Query can be addressed internally
Dec-29-2020 11:39:15 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	For AE sepsis related to Shigella infection: Response to "Is the adverse event serious?" is 'Yes' but "Serious Adverse Event Number" is blank.
Dec-29-2020 11:39:15 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: YES Is this serious event associated with congenital anomaly or bir th defect? NO Did this serious event result in death? YES Did this serious event require or prolong hospitalization?	Initial Entry

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			<p>YES</p> <p>Did this serious event result in persistent or significant disability/incapacity?</p> <p>NO</p> <p>Is this serious event life threatening?</p> <p>YES</p> <p>Other medically important serious event</p> <p>NO</p>	
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8. Is this adverse event the result of a study Medication Error?

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

Date	Location	User	Value	Reason
Dec-29-2020 11:39:15 (UTC-08:00) Pacific 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
Dec-29-2020 11:39:15 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: NOT RELATED If Not Related to study treatment(s), this event is due to: OTHER <i>If Other, specify:</i> Shigella infection	Initial Entry

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
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Header Text: c4591001**Visit:** Logs - Unscheduled**Form Version:** 22-Apr-2020 21:02**Site No:** 1152**Subject No:** 11521497**Generated By:** (b) (4)**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History**Form Status:** Data Complete, Frozen**Site Name:** (1152) California Research Foundation**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 11:56

Mar-08-2021 12:27:27 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Hayley Wyper (b) (4)	Query 1: Closed	AE entry confirmed correct by site; EOT change to be reviewed
Mar-08-2021 08:57:27 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Query 1: Answered	I WOULD CHANGE THAT DATE, BUT THE PAGE IS FROZEN AND LOCKED.
Feb-25-2021 02:32:14 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b)(6)	Query 1: Opened	CLINQUERY: EOT page reports treatment was discontinued on 06Nov20 prior to death on 11Nov20. Please review if this data is correct. If so, please then review in connection with the AE, and review if drug was withdrawn as reported
Feb-23-2021 04:10:22 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Hayley Wyper (b) (4)	Query 1: Candidate	CLINQUERY: EOT page reports treatment was discontinued on 06Nov20 prior to death on 11Nov20. Please review if this data is correct. If so, please then review in connection with the AE, and review if drug was withdrawn as reported
Dec-29-2020 11:39:15 (UTC-08:00) Pacific 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
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Header Text: c4591001

Visit: Logs - Unscheduled

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Dec-29-2020 11:39:15 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: YES	Initial Entry
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12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Dec-29-2020 11:39:15 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: YES	Initial Entry

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

Date	Location	User	Value	Reason
Dec-29-2020 11:39:15 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: FATAL	Initial Entry

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

Date	Location	User	Value	Reason
Dec-29-2020 22:04:30 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Query 1: Closed	Response satisfies query
Dec-29-2020 11:42:49 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b)(6)	Query 1: Answered	OK. They both did . ..
Dec-29-2020 11:39:15 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	More than 1 AE for this patient has "Did the adverse event cause the subject to be discontinued from the study?" marked as 'Yes'.
Dec-29-2020 11:39:15 (UTC-08:00) Pacific 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
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Visit: Logs - Unscheduled

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Generated By: (b) (4)

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Subject Initials: ---

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Jan-04-2021 01:02:59 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b)(6)	Data Entry: 2020437859	Initial Entry
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090177e196ae2fce\Final\Final On: 01-Apr-2021 03:52 (GMT)

Header Text: c4591001

Visit: End of Treatment - Unscheduled

Form Version: 15-Sep-2020 21:55

Site No: 1152

Subject No: 11521497

Generated By: (b) (4)

Form: DISPOSITION - TREATMENT - eCRF Audit Trail History

Form Status: Data Complete, Queries, Verified

Site Name: (1152) California Research Foundation

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:56

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1. Date of Completion/Discontinuation/Death :

Date	Location	User	Value	Reason
Mar-11-2021 05:02:14 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Hayley Wyper (b) (4)	Query 1: Opened	CLINQUERY: Per query response on AE data, request was made to unfreeze EOT page for update. Please review as needed
Nov-16-2020 09:05:04 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: Nov/6/2020	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Nov-16-2020 09:05:04 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: VACCINATION	Initial Entry

3. Status:

Date	Location	User	Value	Reason
Nov-16-2020 18:11:14 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b)(6)	Query 1: Closed	Response satisfies query
Nov-16-2020 16:32:05 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b)(6)	Query 1: Answered	Not so. Please review.
Nov-16-2020 12:24:50 (UTC-08:00) Pacific Time	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (b) (4)	Query 1: Opened	DMW5388814;Status is reported as Adverse Event, but there is no Adverse

090177e196ae2fce\Final\Final On: 01-Apr-2021 03:52 (GMT)

Header Text: c4591001

Visit: End of Treatment - Unscheduled

Form Version: 15-Sep-2020 21:55

Site No: 1152

Subject No: 11521497

Generated By: (b) (4)

Form: DISPOSITION - TREATMENT - eCRF Audit Trail History

Form Status: Data Complete, Queries, Verified

Site Name: (1152) California Research Foundation

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:56

(US & Canada)				Event with 'Latest Action Taken with Study Treatment' reported as DRUG WITHDRAWN. Please review and update as appropriate.
Nov-16-2020 09:05:04 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b)(6)	Data Entry : ADV ERSE EVE NT	Initial Entry

090177e196ae2fce\Final\Final On: 01-Apr-2021 03:52 (GMT)

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: 1152

Site Name: (1152) California Research Foundation

Subject No: 11521497

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

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1. Date of Completion/Discontinuation/Death :

Date	Location	User	Value	Reason
Nov-18-2020 11:26:32 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: Nov/11/2020	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Nov-18-2020 11:26:32 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: FOLLOW-UP	Initial Entry

3. Status:

Date	Location	User	Value	Reason
Nov-18-2020 11:26:58 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Nov-18-2020 11:26:32 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	'Response to 'Status' is 'Death' on Disposition- Folow up, but 'Death' CRF is not yet initiated. Please review and update as appropriate.
Nov-18-2020 11:26:32 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: DEATH	Initial Entry

090177e196ae2fce\Final\Final On: 01-Apr-2021 03:52 (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: 1152

Site Name: (1152) California Research Foundation

Subject No: 11521497

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

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1. Date of Collection / Notification of Death:

Date	Location	User	Value	Reason
Nov-18-2020 11:26:58 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: Nov/11/2020	Initial Entry

2.a

Date	Location	User	Value	Reason
Feb-15-2021 09:12:55 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: Cause of Death Status: PRIMARY CAUSE OF DEATH Cause of Death: SEPSIS RELATED TO SHIGELLA INFECTION	YES, THANK YOU.
Nov-18-2020 16:03:43 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: Cause of Death Status: PRIMARY CAUSE OF DEATH Cause of Death: Unknown diagnosis.	Changed Information
Nov-18-2020 11:27:20 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: Cause of Death Status: PRIMARY CAUSE OF DEATH Cause of Death: Unknown at this time.	Initial Entry

2.a Cause of Death Status:

Date	Location	User	Value	Reason
Feb-23-2021 08:38:35 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Giselle Castillo (b) (4)	Query 1: Closed	Response satisfies query
Feb-23-2021 02:56:49 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b)(6)	Query 1: Answered	Subject died while in ICU

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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: 1152

Site Name: (1152) California Research Foundation

Subject No: 11521497

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

Feb-22-2021 15:03:38 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Giselle Castillo (b) (4)	Query 1: Opened	Medical Monitor_ Pls advice if the subject was discharged from hospital prior death or died while in ICU? Thanks
Nov-18-2020 11:27:20 (UTC-08:00) Pacific 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
Feb-16-2021 15:09:18 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b)(6)	Query 2: Clo sed	Response satisfies query
Feb-15-2021 09:12:55 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Ans wered	YES, THANK YOU.
Feb-15-2021 09:12:55 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b)(6)	Data Entry: SEPSIS REL ATED TO S HIGELLA I NFECTION	YES, THANK YOU.
Feb-12-2021 13:34:48 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b)(6)	Query 2: Ope ned	CLINQUERY: please clarify if the cause of death should be updated to sepsis related to Shigella infection to align with the AE reported as fatal.
Nov-18-2020 18:38:19 (UTC-08:00) Pacific Time	ACV0PFEINFP6000.InFormAdapter.Discrepancy	PFETMS Oracle (b) (4)	Query 1: Clo sed	Discrepancy has been closed.

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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: 1152

Site Name: (1152) California Research Foundation

Subject No: 11521497

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

(US & Canada)				
Nov-18-2020 16:03:43 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Ans wered	Changed Information
Nov-18-2020 16:03:43 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b)(6)	Data Entry: Unknown dia gnosis.	Changed Information
Nov-18-2020 14:41:04 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	PFETMS Oracle (b) (4)	Query 1: Ope ned	Clarify UNKNOWN AT THIS TIME. as follow...Term appears incomplete. Are you reporting UNKNOWN DIAGNOSIS? UNKNOWN DIAGNOSTIC PROCEDURE? UNKNOWN THERAPEUTIC PROCEDURE? Please edit and clarify further. Thank you.
Nov-18-2020 11:27:20 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b)(6)	Data Entry: Unknown at t his time.	Initial Entry

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Header Text: c4591001**Visit:** Subject Status - Unscheduled**Form Version:** 22-Apr-2020 21:03**Site No:** 1152**Subject No:** 11521497**Generated By:** (b) (4)**Form:** SUBJECT STATUS - eCRF Audit Trail History**Form Status:** Data Complete, Verified**Site Name:** (1152) California Research Foundation**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 11:56[Back to Form](#)***1. Subject Status***

Date	Location	User	Value	Reason
Mar-04-2021 13:04:43 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Rivkah Rosen (b) (4)	Query 1: Closed	Response satisfies query
Mar-04-2021 07:52:05 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b)(6)	Query 1: Answered	OK. AS YOU CAN TELL, SUBJECT IS DECEASED.
Mar-02-2021 02:47:23 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b)(6)	Query 1: Opened	DM: Visit 2 is overdue based on expected visit window. If visit 2 will never occur, please mark Date of Visit as 'Not Done' with form level comment.
Nov-18-2020 11:26:32 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: DISCONTINUED	Initial Entry
Nov-16-2020 09:05:04 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: DISCONTINUED	Initial Entry
Oct-07-2020 17:28:07 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: ENROLLED/RANDOMIZED	Initial Entry
Oct-07-2020 16:41:48 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SCREENED	Initial Entry

2. Subject Status Date

Date	Location	User	Value	Reason
Nov-18-2020 11:26:32 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Nov/11/2020	Initial Entry

Header Text: c4591001

Visit: Subject Status - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1152

Subject No: 11521497

Generated By: (b) (4)

Form: SUBJECT STATUS - eCRF Audit Trail History

Form Status: Data Complete, Verified

Site Name: (1152) California Research Foundation

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:56

Nov-16-2020 09:05:04 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Nov/6/2020	Initial Entry
Oct-07-2020 17:28:07 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Oct/7/2020	Initial Entry
Oct-07-2020 16:41:48 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Oct/7/2020	Initial Entry

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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: 1152

Site Name: (1152) California Research Foundation

Subject No: 11521497

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

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I. Casebook Signature

Date	Location	User	Value	Reason
Nov-10-2020 13:18:59 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: Click Here to Enable	Initial Entry