

Header Text: c4591001

Visit: COHORT_SELECTION

Form Version: 15-Sep-2020 21:55

Site No: 1152

Subject No: 11521476

Generated By: (b) (4)

Form: COHORT_SELECTION

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](#)

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: MAIN INFORMED CONSENT

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1152

Site Name: (1152) California Research Foundation

Subject No: 11521476

Subject Initials: ---

Generated By: (b) (4)

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

[eCRF Audit Trail History](#)

Informed Consent

1.	Consent Was:	OBTAINED Date Written Consent Obtained Sep/25/2020
----	--------------	--

Header Text: c4591001

Visit: COHORT_SELECTION

Form: DEMOGRAPHY

Form Version: 15-Sep-2020 21:54

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1152

Site Name: (1152) California Research Foundation

Subject No: 11521476

Subject Initials: ---

Generated By: (b) (4)

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

[eCRF Audit Trail History](#)

Demography

1.	Subject ID	[11521476]
2.	Birth Date:	(b) (6) 1959
3.	Sex:	FEMALE
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: 11521476

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	Sep/25/2020
2.	Erroneous Visit	

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 15-Sep-2020 21:53

Site No: 1152

Subject No: 11521476

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 _____
----	---	-------------------------

Exclusion Criteria Met

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

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 15-Sep-2020 21:52

Site No: 1152

Subject No: 11521476

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	Sep/25/2020
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: 11521476

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:	[Gall Bladder Stones]
	Start Date:	UNK/UNK/2001
	Ongoing:	NO End Date: UNK/UNK/2001
1.b	Line/MH Number:	[2]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Aspirin Allergy]
	Start Date:	UNK/UNK/1985
	Ongoing:	YES
1.c	Line/MH Number:	[3]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Penicillin Allergy]
	Start Date:	UNK/UNK/1970
	Ongoing:	YES
1.d	Line/MH Number:	[4]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[allergy to black olives]
	Start Date:	UNK/UNK/1975
	Ongoing:	YES

090177e196ae2fcd\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: 11521476

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:	[Gall Bladder Removal]
	Start Date:	UNK/UNK/2001
	Ongoing:	NO End Date: UNK/UNK/2001
1.f	Line/MH Number:	[6]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Breast Surgery for Fibrocystic Removal (left)]
	Start Date:	UNK/UNK/2005
	Ongoing:	NO End Date: UNK/UNK/2005
1.g	Line/MH Number:	[7]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Breast Surgery for Fibrocystic Removal (right)]
	Start Date:	UNK/UNK/1990
	Ongoing:	NO End Date: UNK/UNK/1990
1.h	Line/MH Number:	[8]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Fibrocystic Left Breast]
	Start Date:	UNK/UNK/2005
	Ongoing:	NO End Date: UNK/UNK/2005

090177e196ae2fcd\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: 11521476

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.i	Line/MH Number:	[9]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Fibrocystic Right Breast]
	Start Date:	UNK/UNK/1990
	Ongoing:	NO End Date: UNK/UNK/1990

090177e196ae2fcd\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: 11521476

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: 11521476

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:	Sep/25/2020
2.	Weight:	[129.6]
3.	Unit:	LB
4.	Height:	[59.0]
5.	Unit:	in
6.	Body Mass Index:	[26.2]

Vital Signs Details

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

090177e196ae2fcd\Final\Final On: 01-Apr-2021 03:52 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 15-Sep-2020 21:51

Site No: 1152

Subject No: 11521476

Generated By: (b) (4)

Form: LAB URINALYSIS - PREGNANCY TEST

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](#)

Lab Urinalysis

1.	Lab Panel:		
2.	Lab Sub-Panel:		
3.	Collection Date:	Not Applicable //	Comments
4.	Laboratory Name and Address (Derived)	[]	
5.	Specimen Type:		

Lab Result

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

090177e196ae2fcd\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: 11521476

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 :	Sep/25/2020
2.	Randomization Number:	[265209]
3.	Randomization Group:	[]

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1152

Subject No: 11521476

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: Sep/25/2020
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	[BP9K7H]
5.b	Sample ID	[BP9K7G]
5.c	Sample ID	[BNT39D]

090177e196ae2fcd\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: 11521476

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: Sep/25/2020
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	[BPOSH1]
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090177e196ae2fcd\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: 11521476

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:	Sep/25/2020 09:33
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

090177e196ae2fcd\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: 11521476

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
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Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 1152

Subject No: 11521476

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/15/2020
2.	Erroneous Visit	

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 10-Oct-2020 16:01

Site No: 1152

Subject No: 11521476

Generated By: (b) (4)

Form: VITAL SIGNS - TEMP

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/15/2020
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Vital Signs Details

2.a	Record Identifier:	1
	Temperature:	[98.0]
	Unit:	F
	Temperature Location:	ORAL CAVITY

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 15-Sep-2020 21:51

Site No: 1152

Subject No: 11521476

Generated By: (b) (4)

Form: LAB URINALYSIS - PREGNANCY TEST

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

Lab Urinalysis

1.	Lab Panel:	Not Applicable _____	Comments
2.	Lab Sub-Panel:	Not Applicable _____	Comments
3.	Collection Date:	Not Applicable _____ //	Comments
4.	Laboratory Name and Address (Derived)	Not Applicable _____ []	Comments
5.	Specimen Type:	Not Applicable _____	Comments

Lab Result

6.a	Sponsor ID:	Not Applicable _____ []	Comments
	Test:	Not Applicable _____ Choriogonadotropin Beta_PX113	
	Result:	Not Applicable _____	Comments
	Not Done:	Not Applicable _____	Comments

090177e196ae2fcd\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: 11521476

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/15/2020
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[BR920D barcode was taken in error and the sample will be destroyed.]

Aliquot

Please enter barcode for each aliquot.

5.a	Sample ID	[BR920D]
5.b	Sample ID	[BR9236]

090177e196ae2fcd\Final\Final On: 01-Apr-2021 03:52 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1152

Subject No: 11521476

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?	YES Date of First Delay: Oct/15/2020 Reason(s) for Temporary Delay of Vaccination FEVER OR ACUTE ILLNESS	
2.	Treatment Name	[]	
3.	Formulation:		
4.	Dose Date Time:	Not Done _____ //	Comments
5.	Anatomical Location:		
6.	Body Side:	Not Done _____	Comments
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?	Not Done _____	Comments

090177e196ae2fcd\Final\Final On: 01-Apr-2021 03:52 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form: DATE OF VISIT

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen, Verified

Site No: 1152

Site Name: (1152) California Research Foundation

Subject No: 11521476

Subject Initials: ---

Generated By: (b) (4)

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

[eCRF Audit Trail History](#)

Date of Visit

1.	Date of Visit	Dec/4/2020
2.	Erroneous Visit	

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form Version: 22-Apr-2020 21:03

Site No: 1152

Subject No: 11521476

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

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](#)

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	SERUM
3.	Sample Collected?	YES Date of Collection: Dec/4/2020
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	[BRJN97]
5.b	Sample ID	[BRJN98]
5.c	Sample ID	[BS6K7D]

090177e196ae2fcd\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: 11521476

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: 11521476

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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Header Text: c4591001

Visit: V5_MONTH12_L

Form Version: 22-Apr-2020 21:02

Site No: 1152

Subject No: 11521476

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: 11521476

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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Header Text: c4591001

Visit: V6_MONTH24_L

Form Version: 22-Apr-2020 21:02

Site No: 1152

Subject No: 11521476

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: 11521476

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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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: 11521476

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: 11521476

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

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: 11521476

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

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: 11521476

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

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: 11521476

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?	
----	--	--

090177e196ae2fcd\Final\Final On: 01-Apr-2021 03:52 (GMT)

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: 11521476

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: 11521476

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:	
----	-------------------------	--

090177e196ae2fcd\Final\Final On: 01-Apr-2021 03:52 (GMT)

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: 11521476

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

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: 11521476

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:	
----	-----------------------	--

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: 11521476

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

Header Text: c4591001

Visit: Unplanned 1 - Unscheduled Visit on
Oct/29/2020

Form: DATE OF VISIT

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1152

Site Name: (1152) California Research Foundation

Subject No: 11521476

Subject Initials: ---

Generated By: (b) (4)

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

[eCRF Audit Trail History](#)

Date of Visit

1.	Date of Visit	Oct/29/2020
2.	Erroneous Visit	

Header Text: c4591001

Visit: Unplanned 1 - Unscheduled Visit on
Oct/29/2020

Form: UNPLANNED VISIT

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1152

Site Name: (1152) California Research Foundation

Subject No: 11521476

Subject Initials: ---

Generated By: (b) (4)

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

[eCRF Audit Trail History](#)

Unplanned Assessments

1.	Assessments	CONTACT OUTCOME
----	-------------	-----------------

Header Text: c4591001

Visit: Unplanned 1 - Unscheduled Visit on
Oct/29/2020

Form: CONTACT OUTCOME - UNPLANNED

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1152

Site Name: (1152) California Research Foundation

Subject No: 11521476

Subject Initials: ---

Generated By: (b) (4)

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

[eCRF Audit Trail History](#)

Contact Outcome

1.	Contact Type:	TELEPHONE VISIT
2.	Was contact made?	YES Date of Contact: Oct/29/2020 Contact Outcome: VISIT ARRANGED
3.	Comments:	[Visit 2 vaccine was delayed. Subject returned for rescheduled Visit 2 today. Second vaccine was canceled by sub-I.]

090177e196ae2fcd\Final\Final On: 01-Apr-2021 03:52 (GMT)

Header Text: c4591001

Visit: Unplanned 1 - Unscheduled Visit on
Oct/29/2020

Form: VITAL SIGNS - TEMP

Form Version: 10-Oct-2020 16:01

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1152

Site Name: (1152) California Research Foundation

Subject No: 11521476

Subject Initials: ---

Generated By: (b) (4)

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

[eCRF Audit Trail History](#)

Vital Signs

1.	Date:	Oct/29/2020
----	-------	-------------

Vital Signs Details

2.a	Record Identifier:	1
	Temperature:	[98.5]
	Unit:	F
	Temperature Location:	ORAL CAVITY

Header Text: c4591001**Visit:** Unplanned 1 - Unscheduled Visit on
Oct/29/2020**Form:** UNPLANNED ASSESSMENT OF LOCAL REACTION - SYSTEMIC
EVENT**Form Version:** 10-Oct-2020 15:57**Form Status:** Data Complete, Locked, Frozen, Verified**Site No:** 1152**Site Name:** (1152) California Research Foundation**Subject No:** 11521476**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 11:56**Form Comments**
eCRF Audit Trail History**Unplanned Assessment Of Local Reaction**

1.	Date of Assessment:	Not Applicable _____ //	Comments
2.	Injection Site Location	Not Applicable _____	Comments
3.	Injection Site Body Side:	Not Applicable _____	Comments

Reaction

4.a	Reaction:	REDNESS	
	Reaction Present:	Not Applicable _____	Comments
4.b	Reaction:	SWELLING	
	Reaction Present:	Not Applicable _____	Comments

Symptom

5.a	Symptom:	PAIN AT INJECTION SITE	
	Symptom Present:	Not Applicable _____	Comments
5.b	Symptom:	FATIGUE/TIREDNESS	
	Symptom Present:	Not Applicable _____	Comments
5.c	Symptom:	HEADACHE	
	Symptom Present:	Not Applicable _____	Comments
5.d	Symptom:	VOMITING	
	Symptom Present:	Not Applicable _____	Comments
5.e	Symptom:	DIARRHEA	
	Symptom Present:	Not Applicable _____	Comments

Header Text: c4591001

Visit: Unplanned 1 - Unscheduled Visit on
Oct/29/2020

Form Version: 10-Oct-2020 15:57

Site No: 1152

Subject No: 11521476

Generated By: (b) (4)

Form: UNPLANNED ASSESSMENT OF LOCAL REACTION - SYSTEMIC
EVENT

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1152) California Research Foundation

Subject Initials: ---

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

5.f	Symptom:	NEW OR WORSENERED MUSCLE PAIN	
	Symptom Present:	Not Applicable _____	Comments
5.g	Symptom:	NEW OR WORSENERED JOINT PAIN	
	Symptom Present:	Not Applicable _____	Comments
5.h	Symptom:	CHILLS	
	Symptom Present:	Not Applicable _____	Comments

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: 11521476

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 On going	Form Instance
1.	ADVERSE EVENT	1	hearing loss right ear	Oct/14/2020 UNK:UNK	NO End Date Time: Oct/23/2020 UNK:UNK	Repeating Pages

090177e196ae2fcd\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: 11521476

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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[eCRF Audit Trail History](#)

[Form Audit Trail](#)

Adverse Event Report

1.	Category:	ADVERSE EVENT
2.	AE ID:	[1]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[hearing loss right ear]
4.	Start Date Time:	Oct/14/2020 UNK:UNK
5.	Is the adverse event still ongoing?	NO End Date Time: Oct/23/2020 UNK:UNK
6.	Toxicity Grade:	3
7.	Is the adverse event serious? If Yes, NOTIFY PFIZER IMMEDIATELY. Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).	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:	RELATED
10.	Latest Action Taken with Study Treatment:	DRUG WITHDRAWN
11.	Was a Concomitant Medication given?	YES
12.	Was a Non-Drug Treatment given?	NO
13.	What was the outcome of this adverse event?:	RECOVERED/RESOLVED

090177e196ae2fcd\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: 11521476

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

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

Header Text: c4591001

Visit: Logs

Form: MEDICATION ERROR

Form Version: 17-Jul-2020 21:54

Site No: 1152

Site Name: (1152) California Research Foundation

Subject No: 11521476

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: 11521476

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

[Back to Form](#)

Medication Error

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

090177e196ae2fcd\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: 11521476

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 Version: 22-Apr-2020 21:03

Site No: 1152

Subject No: 11521476

Generated By: (b) (4)

Form: CONCOMITANT MEDICATIONS - NON STUDY VACCINATIONS

Form Status: Not Started

Site Name: (1152) California Research Foundation

Subject Initials: ---

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

[Back to Form](#)

Concomitant Medications

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

090177e196ae2fcd\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: 11521476

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: 11521476

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?	

090177e196ae2fcd\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: 11521476

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: 11521476

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

[Back to Form](#)

Radiation Treatment

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

Header Text: c4591001

Visit: Logs

Form: TRANSFUSIONS

Form Version: 22-Apr-2020 21:03

Site No: 1152

Site Name: (1152) California Research Foundation

Subject No: 11521476

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: 11521476

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 Version: 15-Sep-2020 21:55

Site No: 1152

Subject No: 11521476

Generated By: (b) (4)

Form: DISPOSITION - TREATMENT

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 - Treatment

1.	Date of Completion/Discontinuation /Death :	Oct/15/2020
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: 11521476

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: 11521476

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: LAB URINALYSIS - PREGNANCY TEST

Form Version: 20-Feb-2021 02:14

Form Status: Not Started

Site No: 1152

Site Name: (1152) California Research Foundation

Subject No: 11521476

Subject Initials: ---

Generated By: (b) (4)

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

Lab Urinalysis

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

Lab Result

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

090177e196ae2fcd\Final\Final On: 01-Apr-2021 03:52 (GMT)

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: 11521476

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?	

090177e196ae2fcd\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: 11521476

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: 11521476

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: Data Complete, Frozen, Verified

Site No: 1152

Site Name: (1152) California Research Foundation

Subject No: 11521476

Subject Initials: ---

Generated By: (b) (4)

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

[eCRF Audit Trail History](#)

Date of Visit

1.	Date of Visit	Feb/23/2021
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: Data Complete, Frozen, Verified

Site No: 1152

Site Name: (1152) California Research Foundation

Subject No: 11521476

Subject Initials: ---

Generated By: (b) (4)

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

[eCRF Audit Trail History](#)

Informed Consent - Asymptomatic Surveillance

1.	Consent Was:	OBTAINED Date Written Consent Obtained Feb/23/2021
----	--------------	--

Header Text: c4591001

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1152

Site Name: (1152) California Research Foundation

Subject No: 11521476

Subject Initials: ---

Generated By: (b) (4)

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: Feb/23/2021
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[]

Aliquot

Please enter barcode for each aliquot.

5.a	Sample ID	[BRCMZZ]
5.b	Sample ID	[BRCN00]
5.c	Sample ID	[BS6KWG]

090177e196ae2fcd\Final\Final On: 01-Apr-2021 03:52 (GMT)

Header Text: c4591001

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1152

Site Name: (1152) California Research Foundation

Subject No: 11521476

Subject Initials: ---

Generated By: (b) (4)

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: Feb/23/2021
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[]

Aliquot

Please enter barcode for each aliquot.

5.a	Sample ID	[BRMT3M]
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090177e196ae2fcd\Final\Final On: 01-Apr-2021 03:52 (GMT)

Header Text: c4591001

Visit: Follow-Up - Unscheduled

Form Version: 15-Sep-2020 21:53

Site No: 1152

Subject No: 11521476

Generated By: (b) (4)

Form: DISPOSITION - FOLLOW-UP

Form Status: Incomplete, 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 :	//
2.	Phase of Disposition:	
3.	Status:	
4.	Specify Status:	[]

Header Text: c4591001

Visit: V202_SURVEIL_SWAB 1 - Unscheduled
Visit on Mar/10/2021

Form: DATE OF VISIT - ASYMPTOMATIC SURVEILLANCE

Form Version: 14-Jan-2021 02:22

Form Status: Data Complete, Verified

Site No: 1152

Site Name: (1152) California Research Foundation

Subject No: 11521476

Subject Initials: ---

Generated By: (b) (4)

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

[eCRF Audit Trail History](#)

Date of Visit

1.	Date of Visit	Mar/10/2021
2.	Erroneous Visit	

COVID-19 Surveillance Visit

3.	COVID-19 Surveillance Visit:	SSWAB_WEEK2
----	------------------------------	-------------

Header Text: c4591001

Visit: V202_SURVEIL_SWAB 1 - Unscheduled
Visit on Mar/10/2021

Form: ELECTRONIC SAMPLE TRACKING - REPEAT SWAB

Form Version: 10-Oct-2020 15:57

Form Status: Data Complete, Verified

Site No: 1152

Site Name: (1152) California Research Foundation

Subject No: 11521476

Subject Initials: ---

Generated By: (b) (4)

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

[eCRF Audit Trail History](#)

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB_SELF
3.	Sample Collected?	YES Date of Collection: Mar/10/2021
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[]

Aliquot

Please enter barcode for each aliquot.

5.a	Sample ID	[AA00003]
-----	-----------	-----------

090177e196ae2fcd\Final\Final On: 01-Apr-2021 03:52 (GMT)

Header Text: c4591001

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

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen, Verified

Site No: 1152

Site Name: (1152) California Research Foundation

Subject No: 11521476

Subject Initials: ---

Generated By: (b) (4)

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

[eCRF Audit Trail History](#)

Date of Visit

1.	Date of Visit	Feb/19/2021
2.	Erroneous Visit	

Header Text: c4591001

Visit: Potential ReVax Initial Contact - Unscheduled **Form:** FURTHER VACCINATION CONFIRMATION

Form Version: 10-Dec-2020 02:25

Form Status: Data Complete, Frozen

Site No: 1152

Site Name: (1152) California Research Foundation

Subject No: 11521476

Subject Initials: ---

Generated By: (b) (4)

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

[eCRF Audit Trail History](#)

Further Vaccination Confirmation

1.	Select appropriate response - Is participant willing to return for Vaccination 3?	Participant is willing to return for Vaccination 3 Participant is: eligible and NOT confirmed to have received only placebo at Vaccination 1/2
----	---	--

090177e196ae2fcd\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: 11521476

Generated By: (b) (4)

Form: TREATMENT UNBLINDED

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](#)

Treatment Unblinded

1.	Date Treatment Unblinded :	Feb/19/2021
2.	Primary Reason for Unblinding:	ASSESS ELIGIBILITY FOR ADDITIONAL VACCINATION

Header Text: c4591001

Visit: Disposition - Unscheduled

Form: WITHDRAWAL OF CONSENT

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1152

Site Name: (1152) California Research Foundation

Subject No: 11521476

Subject Initials: ---

Generated By: (b) (4)

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

Withdrawal Of Consent

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

Header Text: c4591001

Visit: Disposition - Unscheduled

Form: DEATH DETAILS CODED

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1152

Site Name: (1152) California Research Foundation

Subject No: 11521476

Subject Initials: ---

Generated By: (b) (4)

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

Death Details

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

Cause of Death

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

Header Text: c4591001

Visit: Subject Status - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1152

Subject No: 11521476

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	Oct/15/2020

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: 11521476

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

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: 11521476

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: 11521476

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	Sep-25-2020 15:27:30 (UTC-08:00) Pacific Time (US & Canada)	(b)(4),(b)(6)	Not Applicable

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 15-Sep-2020 21:51

Site No: 1152

Subject No: 11521476

Generated By: (b) (4)

Form: LAB URINALYSIS - PREGNANCY TEST - 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
3	Sep-25-2020 15:45:37 (UTC-08:00) Pacific Time (US & Canada)	(b)(4),(b)(6)	Post-menopausal 2004
			Not Applicable

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 15-Sep-2020 21:51

Site No: 1152

Subject No: 11521476

Generated By: (b) (4)

Form: LAB URINALYSIS - PREGNANCY TEST - 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-21-2020 19:11:19 (UTC-08:00) Pacific Time (US & Canada)	(b)(4),(b)(6)	sSUBJECT IS OVER 60 AND POST MENOPAUSAL <hr/> Not Applicable

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 15-Sep-2020 21:51

Site No: 1152

Subject No: 11521476

Generated By: (b) (4)

Form: LAB URINALYSIS - PREGNANCY TEST - 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
1	Oct-21-2020 19:11:19 (UTC-08:00) Pacific Time (US & Canada)	(b)(4),(b)(6)	sSUBJECT IS OVER 60 AND POST MENOPAUSAL
			Not Applicable

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 15-Sep-2020 21:51

Site No: 1152

Subject No: 11521476

Generated By: (b) (4)

Form: LAB URINALYSIS - PREGNANCY TEST - Comments

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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Item	Date	User	Comment
2	Oct-21-2020 19:11:19 (UTC-08:00) Pacific Time (US & Canada)	(b)(4),(b)(6)	sSUBJECT IS OVER 60 AND POST MENOPAUSAL
			Not Applicable

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 15-Sep-2020 21:51

Site No: 1152

Subject No: 11521476

Generated By: (b) (4)

Form: LAB URINALYSIS - PREGNANCY TEST - Comments

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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Item	Date	User	Comment
3	Oct-21-2020 19:11:19 (UTC-08:00) Pacific Time (US & Canada)	(b)(4),(b)(6)	sSUBJECT IS OVER 60 AND POST MENOPAUSAL
			Not Applicable

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 15-Sep-2020 21:51

Site No: 1152

Subject No: 11521476

Generated By: (b) (4)

Form: LAB URINALYSIS - PREGNANCY TEST - Comments

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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Item	Date	User	Comment
4	Oct-21-2020 19:11:19 (UTC-08:00) Pacific Time (US & Canada)	(b)(4),(b)(6)	sSUBJECT IS OVER 60 AND POST MENOPAUSAL
			Not Applicable

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 15-Sep-2020 21:51

Site No: 1152

Subject No: 11521476

Generated By: (b) (4)

Form: LAB URINALYSIS - PREGNANCY TEST - Comments

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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Item	Date	User	Comment
5	Oct-21-2020 19:11:19 (UTC-08:00) Pacific Time (US & Canada)	(b)(4),(b)(6)	sSUBJECT IS OVER 60 AND POST MENOPAUSAL
			Not Applicable

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 15-Sep-2020 21:51

Site No: 1152

Subject No: 11521476

Generated By: (b) (4)

Form: LAB URINALYSIS - PREGNANCY TEST - 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
6.a	Oct-21-2020 19:11:19 (UTC-08:00) Pacific Time (US & Canada)	(b)(4),(b)(6)	sSUBJECT IS OVER 60 AND POST MENOPAUSAL
			Not Applicable

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 15-Sep-2020 21:51

Site No: 1152

Subject No: 11521476

Generated By: (b) (4)

Form: LAB URINALYSIS - PREGNANCY TEST - 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
6.a	Oct-21-2020 19:11:19 (UTC-08:00) Pacific Time (US & Canada)	(b)(4),(b)(6)	sSUBJECT IS OVER 60 AND POST MENOPAUSAL
			Not Applicable

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 15-Sep-2020 21:51

Site No: 1152

Subject No: 11521476

Generated By: (b) (4)

Form: LAB URINALYSIS - PREGNANCY TEST - Comments

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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Item	Date	User	Comment
6.a	Oct-21-2020 19:11:19 (UTC-08:00) Pacific Time (US & Canada)	(b)(4),(b)(6)	sSUBJECT IS OVER 60 AND POST MENOPAUSAL
			Not Applicable

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1152

Subject No: 11521476

Generated By: (b) (4)

Form: VACCINATION - Comments

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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Item	Date	User	Comment
4	Oct-28-2020 08:23:51 (UTC-08:00) Pacific Time (US & Canada)	(b)(4),(b)(6)	Not Done

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1152

Subject No: 11521476

Generated By: (b) (4)

Form: VACCINATION - Comments

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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Item	Date	User	Comment
6	Oct-28-2020 08:24:05 (UTC-08:00) Pacific Time (US & Canada)	(b)(4),(b)(6)	Not Done

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1152

Subject No: 11521476

Generated By: (b) (4)

Form: VACCINATION - Comments

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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Item	Date	User	Comment
11	Oct-28-2020 08:24:17 (UTC-08:00) Pacific Time (US & Canada)	(b)(4),(b)(6)	Not Done

Header Text: c4591001

Visit: Unplanned 1 - Unscheduled Visit on
Oct/29/2020

Form Version: 10-Oct-2020 15:57

Site No: 1152

Subject No: 11521476

Generated By: (b) (4)

Form: UNPLANNED ASSESSMENT OF LOCAL REACTION - SYSTEMIC
EVENT - Comments

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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Item	Date	User	Comment
Form	Nov-03-2020 07:04:17 (UTC-08:00) Pacific Time (US & Canada)	(b)(4),(b)(6)	Not Applicable

Header Text: c4591001

Visit: Unplanned 1

Form: UNPLANNED ASSESSMENT OF LOCAL REACTION - SYSTEMIC EVENT - Comments

Form Version: 10-Oct-2020 15:57

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1152

Site Name: (1152) California Research Foundation

Subject No: 11521476

Subject Initials: ---

Generated By: (b) (4)

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

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Item	Date	User	Comment
1	Nov-03-2020 07:04:17 (UTC-08:00) Pacific Time (US & Canada)	(b)(4),(b)(6)	Not Applicable

Header Text: c4591001

Visit: Unplanned 1

Form: UNPLANNED ASSESSMENT OF LOCAL REACTION - SYSTEMIC EVENT - Comments

Form Version: 10-Oct-2020 15:57

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1152

Site Name: (1152) California Research Foundation

Subject No: 11521476

Subject Initials: ---

Generated By: (b) (4)

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

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Item	Date	User	Comment
2	Nov-03-2020 07:04:17 (UTC-08:00) Pacific Time (US & Canada)	(b)(4),(b)(6)	Not Applicable

Header Text: c4591001

Visit: Unplanned 1

Form: UNPLANNED ASSESSMENT OF LOCAL REACTION - SYSTEMIC EVENT - Comments

Form Version: 10-Oct-2020 15:57

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1152

Site Name: (1152) California Research Foundation

Subject No: 11521476

Subject Initials: ---

Generated By: (b) (4)

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

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Item	Date	User	Comment
3	Nov-03-2020 07:04:17 (UTC-08:00) Pacific Time (US & Canada)	(b)(4),(b)(6)	Not Applicable

Header Text: c4591001

Visit: Unplanned 1

Form: UNPLANNED ASSESSMENT OF LOCAL REACTION - SYSTEMIC EVENT - Comments

Form Version: 10-Oct-2020 15:57

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1152

Site Name: (1152) California Research Foundation

Subject No: 11521476

Subject Initials: ---

Generated By: (b) (4)

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

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Item	Date	User	Comment
4.a	Nov-03-2020 07:04:17 (UTC-08:00) Pacific Time (US & Canada)	(b)(4),(b)(6)	Not Applicable

Header Text: c4591001

Visit: Unplanned 1

Form: UNPLANNED ASSESSMENT OF LOCAL REACTION - SYSTEMIC EVENT - Comments

Form Version: 10-Oct-2020 15:57

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1152

Site Name: (1152) California Research Foundation

Subject No: 11521476

Subject Initials: ---

Generated By: (b) (4)

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

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Item	Date	User	Comment
4.b	Nov-03-2020 07:04:17 (UTC-08:00) Pacific Time (US & Canada)	(b)(4),(b)(6)	Not Applicable

090177e196ae2fcd\Final\Final On: 01-Apr-2021 03:52 (GMT)

Header Text: c4591001

Visit: Unplanned 1

Form: UNPLANNED ASSESSMENT OF LOCAL REACTION - SYSTEMIC EVENT - Comments

Form Version: 10-Oct-2020 15:57

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1152

Site Name: (1152) California Research Foundation

Subject No: 11521476

Subject Initials: ---

Generated By: (b) (4)

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

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Item	Date	User	Comment
5.a	Nov-03-2020 07:04:17 (UTC-08:00) Pacific Time (US & Canada)	(b)(4),(b)(6)	Not Applicable

Header Text: c4591001

Visit: Unplanned 1

Form: UNPLANNED ASSESSMENT OF LOCAL REACTION - SYSTEMIC EVENT - Comments

Form Version: 10-Oct-2020 15:57

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1152

Site Name: (1152) California Research Foundation

Subject No: 11521476

Subject Initials: ---

Generated By: (b) (4)

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

[Back to Form](#)

Item	Date	User	Comment
5.b	Nov-03-2020 07:04:17 (UTC-08:00) Pacific Time (US & Canada)	(b)(4),(b)(6)	Not Applicable

090177e196ae2fcd\Final\Final On: 01-Apr-2021 03:52 (GMT)

Header Text: c4591001

Visit: Unplanned 1

Form: UNPLANNED ASSESSMENT OF LOCAL REACTION - SYSTEMIC EVENT - Comments

Form Version: 10-Oct-2020 15:57

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1152

Site Name: (1152) California Research Foundation

Subject No: 11521476

Subject Initials: ---

Generated By: (b) (4)

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

[Back to Form](#)

Item	Date	User	Comment
5.c	Nov-03-2020 07:04:17 (UTC-08:00) Pacific Time (US & Canada)	(b)(4),(b)(6)	Not Applicable

Header Text: c4591001

Visit: Unplanned 1

Form: UNPLANNED ASSESSMENT OF LOCAL REACTION - SYSTEMIC EVENT - Comments

Form Version: 10-Oct-2020 15:57

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1152

Site Name: (1152) California Research Foundation

Subject No: 11521476

Subject Initials: ---

Generated By: (b) (4)

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

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Item	Date	User	Comment
5.d	Nov-03-2020 07:04:17 (UTC-08:00) Pacific Time (US & Canada)	(b)(4),(b)(6)	Not Applicable

Header Text: c4591001

Visit: Unplanned 1

Form: UNPLANNED ASSESSMENT OF LOCAL REACTION - SYSTEMIC EVENT - Comments

Form Version: 10-Oct-2020 15:57

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1152

Site Name: (1152) California Research Foundation

Subject No: 11521476

Subject Initials: ---

Generated By: (b) (4)

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

[Back to Form](#)

Item	Date	User	Comment
5.e	Nov-03-2020 07:04:17 (UTC-08:00) Pacific Time (US & Canada)	(b)(4),(b)(6)	Not Applicable

Header Text: c4591001

Visit: Unplanned 1

Form: UNPLANNED ASSESSMENT OF LOCAL REACTION - SYSTEMIC EVENT - Comments

Form Version: 10-Oct-2020 15:57

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1152

Site Name: (1152) California Research Foundation

Subject No: 11521476

Subject Initials: ---

Generated By: (b) (4)

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

[Back to Form](#)

Item	Date	User	Comment
5.f	Nov-03-2020 07:04:17 (UTC-08:00) Pacific Time (US & Canada)	(b)(4),(b)(6)	Not Applicable

Header Text: c4591001

Visit: Unplanned 1

Form: UNPLANNED ASSESSMENT OF LOCAL REACTION - SYSTEMIC EVENT - Comments

Form Version: 10-Oct-2020 15:57

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1152

Site Name: (1152) California Research Foundation

Subject No: 11521476

Subject Initials: ---

Generated By: (b) (4)

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

[Back to Form](#)

Item	Date	User	Comment
5.g	Nov-03-2020 07:04:17 (UTC-08:00) Pacific Time (US & Canada)	(b)(4),(b)(6)	Not Applicable

Header Text: c4591001

Visit: Unplanned 1

Form: UNPLANNED ASSESSMENT OF LOCAL REACTION - SYSTEMIC EVENT - Comments

Form Version: 10-Oct-2020 15:57

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1152

Site Name: (1152) California Research Foundation

Subject No: 11521476

Subject Initials: ---

Generated By: (b) (4)

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

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Item	Date	User	Comment
5.h	Nov-03-2020 07:04:17 (UTC-08:00) Pacific Time (US & Canada)	(b)(4),(b)(6)	Not Applicable

090177e196ae2fcd\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: 11521476

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	Jan-30-2021 14:55:29 (UTC-08:00) Pacific Time (US & Canada)		Edit - All signatures invalidated

Affidavit:

N/A

Donald Brandon	Approved	Jan-21-2021 11:27:28 (UTC-08:00) Pacific Time (US & Canada)	BOOK	Signed
----------------	----------	---	------	--------

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-04-2020 10:45:47 (UTC-08:00) Pacific Time (US & Canada)		Edit - All signatures invalidated
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Affidavit:

N/A

Donald Brandon	Approved	Nov-17-2020 12:38:51 (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 19:43:23 (UTC-08:00) Pacific Time (US & Canada)		Edit - All signatures invalidated
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090177e196ae2fcd\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: 11521476

Subject Initials: ---

Generated By: (b) (4)

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

Affidavit:

N/A

Donald Brandon	Approved	Nov-16-2020 12:28:44 (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-16-2020 06:43:01 (UTC-08:00) Pacific Time (US & Canada)		Edit - All signatures invalidated
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Affidavit:

N/A

Donald Brandon	Approved	Nov-13-2020 09:59:18 (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-12-2020 14:35:25 (UTC-08:00) Pacific Time (US & Canada)		Edit - All signatures invalidated
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Affidavit:

N/A

Donald Brandon	Approved	Nov-06-2020 08:52:50 (UTC-08:00) Pacific Time (US & Canada)	BOOK	Signed
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090177e196ae2fcd\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: 11521476

Subject Initials: ---

Generated By: (b) (4)

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

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-06-2020 07:30:17 (UTC-08:00) Pacific Time (US & Canada)		Edit - All signatures invalidated
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Affidavit:

N/A

Donald Brandon	Approved	Nov-04-2020 12:47:50 (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-04-2020 06:30:42 (UTC-08:00) Pacific Time (US & Canada)		Edit - All signatures invalidated
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Affidavit:

N/A

Donald Brandon	Approved	Nov-03-2020 16:27:04 (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.

090177e196ae2fcd\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: 11521476

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
Sep-25-2020 15:26:13 (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
Sep-25-2020 15:26:13 (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: 11521476

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

[Back to Form](#)

I. Consent Was:

Date	Location	User	Value	Reason
Sep-25-2020 15:26:20 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Data Entry: OBTAINED Date Written Consent Obtained Sep/25/2020	Initial Entry

Header Text: c4591001

Visit: COHORT_SELECTION

Form: DEMOGRAPHY - eCRF Audit Trail History

Form Version: 15-Sep-2020 21:54

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1152

Site Name: (1152) California Research Foundation

Subject No: 11521476

Subject Initials: ---

Generated By: (b) (4)

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

[Back to Form](#)

1. Subject ID

Date	Location	User	Value	Reason
Sep-25-2020 15:25:55 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 11521476	Item copied from previous form

2. Birth Date:

Date	Location	User	Value	Reason
Sep-25-2020 15:25:52 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: (b) (6) 1959	Enrollment Entry

3. Sex:

Date	Location	User	Value	Reason
Sep-25-2020 15:27:12 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Data Entry: FEMALE	Initial Entry

4. Ethnicity:

Date	Location	User	Value	Reason
Sep-25-2020 15:27:12 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Data Entry: HISPANIC OR LATINO(A) OR OF SPANISH ORIGIN	Initial Entry

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

Date	Location	User	Value	Reason
Sep-25-2020 15:27:12 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Data Entry: WHITE	Initial Entry

090177e196ae2fcd\Final\Final On: 01-Apr-2021 03:52 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:02

Site No: 1152

Subject No: 11521476

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

[Back to Form](#)

I. Date of Visit

Date	Location	User	Value	Reason
Sep-25-2020 15:27:22 (UTC-08:00) Pacific Time (US & Canada)	ACVOPFEINFP6000	(b) (4), (b)(6)	Data Entry: Sep/25/2020	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: DISPOSITION - SCREENING - eCRF Audit Trail History

Form Version: 15-Sep-2020 21:52

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1152

Site Name: (1152) California Research Foundation

Subject No: 11521476

Subject Initials: ---

Generated By: (b) (4)

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

[Back to Form](#)

1. Date of Completion/Discontinuation/Death

Date	Location	User	Value	Reason
Sep-25-2020 15:27:58 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Data Entry: Sep/25/2020	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Sep-25-2020 15:27:58 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SCREENING	Initial Entry

3. Status:

Date	Location	User	Value	Reason
Sep-25-2020 15:27:58 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Data Entry: COMPLETED	Initial Entry

090177e196ae2fcd\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: 11521476

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

[Back to Form](#)

I.a

Date	Location	User	Value	Reason
Sep-25-2020 15:30:10 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 1 Medical History Term: Gall Bladder Stones Start Date: UNK/UNK/2001 Ongoing: NO End Date: UNK/UNK/2001	Initial Entry

I.a Line/MH Number:

Date	Location	User	Value	Reason
Sep-25-2020 15:30:10 (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
Sep-25-2020 15:30:10 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Data Entry: Gall Bladder Stones	Initial Entry

I.a Start Date:

Date	Location	User	Value	Reason
Sep-25-2020 15:30:10 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Data Entry: UNK/UNK/2001	Initial Entry

I.a Ongoing:

Date	Location	User	Value	Reason
Sep-25-2020 15:30:10 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Data Entry: NO End Date: UNK/UNK/2001	Initial Entry

090177e196ae2fcd\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: 11521476

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
Sep-25-2020 15:32:09 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Data Entry: Line/MH Number: 2 Medical History Term: Aspirin Allergy Start Date: UNK/UNK/1985 Ongoing: YES	Transcription Error
Sep-25-2020 15:31:10 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 2 Medical History Term: Aspirin Allergy Start Date: UNK/UNK/1985 Ongoing: NO End Date: UNK/UNK/1985	Initial Entry

090177e196ae2fcd\Final\Final On: 01-Apr-2021 03:52 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1152

Site Name: (1152) California Research Foundation

Subject No: 11521476

Subject Initials: ---

Generated By: (b) (4)

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

I.b Line/MH Number:

Date	Location	User	Value	Reason
Sep-25-2020 15:31:10 (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
Sep-25-2020 15:31:10 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Data Entry: Aspirin Allergy	Initial Entry

I.b Start Date:

Date	Location	User	Value	Reason
Sep-25-2020 15:31:10 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Data Entry: UNK/UNK/1985	Initial Entry

I.b Ongoing:

Date	Location	User	Value	Reason
Sep-25-2020 15:32:09 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Data Entry: YES	Transcription Error
Sep-25-2020 15:31:10 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Data Entry: NO End Date: UNK/UNK/1985	Initial Entry

I.c

Date	Location	User	Value	Reason
Sep-25-2020 15:31:49 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 3 Medical History Term: Penicillin Allergy Start Date: UNK/UNK/1970 Ongoing: YES	Initial Entry

090177e196ae2fcd\Final\Final On: 01-Apr-2021 03:52 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1152

Site Name: (1152) California Research Foundation

Subject No: 11521476

Subject Initials: ---

Generated By: (b) (4)

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

I.c Line/MH Number:

Date	Location	User	Value	Reason
Sep-25-2020 15:31:49 (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
Sep-25-2020 15:31:49 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Data Entry: Penicillin Allergy	Initial Entry

I.c Start Date:

Date	Location	User	Value	Reason
Sep-25-2020 15:31:49 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Data Entry: UNK/UNK/1970	Initial Entry

I.c Ongoing:

Date	Location	User	Value	Reason
Sep-25-2020 15:31:49 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Data Entry: YES	Initial Entry

I.d

Date	Location	User	Value	Reason
Sep-28-2020 08:23:29 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Data Entry: Line/MH Number: 4 Medical History Term: allergy to black olives Start Date: UNK/UNK/1975 Ongoing: YES	Changed Information
Sep-25-2020 15:32:37 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 4 Medical History Term: Black Olives Start Date: UNK/UNK/1975	Initial Entry

090177e196ae2fcd\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: 11521476

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:	YES	
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Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1152

Site Name: (1152) California Research Foundation

Subject No: 11521476

Subject Initials: ---

Generated By: (b) (4)

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

I.d Line/MH Number:

Date	Location	User	Value	Reason
Sep-25-2020 15:32:37 (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
Sep-28-2020 10:41:54 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	PFETMS Oracle (b) (4)	Query 1: Closed	Discrepancy has been closed.
Sep-28-2020 08:23:29 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Changed Information
Sep-28-2020 08:23:29 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b)(6)	Data Entry: allergy to black olives	Changed Information
Sep-25-2020 23:24:47 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	PFETMS Oracle (b) (4)	Query 1: Opened	Clarify BLACK OLIVES as follows...Are you reporting ALLERGY TO BLACK OLIVES CAUSE INDIGESTION? or Other? If so please edit as such, Otherwise, clarify further. Thank you.
Sep-25-2020 15:32:37 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Data Entry: Black Olives	Initial Entry

I.d Start Date:

090177e196ae2fcd\Final\Final On: 01-Apr-2021 03:52 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1152

Site Name: (1152) California Research Foundation

Subject No: 11521476

Subject Initials: ---

Generated By: (b) (4)

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

Date	Location	User	Value	Reason
Sep-25-2020 15:32:37 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Data Entry: UNK/UNK/1975	Initial Entry

I.d Ongoing:

Date	Location	User	Value	Reason
Sep-25-2020 15:32:37 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Data Entry: YES	Initial Entry

I.e

Date	Location	User	Value	Reason
Sep-25-2020 15:33:23 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number 5 : Medical History T Gall Bladder Rem erm: oval Start Date: UNK/UNK/2001 Ongoing: NO End Date: UNK/UNK/20 01	Initial Entry

090177e196ae2fcd\Final\Final On: 01-Apr-2021 03:52 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1152

Site Name: (1152) California Research Foundation

Subject No: 11521476

Subject Initials: ---

Generated By: (b) (4)

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

I.e Line/MH Number:

Date	Location	User	Value	Reason
Sep-25-2020 15:33:23 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 5	Initial Entry

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

Date	Location	User	Value	Reason
Sep-25-2020 15:33:23 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Data Entry: Gall Bladder Removal	Initial Entry

I.e Start Date:

Date	Location	User	Value	Reason
Sep-25-2020 15:33:23 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Data Entry: UNK/UNK/2001	Initial Entry

I.e Ongoing:

Date	Location	User	Value	Reason
Sep-25-2020 15:33:23 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Data Entry: NO End Date: UNK/UNK/2001	Initial Entry

I.f

Date	Location	User	Value	Reason
Sep-25-2020 15:35:53 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Data Entry: Line/MH 6 Number: Medical Hi Breast Surgery for Fib story Term rocystic Removal (left :) Start Date: UNK/UNK/2005 Ongoing: NO End Date: UNK/UNK/2005	Changed Information
Sep-25-2020 15:35:35 (UTC-08:00) Pacific Time	ACV0PFEINFP6000	(b) (6)	Data Entry:	New Information

090177e196ae2fcd\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: 11521476

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

(US & Canada)		(b) (4)	Line/MH N 6 umber: Medical Hi Breast Surgery for Fib story Term: rocystic Removal (left) Start Date: UNK/UNK/2005 Ongoing: YES	
Sep-25-2020 15:34:43 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Nu 6 mber: Medical Hist Breast Surgery for Fi ory Term: brocystic Removal Start Date: UNK/UNK/2005 Ongoing: YES	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1152

Subject No: 11521476

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.f Line/MH Number:

Date	Location	User	Value	Reason
Sep-25-2020 15:34:43 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 6	Initial Entry

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

Date	Location	User	Value	Reason
Sep-25-2020 15:35:35 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Data Entry: Breast Surgery for Fibrocystic Rem oval (left)	New Information
Sep-25-2020 15:34:43 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Data Entry: Breast Surgery for Fibrocystic Rem oval	Initial Entry

I.f Start Date:

Date	Location	User	Value	Reason
Sep-25-2020 15:34:43 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Data Entry: UNK/UNK/2005	Initial Entry

I.f Ongoing:

Date	Location	User	Value	Reason
Sep-25-2020 15:35:53 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Data Entry: NO End Date: UNK/UNK/2005	Changed Information
Sep-25-2020 15:34:43 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Data Entry: YES	Initial Entry

I.g

Date	Location	User	Value	Reason
Sep-25-2020 15:36:06 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Data Entry: Line/MH 7 Number: Medical Hi Breast Surgery for Fibr story Term ocystic Removal (right :)	New Information

090177e196ae2fcd\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: 11521476

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

			Start Date: UNK/UNK/1990 Ongoing: NO End Date: UNK/UNK/1990	
Sep-25-2020 15:35:15 (UTC-08:00) Pacific Time (US & Canada)	ACVOPFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH N umber: 7 Medical History Term: Breast Surgery for Fibrocystic Removal Start Date: UNK/UNK/1990 Ongoing: NO End Date: UNK/UNK/1990	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1152

Subject No: 11521476

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
Sep-25-2020 15:35:15 (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
Sep-25-2020 15:36:06 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Data Entry: Breast Surgery for Fibrocystic Rem oval (right)	New Information
Sep-25-2020 15:35:15 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Data Entry: Breast Surgery for Fibrocystic Rem oval	Initial Entry

I.g Start Date:

Date	Location	User	Value	Reason
Sep-25-2020 15:35:15 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Data Entry: UNK/UNK/1990	Initial Entry

I.g Ongoing:

Date	Location	User	Value	Reason
Sep-25-2020 15:35:15 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Data Entry: NO End Date: UNK/UNK/1990	Initial Entry

I.h

Date	Location	User	Value	Reason
Sep-25-2020 15:38:02 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 8 r: Medical History: Fibrocystic Left Breast Term: Start Date: UNK/UNK/2005	Initial Entry

090177e196ae2fcd\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: 11521476

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/20	
				05	

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1152

Site Name: (1152) California Research Foundation

Subject No: 11521476

Subject Initials: ---

Generated By: (b) (4)

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

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1.h Line/MH Number:

Date	Location	User	Value	Reason
Sep-25-2020 15:38:02 (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
Sep-25-2020 15:38:02 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Data Entry: Fibrocystic Left Breast	Initial Entry

1.h Start Date:

Date	Location	User	Value	Reason
Sep-25-2020 15:38:02 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Data Entry: UNK/UNK/2005	Initial Entry

1.h Ongoing:

Date	Location	User	Value	Reason
Sep-25-2020 15:38:02 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Data Entry: NO End Date: UNK/UNK/2005	Initial Entry

1.i

Date	Location	User	Value	Reason
Sep-25-2020 15:38:42 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Numbe 9 r: Medical History Fibrocystic Right Term: Breast Start Date: UNK/UNK/1990 Ongoing: NO End Date: UNK/UNK/1990	Initial Entry

090177e196ae2fcd\Final\On: 01-Apr-2021 03:52 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1152

Site Name: (1152) California Research Foundation

Subject No: 11521476

Subject Initials: ---

Generated By: (b) (4)

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

L.i Line/MH Number:

Date	Location	User	Value	Reason
Sep-25-2020 15:38:42 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 9	Initial Entry

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

Date	Location	User	Value	Reason
Sep-25-2020 15:38:42 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Data Entry: Fibrocystic Right Breast	Initial Entry

L.i Start Date:

Date	Location	User	Value	Reason
Sep-25-2020 15:38:42 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Data Entry: UNK/UNK/1990	Initial Entry

L.i Ongoing:

Date	Location	User	Value	Reason
Sep-25-2020 15:38:42 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Data Entry: NO End Date: UNK/UNK/1990	Initial Entry

090177e196ae2fcd\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: 11521476

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
Sep-25-2020 15:43:16 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Data Entry: The subject is NOT known to be HI V POSITIVE	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 15-Sep-2020 21:56

Site No: 1152

Subject No: 11521476

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
Sep-25-2020 15:44:01 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Data Entry: Sep/25/2020	Initial Entry

2. Weight:

Date	Location	User	Value	Reason
Sep-25-2020 15:44:01 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Data Entry: 129.6	Initial Entry

3. Unit:

Date	Location	User	Value	Reason
Sep-25-2020 15:44:01 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Data Entry: LB	Initial Entry

4. Height:

Date	Location	User	Value	Reason
Sep-25-2020 15:44:01 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Data Entry: 59.0	Initial Entry

5. Unit:

Date	Location	User	Value	Reason
Sep-25-2020 15:44:01 (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
Sep-25-2020 15:44:01 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 26.2	Initial Entry

7.a

090177e196ae2fcd\Final\Final On: 01-Apr-2021 03:52 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: VITAL SIGNS - BASELINE - eCRF Audit Trail History

Form Version: 15-Sep-2020 21:56

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1152

Site Name: (1152) California Research Foundation

Subject No: 11521476

Subject Initials: ---

Generated By: (b) (4)

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

Date	Location	User	Value	Reason
Sep-25-2020 15:44:01 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Data Entry: Record Identifier:: 1 Temperature: 97.9 Temperature Unit: F Temperature Location:: ORAL CAVITY	Initial Entry

7.a Record Identifier:

Date	Location	User	Value	Reason
Sep-25-2020 15:44:01 (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
Sep-25-2020 15:44:01 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Data Entry: 97.9	Initial Entry

7.a Unit:

Date	Location	User	Value	Reason
Sep-25-2020 15:44:01 (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
Sep-25-2020 15:44:01 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Data Entry: ORAL CAVITY	Initial Entry

090177e196ae2fcd\Final\Final On: 01-Apr-2021 03:52 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 15-Sep-2020 21:51

Site No: 1152

Subject No: 11521476

Generated By: (b) (4)

Form: LAB URINALYSIS - PREGNANCY TEST - 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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3. Collection Date:

Date	Location	User	Value	Reason
Sep-25-2020 15:45:37 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Data Entry: Not Applicable	Initial Entry

6.a

Date	Location	User	Value	Reason
Sep-25-2020 15:45:07 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sponsor-Defined Identifier: 113 Test:: Choriogonadotropin Beta_PX113 Result:: Not Done:: NOT DONE	Initial Entry

6.a Sponsor ID:

Date	Location	User	Value	Reason
Sep-25-2020 15:45:07 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 113	Initial Entry

6.a Test:

Date	Location	User	Value	Reason
Sep-25-2020 15:45:07 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Data Entry: Choriogonadotropin Beta_PX113	Initial Entry

6.a Not Done:

Date	Location	User	Value	Reason
Sep-25-2020 15:45:07 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Data Entry: NOT DONE	Initial Entry

090177e196ae2fcd\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: 11521476

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
Sep-25-2020 15:49:17 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Data Entry: Sep/25/2020	Initial Entry

2. Randomization Number:

Date	Location	User	Value	Reason
Sep-25-2020 15:49:17 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Data Entry: 265209	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:** 11521476**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 11:56[Back to Form](#)**1. Data Origin**

Date	Location	User	Value	Reason
Sep-25-2020 15:49:24 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Sep-25-2020 15:49:24 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SERUM	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Sep-28-2020 08:44:13 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Sep-26-2020 02:36:17 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b) (6)	Query 1: Opened	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Sep-25-2020 15:49:24 (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.
Sep-25-2020 15:49:24 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Data Entry: YES Date of Collection: Sep/25/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Sep-28-2020 08:44:13	ACV0PFEINFP6000	(b) (6)	Data Entry:	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: 11521476

Subject Initials: ---

Generated By: (b) (4)

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

(UTC-08:00) Pacific Time
(US & Canada)

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

Sample ID: BP9K7H

5.a Sample ID

Date	Location	User	Value	Reason
Sep-28-2020 08:44:13 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	<u>Data Entry:</u> BP9K7H	Initial Entry

5.b

Date	Location	User	Value	Reason
Sep-28-2020 08:44:25 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	<u>Data Entry:</u> Sample ID: BP9K7G	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Sep-28-2020 08:44:25 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	<u>Data Entry:</u> BP9K7G	Initial Entry

5.c

Date	Location	User	Value	Reason
Sep-28-2020 18:10:33 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	<u>Data Entry:</u> Sample ID: BNT39D	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Sep-28-2020 18:10:33 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	<u>Data Entry:</u> BNT39D	Initial Entry

090177e196ae2fcd\Final\Final On: 01-Apr-2021 03:52 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1152

Site Name: (1152) California Research Foundation

Subject No: 11521476

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
Sep-25-2020 15:49:32 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Sep-25-2020 15:49:32 (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
Sep-28-2020 08:09:29 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Sep-26-2020 02:36:17 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b) (6)	Query 1: Opened	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Sep-25-2020 15:49:32 (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.
Sep-25-2020 15:49:32 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Data Entry: YES Date of Collection: Sep/25/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Sep-28-2020 08:09:29	ACV0PFEINFP6000	(b) (6)	Data Entry:	Initial Entry

090177e196ae2fcd\Final\Final On: 01-Apr-2021 03:52 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1152

Site Name: (1152) California Research Foundation

Subject No: 11521476

Subject Initials: ---

Generated By: (b) (4)

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

(UTC-08:00) Pacific Time
(US & Canada)

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

Sample ID: BP0SH1

5.a Sample ID

Date	Location	User	Value	Reason
Sep-28-2020 08:09:29 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Data Entry: BP0SH1	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:04

Site No: 1152

Subject No: 11521476

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
Sep-25-2020 15:49:49 (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
Sep-25-2020 15:49:49 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: BLINDED THERAPY	Initial Entry

3. Formulation:

Date	Location	User	Value	Reason
Sep-25-2020 15:49:49 (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
Sep-25-2020 15:49:49 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Data Entry: Sep/25/2020 09:33	Initial Entry

5. Anatomical Location:

Date	Location	User	Value	Reason
Sep-25-2020 15:49:49 (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
Sep-25-2020 15:49:49 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Data Entry: LEFT	Initial Entry

7. Route:

090177e196ae2fcd\Final\Final On: 01-Apr-2021 03:52 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: VACCINATION - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1152

Site Name: (1152) California Research Foundation

Subject No: 11521476

Subject Initials: ---

Generated By: (b) (4)

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

Date	Location	User	Value	Reason
Sep-25-2020 15:49:49 (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
Sep-25-2020 15:49:49 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: THE PROTOCOL SPECIFIED OBSE RVATION PERIOD	Initial Entry

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

Date	Location	User	Value	Reason
Sep-25-2020 15:49:49 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Data Entry: YES	Initial Entry

090177e196ae2fcd\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: 11521476

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
Sep-25-2020 15:50:17 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Data Entry: NO - REACTOGENICITY E-DIARY NOT COLLECTED FOR THIS SUBJECT	Initial Entry

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 1152

Subject No: 11521476

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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I. Date of Visit

Date	Location	User	Value	Reason
Nov-07-2020 02:54:08 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b)(6)	Query 1 : Closed	Response satisfies query
Nov-06-2020 13:05:56 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (b) (4)	Query 2 : Closed	Auto closed by Validation Check: VC_SV001_04_AN
Nov-06-2020 07:32:56 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b)(6)	Query 2 : Answered	I was instructed in a previous query to complete the FUP form. I would not have completed the FUP form had I not been erroneously instructed to do so.
Nov-06-2020 07:22:20 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b)(6)	Query 2 : Reissued: Opened	Date on DISPOSITION FOLLOW UP CRF should be the date at which subjects ends the STUDY. Date on DISPOSITION TREATMENT CRF should be the date at which subject ends the TREATMENT/STUDY DRUG. Please review and update for all dates to be in logical order.
Nov-06-2020 07:20:54 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b)(6)	Query 1 : Answered	My apologies, but I just cannot understand this run-on sentence. The subject will continue in the study per protocol, as previously indicated. Please clarify if this does not answer the query.
Nov-06-2020	ACV0PFEINFP6000	(b) (6)	Query 1	DM2: Subject discontinued

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Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 1152

Subject No: 11521476

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

00:58:13 (UTC-08:00) Pacific Time (US & Canada)		(b) (4)	: Reissued:Opened	treatment as soon as Vaccination 1 received on 25SEP2020. Please confirm if subject is in follow up status if Yes, the follow up form is not expected to enter now if not update FUP date when subject disagree to be in FUP.
Nov-05-2020 08:46:28 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b)(6)	Query 1 : Answered	The same question gets the same answer. Sorry.
Nov-05-2020 01:27:37 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b)(6)	Query 1 : Reissued:Opened	V2 DOV 15Oct2020 is after the DISPOSITION - FOLLOW-UP date 25Sep2020 under Follow-up (FUP) visit. Please correct or clarify.
Nov-04-2020 16:52:41 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b)(6)	Query 2 : Answered	What do you want here? Isn't the Date of Completion the date of the final vaccine?
Nov-04-2020 14:54:01 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (b) (4)	Query 2 : Opened	DMW5284890;'Date of Visit' is after 'Date of Completion/Discontinuation /Death' on the Disposition - Follow-up eCRF. Please clarify or correct.
Nov-04-2020 06:38:44 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b)(6)	Query 1 : Answered	Isn't the date of completion the date of the last vaccine? Even if the last vaccine was the FIRST vaccine? If not, what SHOULD it be?
Nov-04-2020 06:30:42 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1 : Opened	Date of Visit is after the Date of Completion/Discontinuation /Death on the Follow-Up Disposition form. Please review and update as appropriate.

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Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 1152

Subject No: 11521476

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

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

Oct-21-2020 19:09:08 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b)(6)	Data Entry: Oct/15/ 2020	Initial Entry
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Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 10-Oct-2020 16:01

Site No: 1152

Subject No: 11521476

Generated By: (b) (4)

Form: VITAL SIGNS - TEMP - 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. Date:

Date	Location	User	Value	Reason
Nov-05-2020 21:44:12 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b)(6)	Query 1 : Closed	Response satisfies query
Nov-05-2020 08:48:28 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b)(6)	Query 1 : Answered	Treatment ended with the first vaccine, since she had no second vaccine. The subject had not ended the study - she will continue as per protocol, only having had one vaccination.
Nov-05-2020 00:25:40 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b)(6)	Query 1 : Reissued: Opened	The date on form DISPOSITION - TREATMENT at EOT visit should be a date of when the TREATMENT ended. The date on form DISPOSITION - FOLLOW-UP at visit named FUP should be a date of when the subject ended the STUDY. Please update accordingly or clarify.
Nov-04-2020 16:52:54 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b)(6)	Query 1 : Answered	What do you want here? Isn't the Date of Completion the date of the final vaccine?
Nov-04-2020 14:54:01 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (b) (4)	Query 1 : Opened	DMW5284889;Date is after 'Date of Completion/Discontinuation /Death' on the Disposition - Follow-up eCRF. Please clarify or correct.
Oct-21-2020 19:09:57 (UTC-08:00)	ACV0PFEINFP6000	(b)(4),(b)(6)	Data Entry: Oct/15/	Initial Entry

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Header Text: c4591001

Visit: V2_VAX2_L

Form: VITAL SIGNS - TEMP - eCRF Audit Trail History

Form Version: 10-Oct-2020 16:01

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1152

Site Name: (1152) California Research Foundation

Subject No: 11521476

Subject Initials: ---

Generated By: (b) (4)

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

Pacific Time (US & Canada)			2020	
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2.a

Date	Location	User	Value	Reason
Oct-21-2020 19:09:57 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: Record Identifier:: 1 Temperature: 98.0 Temperature Unit: F Temperature Location: ORAL CAVITY n:: Y	Initial Entry

2.a Record Identifier:

Date	Location	User	Value	Reason
Oct-21-2020 19:09:57 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: 1	Initial Entry

2.a Temperature:

Date	Location	User	Value	Reason
Oct-21-2020 19:09:57 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: 98.0	Initial Entry

2.a Unit:

Date	Location	User	Value	Reason
Oct-21-2020 19:09:57 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: F	Initial Entry

2.a Temperature Location:

Date	Location	User	Value	Reason
Oct-21-2020 19:09:57 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: ORAL CAVITY	Initial Entry

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Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 15-Sep-2020 21:51

Site No: 1152

Subject No: 11521476

Generated By: (b) (4)

Form: LAB URINALYSIS - PREGNANCY TEST - 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. Lab Panel:

Date	Location	User	Value	Reason
Oct-21-2020 19:11:19 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: Not Applicable	Initial Entry

2. Lab Sub-Panel:

Date	Location	User	Value	Reason
Oct-21-2020 19:11:19 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: Not Applicable	Initial Entry

3. Collection Date:

Date	Location	User	Value	Reason
Oct-21-2020 19:11:19 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: Not Applicable	Initial Entry

4. Laboratory Name and Address (Derived)

Date	Location	User	Value	Reason
Oct-21-2020 19:11:19 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: Not Applicable	Initial Entry

5. Specimen Type:

Date	Location	User	Value	Reason
Oct-21-2020 19:11:19 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: Not Applicable	Initial Entry

6.a

Date	Location	User	Value	Reason
Oct-21-2020 19:11:19 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: Sponsor-Defined Identifier: Not Applicable Test:: Not Applicable	Initial Entry

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Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 15-Sep-2020 21:51

Site No: 1152

Subject No: 11521476

Generated By: (b) (4)

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

Form Status: Data Complete, Locked, Frozen, Verified

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			Result::	Not Applicable
			Not Done::	Not Applicable

6.a Sponsor ID:

Date	Location	User	Value	Reason
Oct-21-2020 19:11:19 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: Not Applicable	Initial Entry

6.a Test:

Date	Location	User	Value	Reason
Oct-21-2020 19:11:19 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: Not Applicable	Initial Entry

6.a Result:

Date	Location	User	Value	Reason
Oct-21-2020 19:11:19 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: Not Applicable	Initial Entry

6.a Not Done:

Date	Location	User	Value	Reason
Oct-21-2020 19:11:19 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: Not Applicable	Initial Entry

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Header Text: c4591001

Visit: V2_VAX2_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1152

Site Name: (1152) California Research Foundation

Subject No: 11521476

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-15-2020 18:19:45 (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-15-2020 18:19:45 (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
Nov-17-2020 12:45:18 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b)(6)	Query 5: Closed	Response satisfies query
Nov-17-2020 09:45:06 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b)(6)	Query 5: Answered	OK. However, if this query had been entered on line 2, where the correction was needed, it could have been answered in one step. Instead, I had to make the correction and then come back here to answer the query. DOUBLE WORK!
Nov-17-2020 04:02:51 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b)(6)	Query 5: Reissued:Opened	DM: Per completion requirement, Enter a comment in the item 'If no sample was collected or sample was not collected according to protocol, please provide reason' indicating BR920D barcode was taken in error and that the

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Header Text: c4591001

Visit: V2_VAX2_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1152

Site Name: (1152) California Research Foundation

Subject No: 11521476

Subject Initials: ---

Generated By: (b) (4)

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				sample will be destroyed.
Nov-17-2020 04:01:12 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b)(6)	Query 4: Closed	As per the update
Nov-16-2020 19:44:40 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b)(6)	Query 5: Answered	BR920D WAS SENT IN ERROR. SUBJECT VISIT 2 DELAYED UNTIL 10/29/20 WILL SUBMIT REQUEST FOR DESTRUCTION
Nov-16-2020 19:43:23 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 5: Opened	There are more than 1 barcode present for sample collection. Please review and correct as appropriate.
Nov-16-2020 19:39:37 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b)(6)	Query 4: Answered	UNFREEZE. SUBJECT'S VISIT 2 WAS DELAYED UNTIL 29 OCT 20. WILL SUBMIT REQUEST FOR DESTRUCTION FOR THIS SAMPLE
Nov-10-2020 08:21:37 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b)(6)	Query 4: Opened	HOLDS: Nasal swab BR9236 was received by the lab for Visit 2. Please review and update or submit updated SCF.
Nov-10-2020 08:21:17 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b)(6)	Query 3: Closed	re-query
Nov-10-2020 08:21:01 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b)(6)	Query 3: Opened	HOLDS: Nasal swab BR9236 was received by the lab for COVID_A. Please review and update or submit updated SCF.
Nov-03-2020 03:43:17 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b)(6)	Query 2: Closed	Response satisfies query

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Header Text: c4591001**Visit:** V2_VAX2_L**Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB - eCRF Audit Trail History**Form Version:** 22-Apr-2020 21:03**Form Status:** Data Complete, Locked, Frozen, Verified**Site No:** 1152**Site Name:** (1152) California Research Foundation**Subject No:** 11521476**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 11:56

Oct-24-2020 04:20:40 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Sandip Namdeorao Suryawanshi (b) (4)	Query 2: Reissued:Candidate	subject met delay of vaccination. Kindly verify and update data once subject completes vaccination. Thank you.
Oct-23-2020 16:05:34 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b)(6)	Query 2: Answered	That can't be completed until the participant received the vaccine
Oct-22-2020 22:56:42 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b) (6)	Query 2: Reissued:Opened	DM1: Response says completed. However still data is not updated in Vaccination form. Kindly consider to update the data in all forms under this visit. Thank you.
Oct-21-2020 19:13:32 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b)(6)	Query 2: Answered	COMPLETED
Oct-21-2020 01:50:30 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b) (6)	Query 2: Opened	DM: Kindly consider to update rest of the forms under this visit or else clarify. Thank you.
Oct-15-2020 18:19:59 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Oct-15-2020 18:19:45 (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-15-2020 18:19:45 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b)(6)	Data Entry: YES Date of Collection: Oct/15/2020	Initial Entry

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

Date	Location	User	Value	Reason
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Header Text: c4591001

Visit: V2_VAX2_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1152

Site Name: (1152) California Research Foundation

Subject No: 11521476

Subject Initials: ---

Generated By: (b) (4)

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

Nov-17-2020 09:42:53 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Data Entry: BR920D barcode was taken in error and the sample will be destroyed.	Initial Entry
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5.a

Date	Location	User	Value	Reason
Oct-15-2020 18:19:59 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: Sample ID: BR920D	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Oct-15-2020 18:19:59 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: BR920D	Initial Entry

5.b

Date	Location	User	Value	Reason
Nov-16-2020 19:43:23 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: Sample ID: BR9236	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Nov-16-2020 19:43:23 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: BR9236	Initial Entry

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Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1152

Subject No: 11521476

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-15-2020 15:01:43 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: YES Date of First Delay: Oct/15/2020 Reason(s) for Temporary Delay of Vaccination FEVER OR ACUTE ILLNESS	Initial Entry

4. Dose Date Time:

Date	Location	User	Value	Reason
Nov-06-2020 01:18:34 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b)(6)	Query 1: Closed	Response satisfies query
Nov-04-2020 16:53:45 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b)(6)	Query 1: Answered	I assume this is an auto-query, as the reason is clear if the form is reviewed.
Nov-04-2020 14:54:01 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (b) (4)	Query 1: Opened	DMW5284856;Randomization number is recorded and the final disposition date is present on the Disposition - Follow-up eCRF, but there is no dosing date present on the Treatment eCRF. Please review and update as appropriate.
Oct-28-2020 08:23:51 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b)(6)	Data Entry: : Not Done	Initial Entry

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Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1152

Subject No: 11521476

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

6. Body Side:

Date	Location	User	Value	Reason
Oct-28-2020 08:24:05 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: Not Done	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-28-2020 08:24:17 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: Not Done	Initial Entry

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 1152

Subject No: 11521476

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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I. Date of Visit

Date	Location	User	Value	Reason
Dec-04-2020 10:45:47 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: Dec/4/2020	Initial Entry

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1152

Site Name: (1152) California Research Foundation

Subject No: 11521476

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
Dec-04-2020 10:45:58 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Dec-04-2020 10:45:58 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SERUM	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Dec-04-2020 17:37:41 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Dec-04-2020 10:45:58 (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.
Dec-04-2020 10:45:58 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: YES Date of Collection: Dec/4/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Dec-04-2020 17:37:41 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: Sample ID: BRJN97	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Dec-04-2020 17:37:41	ACV0PFEINFP6000	(b) (6)	Data Entry:	Initial Entry

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Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1152

Site Name: (1152) California Research Foundation

Subject No: 11521476

Subject Initials: ---

Generated By: (b) (4)

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

(UTC-08:00) Pacific Time (US & Canada)		(b)(4), (b)(6)	BRJN97	
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5.b

Date	Location	User	Value	Reason
Dec-04-2020 17:37:52 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: Sample ID: BRJN98	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Dec-04-2020 17:37:52 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: BRJN98	Initial Entry

5.c

Date	Location	User	Value	Reason
Dec-04-2020 17:38:17 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: Sample ID: BS6K7D	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Dec-04-2020 17:38:17 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: BS6K7D	Initial Entry

090177e196ae2fcd\Final\Final On: 01-Apr-2021 03:52 (GMT)

Header Text: c4591001

Visit: Unplanned 1 - Unscheduled Visit on Oct/29/2020

Form: DATE OF VISIT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1152

Site Name: (1152) California Research Foundation

Subject No: 11521476

Subject Initials: ---

Generated By: (b) (4)

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

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I. Date of Visit

Date	Location	User	Value	Reason
Nov-07-2020 03:22:36 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Sandip Namdeorao Suryawanshi (b) (4)	Query 1 : Closed	closed as data is removed from Disposition follow up.
Nov-06-2020 07:27:42 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b)(6)	Query 1 : Answered	Some previous query told me to complete the FUP form, so I did. Apparently that instruction was incorrect. I would not have completed that eCRF had I not been erroneously instructed to do so.
Nov-06-2020 07:12:04 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b)(6)	Query 1 : Reissued: Opened	Date on DISPOSITION FOLLOW UP CRF should be the date at which subjects ends the STUDY. Date on DISPOSITION TREATMENT CRF should be the date at which subject ends the TREATMENT/STUDY DRUG. Please review and update for all dates to be in logical order.
Nov-05-2020 00:00:40 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b)(6)	Query 2 : Closed	Related query present
Nov-04-2020 16:54:17 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b)(6)	Query 2 : Answered	What do you want here? Isn't the Date of Completion the date of the final vaccine?
Nov-04-2020	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY	Query 2	DMW5284891;'Date of

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Header Text: c4591001

Visit: Unplanned 1 - Unscheduled Visit on Oct/29/2020

Form: DATE OF VISIT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1152

Site Name: (1152) California Research Foundation

Subject No: 11521476

Subject Initials: ---

Generated By: (b) (4)

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

14:54:01 (UTC-08:00) Pacific Time (US & Canada)		(b) (4)	: Opened	Visit' is after 'Date of Completion/Discontinuation /Death' on the Disposition - Follow-up eCRF. Please clarify or correct.
Nov-04-2020 06:38:15 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b)(6)	Query 1 : Answered	Isn't the date of completion the date of the last vaccine? Even if the last vaccine was the FIRST vaccine? If not, what SHOULD it be?
Nov-04-2020 06:30:42 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1 : Opened	Date of Visit is after the Date of Completion/Discontinuation /Death on the Follow-Up Disposition form. Please review and update as appropriate.
Nov-03-2020 06:59:29 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b)(6)	Data Entry: Oct/29/ 2020	Initial Entry

090177e196ae2fcd\Final\Final On: 01-Apr-2021 03:52 (GMT)

Header Text: c4591001

Visit: Unplanned 1 - Unscheduled Visit on
Oct/29/2020

Form: UNPLANNED VISIT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1152

Site Name: (1152) California Research Foundation

Subject No: 11521476

Subject Initials: ---

Generated By: (b) (4)

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

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I. Assessments

Date	Location	User	Value	Reason
Nov-03-2020 07:03:16 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Nov-03-2020 06:59:41 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Contact Outcome is ticked however 'CONTACT OUTCOME' form is not entered. Please review and update as appropriate.
Nov-03-2020 06:59:41 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: CONTACT OUTCOME	Initial Entry

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Header Text: c4591001

Visit: Unplanned 1 - Unscheduled Visit on Oct/29/2020

Form: CONTACT OUTCOME - UNPLANNED - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1152

Site Name: (1152) California Research Foundation

Subject No: 11521476

Subject Initials: ---

Generated By: (b) (4)

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

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1. Contact Type:

Date	Location	User	Value	Reason
Nov-03-2020 07:02:36 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: TELEPHONE VISIT	Initial Entry

2. Was contact made?

Date	Location	User	Value	Reason
Nov-04-2020 21:50:25 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Query 2: Closed	Vitals updated
Nov-04-2020 06:27:42 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Query 2: Answered	Please review, as this query is incorrect.
Nov-04-2020 04:10:41 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Query 2: Opened	PDQ : Contact Outcome' is selected as 'VISIT ARRANGED' but no 'VITAL SIGNS' and/or 'UNPLANNED ASSESSMENT OF LOCAL REACTION' form(s) is/are entered. Please review and update as appropriate.
Nov-03-2020 07:03:16 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Nov-03-2020 07:03:16 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: YES Date of Contact: Oct/29/2020 Contact Outcome: VISIT ARRANGED	New Information
Nov-03-2020 07:02:36 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Candidate	Contact Outcome' is selected as 'VISIT ARRANGED' but no

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Header Text: c4591001

Visit: Unplanned 1 - Unscheduled Visit on Oct/29/2020

Form: CONTACT OUTCOME - UNPLANNED - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1152

Site Name: (1152) California Research Foundation

Subject No: 11521476

Subject Initials: ---

Generated By: (b) (4)

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

				'VITAL SIGNS' and/or 'UNPLANNED ASSESSMENT OF LOCAL REACTION' form(s) is/are entered. Please review and update as appropriate.
Nov-03-2020 07:02:36 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	Response to "Date of Contact" is missing.
Nov-03-2020 07:02:36 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: YES Contact Outcome: VISIT ARRANGED	Initial Entry

3. Comments:

Date	Location	User	Value	Reason
Nov-03-2020 07:02:36 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: Visit 2 vaccine was delayed. Subject r eturned for rescheduled Visit 2 today. Second vaccine was canceled by sub- I.	Initial Entry

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Header Text: c4591001

Visit: Unplanned 1 - Unscheduled Visit on Oct/29/2020

Form: VITAL SIGNS - TEMP - eCRF Audit Trail History

Form Version: 10-Oct-2020 16:01

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1152

Site Name: (1152) California Research Foundation

Subject No: 11521476

Subject Initials: ---

Generated By: (b) (4)

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

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I. Date:

Date	Location	User	Value	Reason
Nov-06-2020 13:05:37 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (b) (4)	Query 1 : Closed	Auto closed by Validation Check: VC_VS001_05_AN
Nov-05-2020 08:50:15 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b)(6)	Query 1 : Answered	The same question gets the same answer. Sorry.
Nov-04-2020 22:00:32 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b)(6)	Query 1 : Reissued: Opened	DM : Date of Completion/Discontinuation /Death (25/Sep/2020) on EOT is prior to Date of visit (5/Sep/2020) on VITAL TEMP CRF. Please review and update. Else, clarify.
Nov-04-2020 16:54:50 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b)(6)	Query 1 : Answered	What do you want here? Isn't the Date of Completion the date of the final vaccine?
Nov-04-2020 14:54:01 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (b) (4)	Query 1 : Opened	DMW5284888;Date is after 'Date of Completion/Discontinuation /Death' on the Disposition - Follow-up eCRF. Please clarify or correct.
Nov-03-2020 07:03:54 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b)(6)	Data Entry: Oct/29/ 2020	Initial Entry

2.a

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Header Text: c4591001

Visit: Unplanned 1 - Unscheduled Visit on Oct/29/2020

Form: VITAL SIGNS - TEMP - eCRF Audit Trail History

Form Version: 10-Oct-2020 16:01

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1152

Site Name: (1152) California Research Foundation

Subject No: 11521476

Subject Initials: ---

Generated By: (b) (4)

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

Date	Location	User	Value	Reason
Nov-03-2020 07:03:54 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: Record Identifier:: 1 Temperature: 98.5 Temperature Unit: F Temperature Location:: ORAL CAVITY	Initial Entry

2.a Record Identifier:

Date	Location	User	Value	Reason
Nov-03-2020 07:03:54 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: 1	Initial Entry

2.a Temperature:

Date	Location	User	Value	Reason
Nov-03-2020 07:03:54 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: 98.5	Initial Entry

2.a Unit:

Date	Location	User	Value	Reason
Nov-03-2020 07:03:54 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: F	Initial Entry

2.a Temperature Location:

Date	Location	User	Value	Reason
Nov-03-2020 07:03:54 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: ORAL CAVITY	Initial Entry

090177e196ae2fcd\Final\Final On: 01-Apr-2021 03:52 (GMT)

Header Text: c4591001**Visit:** Unplanned 1 - Unscheduled Visit on Oct/29/2020**Form Version:** 10-Oct-2020 15:57**Site No:** 1152**Subject No:** 11521476**Generated By:** (b) (4)**Form:** UNPLANNED ASSESSMENT OF LOCAL REACTION - SYSTEMIC EVENT - 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. Date of Assessment:**

Date	Location	User	Value	Reason
Nov-05-2020 08:57:21 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Query 1: Closed	Close per query response
Nov-04-2020 06:29:37 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b)(6)	Query 1: Answered	Subject did not receive a vaccine at this visit, so how can it be anything but "Not Applicable"? What SHOULD be entered here if this is not applicable?
Nov-03-2020 21:05:32 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (b) (4)	Query 1: Opened	DMW5269439;Date of Assessment is not expected to be Unknown or Not Applicable. Please review and update appropriately or clarify
Nov-03-2020 07:04:17 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b)(6)	Data Entry: Not Applicable	Initial Entry

2. Injection Site Location

Date	Location	User	Value	Reason
Nov-03-2020 07:04:17 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: Not Applicable	Initial Entry

3. Injection Site Body Side:

Date	Location	User	Value	Reason
Nov-03-2020 07:04:17 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: Not Applicable	Initial Entry

Header Text: c4591001

Visit: Unplanned 1 - Unscheduled Visit on Oct/29/2020

Form: UNPLANNED ASSESSMENT OF LOCAL REACTION - SYSTEMIC EVENT - eCRF Audit Trail History

Form Version: 10-Oct-2020 15:57

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1152

Site Name: (1152) California Research Foundation

Subject No: 11521476

Subject Initials: ---

Generated By: (b) (4)

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

4.a

Date	Location	User	Value	Reason
Nov-03-2020 07:04:17 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: Reaction:: Not Applicable Reaction Present:: Not Applicable	Initial Entry

4.a Reaction:

Date	Location	User	Value	Reason
Nov-03-2020 07:04:17 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: Not Applicable	Initial Entry

4.a Reaction Present:

Date	Location	User	Value	Reason
Nov-03-2020 07:04:17 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: Not Applicable	Initial Entry

4.b

Date	Location	User	Value	Reason
Nov-03-2020 07:04:17 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: Reaction:: Not Applicable Reaction Present:: Not Applicable	Initial Entry

4.b Reaction:

Date	Location	User	Value	Reason
Nov-03-2020 07:04:17 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: Not Applicable	Initial Entry

4.b Reaction Present:

Date	Location	User	Value	Reason
Nov-03-2020 07:04:17 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: Not Applicable	Initial Entry

5.a

Date	Location	User	Value	Reason
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090177e196ae2fcd\Final\Final On: 01-Apr-2021 03:52 (GMT)

Header Text: c4591001

Visit: Unplanned 1 - Unscheduled Visit on Oct/29/2020

Form: UNPLANNED ASSESSMENT OF LOCAL REACTION - SYSTEMIC EVENT - eCRF Audit Trail History

Form Version: 10-Oct-2020 15:57

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1152

Site Name: (1152) California Research Foundation

Subject No: 11521476

Subject Initials: ---

Generated By: (b) (4)

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

Nov-03-2020 07:04:17 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: Symptom:: Not Applicable Symptom Present:: Not Applicable	Initial Entry
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5.a Symptom:

Date	Location	User	Value	Reason
Nov-03-2020 07:04:17 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: Not Applicable	Initial Entry

5.a Symptom Present:

Date	Location	User	Value	Reason
Nov-03-2020 07:04:17 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: Not Applicable	Initial Entry

5.b

Date	Location	User	Value	Reason
Nov-03-2020 07:04:17 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: Symptom:: Not Applicable Symptom Present:: Not Applicable	Initial Entry

5.b Symptom:

Date	Location	User	Value	Reason
Nov-03-2020 07:04:17 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: Not Applicable	Initial Entry

5.b Symptom Present:

Date	Location	User	Value	Reason
Nov-03-2020 07:04:17 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: Not Applicable	Initial Entry

5.c

Date	Location	User	Value	Reason
Nov-03-2020 07:04:17 (UTC-08:00) Pacific Time	ACV0PFEINFP6000	(b) (6)	Data Entry: Symptom:: Not Applicable	Initial Entry

090177e196ae2fcd\Final\Final On: 01-Apr-2021 03:52 (GMT)

Header Text: c4591001

Visit: Unplanned 1 - Unscheduled Visit on Oct/29/2020

Form: UNPLANNED ASSESSMENT OF LOCAL REACTION - SYSTEMIC EVENT - eCRF Audit Trail History

Form Version: 10-Oct-2020 15:57

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1152

Site Name: (1152) California Research Foundation

Subject No: 11521476

Subject Initials: ---

Generated By: (b) (4)

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

(US & Canada)		(b) (4)	Symptom Present:: Not Applicable	
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5.c Symptom:

Date	Location	User	Value	Reason
Nov-03-2020 07:04:17 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	<u>Data Entry:</u> Not Applicable	Initial Entry

5.c Symptom Present:

Date	Location	User	Value	Reason
Nov-03-2020 07:04:17 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	<u>Data Entry:</u> Not Applicable	Initial Entry

5.d

Date	Location	User	Value	Reason
Nov-03-2020 07:04:17 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	<u>Data Entry:</u> <u>Symptom::</u> Not Applicable <u>Symptom Present::</u> Not Applicable	Initial Entry

5.d Symptom:

Date	Location	User	Value	Reason
Nov-03-2020 07:04:17 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	<u>Data Entry:</u> Not Applicable	Initial Entry

5.d Symptom Present:

Date	Location	User	Value	Reason
Nov-03-2020 07:04:17 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	<u>Data Entry:</u> Not Applicable	Initial Entry

5.e

Date	Location	User	Value	Reason
Nov-03-2020 07:04:17 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	<u>Data Entry:</u> <u>Symptom::</u> Not Applicable <u>Symptom Present::</u> Not Applicable	Initial Entry

090177e196ae2fcd\Final\Final On: 01-Apr-2021 03:52 (GMT)

Header Text: c4591001

Visit: Unplanned 1 - Unscheduled Visit on Oct/29/2020

Form: UNPLANNED ASSESSMENT OF LOCAL REACTION - SYSTEMIC EVENT - eCRF Audit Trail History

Form Version: 10-Oct-2020 15:57

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1152

Site Name: (1152) California Research Foundation

Subject No: 11521476

Subject Initials: ---

Generated By: (b) (4)

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

5.e Symptom:

Date	Location	User	Value	Reason
Nov-03-2020 07:04:17 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: Not Applicable	Initial Entry

5.e Symptom Present:

Date	Location	User	Value	Reason
Nov-03-2020 07:04:17 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: Not Applicable	Initial Entry

5.f

Date	Location	User	Value	Reason
Nov-03-2020 07:04:17 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: Symptom:: Not Applicable Symptom Present:: Not Applicable	Initial Entry

5.f Symptom:

Date	Location	User	Value	Reason
Nov-03-2020 07:04:17 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: Not Applicable	Initial Entry

5.f Symptom Present:

Date	Location	User	Value	Reason
Nov-03-2020 07:04:17 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: Not Applicable	Initial Entry

5.g

Date	Location	User	Value	Reason
Nov-03-2020 07:04:17 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: Symptom:: Not Applicable Symptom Present:: Not Applicable	Initial Entry

090177e196ae2fcd\Final\Final On: 01-Apr-2021 03:52 (GMT)

Header Text: c4591001

Visit: Unplanned 1 - Unscheduled Visit on
Oct/29/2020

Form Version: 10-Oct-2020 15:57

Site No: 1152

Subject No: 11521476

Generated By: (b) (4)

Form: UNPLANNED ASSESSMENT OF LOCAL REACTION - SYSTEMIC
EVENT - 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

5.g Symptom:

Date	Location	User	Value	Reason
Nov-03-2020 07:04:17 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: Not Applicable	Initial Entry

5.g Symptom Present:

Date	Location	User	Value	Reason
Nov-03-2020 07:04:17 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: Not Applicable	Initial Entry

5.h

Date	Location	User	Value	Reason
Nov-03-2020 07:04:17 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: Symptom:: Not Applicable Symptom Present:: Not Applicable	Initial Entry

5.h Symptom:

Date	Location	User	Value	Reason
Nov-03-2020 07:04:17 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: Not Applicable	Initial Entry

5.h Symptom Present:

Date	Location	User	Value	Reason
Nov-03-2020 07:04:17 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: Not Applicable	Initial Entry

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Generated By: (b) (4)

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Date	Location	User	Value	Reason
Oct-16-2020 12:15:08 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Form Created	

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1. Category:

Date	Location	User	Value	Reason
Oct-16-2020 12:15:08 (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
Oct-16-2020 12:15:08 (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
Feb-07-2021 13:41:18 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Query 2: Closed	Response satisfies query
Feb-05-2021 16:31:23 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Query 2: Answered	CONFIRMED NO PAST HISTORY OF SAME.
Feb-05-2021 08:17:55 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Query 2: Opened	clinical: pls confirm subject has no past history of hearing loss, episodes of hearing loss or other ear problems or update MedHx CRF accordingly. Thanks
Feb-02-2021 14:25:07 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Query 1: Closed	Response satisfies query
Feb-02-2021 14:08:06 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Query 1: Answered	60 MG QD FOR 7 DAYS.
Feb-02-2021 06:48:00 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Query 1: Reissued:Opened	clinical: Thanks, what dose and duration of prednisone was given?
Feb-01-2021 14:55:00 (UTC-08:00) Pacific Time	ACV0PFEINFP6000	(b)(6)	Query 1: Answered	THIS IS BASED ON SUBJECT SELF

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(US & Canada)		(b) (4)		REPORT. PREDNISONE WAS GIVEN.
Feb-01-2021 05:19:41 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Query 1: Reissued:Opened	clinical: thanks, but pls confirm hearing back to normal and if this is based on audiometry results or subject self report. What treatment did subject receive?
Jan-30-2021 14:54:50 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Query 1: Answered	RESOLVED. THANK YOU.
Jan-25-2021 05:17:21 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Query 1: Opened	clinical: pls confirm hearing is back to normal, advise if audiometry done and if so what were the results. Advise what treatment the subject received. Thanks.
Oct-16-2020 12:15:08 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: hearing loss right ear	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason
Nov-06-2020 12:41:12 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (b) (4)	Query 2 : Closed	Auto closed by Validation Check: VC_AE001_09_AN
Nov-06-2020 07:23:47 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b)(6)	Query 2 : Answered	Subject discontinued study treatment, but did not discontinue from study follow-up. Another query told me to enter information on the FUP form. Was that incorrect?
Nov-06-2020 02:49:11 (UTC-08:00)	ACV0PFEINFP6000	(b)(4),(b)(6)	Query 2 : Reissued:Opened	Please review date at which subject discontinued the study on FUP

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Pacific Time (US & Canada)			ned	DISPOSITION CRF (currently 25Sep2020), as it occurs before this AE start date (currently 14Oct2020). And correct, or clarify.
Nov-05-2020 21:45:46 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b)(6)	Query 1 : Closed	Response satisfies query
Nov-05-2020 08:49:35 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b)(6)	Query 2 : Answered	The same question gets the same answer. Sorry.
Nov-05-2020 08:49:17 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b)(6)	Query 1 : Answered	The same question gets the same answer. Sorry.
Nov-04-2020 22:04:10 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b)(6)	Query 1 : Reissued: Opened	DM : Date of Completion/Discontinuation/Death (25/Sep/2020) on EOT is prior to AE Start Date (14/Oct/2020). Please review and update. Else, clarify. Kindly contact CRA for further assistance.
Nov-04-2020 22:02:20 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b)(6)	Query 2 : Reissued: Opened	DM : Date of Completion/Discontinuation/Death (25/Sep/2020) on EOT is prior to AE Start Date (14/Oct/2020). Please review and update. Else, clarify.
Nov-04-2020 16:50:35 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b)(6)	Query 2 : Answered	What do you want here? Isn't the Date of Completion the date of the final vaccine?
Nov-04-2020	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY	Query 2	DMW5284868;Start Date'

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14:37:37 (UTC-08:00) Pacific Time (US & Canada)		(b) (4)	: Opened	is after 'Date of Completion/Discontinuation /Death' on the Disposition - Follow-up eCRF. Please clarify or correct.
Nov-04-2020 06:36:24 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b)(6)	Query 1 : Answered	Shouldn't the date of completion be the date of the last vaccine? Even if the last vaccine is the ONLY vaccine? If not, what SHOULD it be?
Nov-04-2020 03:23:20 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b)(6)	Query 1 : Reissued: Opened	DM : Date of Completion/Discontinuation /Death on EOT (25/Sep /2020) is prior to the AE Start Date (14/Oct/2020). Please review and update the data as appropriate. Else,clarify.
Nov-02-2020 07:12:27 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b)(6)	Query 1 : Answered	Please read previous answer. You have asked the exact same question, and thus, the same answer is still correct.
Nov-02-2020 05:27:35 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Query 1 : Reissued: Opened	DM: The Latest Action to Study Treatment is DRUG WITHDRAWN, but the Start Date (14/Oct/2020) of this AE is AFTER the Date of Completion/Discontinuation /Death (25/Sep/2020) on Disposition-Treatment Form. Please review and update as appropriate.
Oct-30-2020 08:35:15 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b)(6)	Query 1 : Answered	What? The subject was discontinued = no second vaccine, due to the AE. So the last vaccine was the first vaccine. How else should this be recorded?
Oct-30-2020 00:42:08 (UTC-08:00) Pacific Time	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (b) (4)	Query 1 : Opened	DMW5220375;The Latest Action to Study Treatment is DRUG WITHDRAWN, but the Start Date of this AE

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(US & Canada)				is AFTER the Date of Completion/Discontinuation /Death on Disposition-Treatment Form. Please review and update as appropriate.
Oct-16-2020 12:15:08 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b)(6)	Data Entry: Oct/14/2020 U NK:UNK	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Nov-06-2020 13:05:17 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (b) (4)	Query 3 : Closed	Auto closed by Validation Check: VC_AE001_10_AN
Nov-04-2020 16:51:11 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b)(6)	Query 3 : Answered	I answered this on that form, more than once. What do you want here? Isn't the Date of Completion the date of the final vaccine?
Nov-04-2020 14:54:01 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (b) (4)	Query 3 : Opened	DMW5284850; 'End Date' is after 'Date of Completion/Discontinuation /Death' on the Disposition - Follow-up eCRF. Please clarify or correct.
Nov-01-2020 10:30:26 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b)(6)	Query 2 : Closed	clinical: Thanks
Oct-31-2020 13:55:44 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b)(6)	Query 2 : Answered	YES. THE SUBJECT WAS ON DISABILITY ONLY FOR HER HEARING LOSS.

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Oct-31-2020 09:48:04 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Query 2 : Reissu ed:Ope ned	clinical: please confirm the short term disability was specifically due to hearing loss and no other issue. Thanks
Oct-30-2020 16:34:40 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b)(6)	Query 2 : Answ red	Yes, this was short term disability. We are waiting on medical records.
Oct-29-2020 06:25:49 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Query 2 : Reissu ed:Ope ned	clinical: Pls confirm reason for disability was because of hearing loss and advise if this was short term disability since hearing restored. Pls also advise what specific testing done to document hearing loss/recovery ie audiometry. Thanks
Oct-28-2020 17:23:03 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b)(6)	Query 2 : Answ red	Yes. Subject has her hearing restored
Oct-28-2020 06:21:14 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Query 2 : Opene d	clinical: pls confirm hearing loss has completely resolved. Thanks
Oct-26-2020 11:16:59 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b)(6)	Data E ntry: NO End D ate Ti me: Oct/ 23/2 020 UN K:U NK	New Information

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Oct-26-2020 06:27:37 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b)(6)	Query 1 : Closed	Response satisfies query
Oct-23-2020 16:07:58 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b)(6)	Query 1 : Answered	Yes. She is improving but still on disability. Will update when resolved
Oct-21-2020 12:00:46 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b)(6)	Query 1 : Opened	ClinQuery: Please verify if Hearing Loss Right Ear is ongoing, then update the END DATE and OUTCOME as appropriate.
Oct-16-2020 12:15:08 (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
Oct-16-2020 12:15:08 (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
Oct-16-2020 12:15:08 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: NO	Initial Entry

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

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

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Date	Location	User	Value	Reason
Oct-16-2020 12:15:08 (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
Oct-27-2020 06:22:54 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Juleen Gayed (b) (4)	Query 2: Closed	Response satisfies query
Oct-26-2020 12:00:46 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Query 2: Answered	The PI feels the IP may have cause the inflammatory reaction. He can't rule it out

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9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Oct-26-2020 08:16:58 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Juleen Gayed (b) (4)	Query 2: Opened	Clin: Please confirm if you have received more information to clarify if this is still considered related
Oct-26-2020 06:19:48 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Query 1: Closed	Response satisfies query
Oct-23-2020 16:06:40 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Query 1: Answered	This could be a delayed immune response. We are waiting for more information from her doctor before the PI can say it is not related.
Oct-21-2020 12:03:55 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Query 1: Opened	ClinQuery: Causality is noted as Related to Study Treatment. However Study Treatment was given more than 2 weeks prior to this AE. Please confirm if this AE is truly related to study treatment, then update the CRF accordingly.
Oct-16-2020 12:15:08 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: RELATED	Initial Entry

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Oct-29-2020 11:35:29 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Query 1: Closed	Response satisfies query
Oct-29-2020 07:52:50 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Query 1: Answered	OK. Thank you.

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Oct-29-2020 07:07:06 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Query 1: Opened	ClinQuery: Since Drug Withdrawn is marked, please complete the EOT CRF as appropriate.
Oct-26-2020 12:01:03 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: DRUG WITHDRAWN	New Information
Oct-16-2020 12:15:08 (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
Jan-30-2021 14:55:29 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: YES	Changed Information
Oct-16-2020 12:15:08 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: NO	Initial Entry

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Oct-16-2020 12:15:08 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: NO	Initial Entry

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

Date	Location	User	Value	Reason
Oct-26-2020 11:17:17 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Oct-26-2020 11:17:17 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: RECOVERED/RESOLVED	New Information
Oct-26-2020 11:16:59 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	For AE hearing loss right ear: Response to "What was the outcome of this adverse event?" is 'Not Recovered/Not

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				Resolved' but AE End Date/Time is present.
Oct-16-2020 12:15:08 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: NOT RECOVERED/NOT RESOLVED	Initial Entry

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

Date	Location	User	Value	Reason
Nov-16-2020 12:31:55 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Query 2: Closed	Response satisfies query
Nov-16-2020 06:43:01 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Answered	OK. I hope this does not result in more and more queries . . .
Nov-16-2020 06:43:01 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b)(6)	Data Entry: NO	OK. I hope this does not result in more and more queries . . .
Nov-14-2020 06:47:28 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Query 2: Reissued:Opened	IF the subject did NOT discontinue the study, then question "Did the adverse event cause the subject to be discontinued from the study?" should be NO. Please update response.
Nov-12-2020 13:13:17 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Query 2: Reissued:Candidate	Sent to Triad team to review.
Nov-11-2020 06:33:36 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b)(6)	Query 2: Answered	Please read previous response. I am not going to complete the FUP form again only to be told to remove it because the subject did NOT DISCONTINUE THE STUDY. I believe the query is WRONG. Please review.
Nov-11-2020 01:55:48	ACV0PFEINFP6000	(b) (6)	Query 2: Reissued:Opened	DM: As response to

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(UTC-08:00) Pacific Time (US & Canada)		(b) (4)		Did the adverse event cause the subject to be discontinued from the study?' is marked as YES. Therefore, please complete disposition follow up CRF with the reason indicating as adverse event. Thank you.
Nov-10-2020 10:17:43 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b)(6)	Query 2: Answered	I already did that and then had to change it. I entered yes here due to the previous query. I will not change this over and over, so please decide how this should be done and I will do that one last time. Thank you.
Nov-09-2020 23:14:38 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Balaji Prabu R (b) (4)	Query 2: Opened	Did the adverse event cause the subject to be discontinued from the study? is marked as YES, hence please complete disposition follow up CRF with the reason indicating as adverse event. If subject not discontinued from study due to this AE, update to NO
Nov-09-2020 23:12:51 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Balaji Prabu R (b) (4)	Query 1: Closed	Invalid query, new query raised
Nov-07-2020 05:30:58 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Query 1: Reissued:Candidate	Please review and action as appropriate.
Nov-05-2020 08:52:41 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b)(6)	Query 1: Answered	Isn't the end of treatment the day of the last vaccination if subject did not have a second vaccine? I don't know what to enter here.

090177e196ae2fcd\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: 11521476

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

<p>Nov-05-2020 00:06:06 (UTC-08:00) Pacific Time (US & Canada)</p>	<p>ACV0PFEINFP6000</p>	<p>(b)(4),(b)(6)</p>	<p>Query 1: Reissued:Opened</p>	<p>You are welcome. Please check date entered on FUP DISPOSITION CRF (currently 25Sep2020) as it doesn't correspond to the AE dates (currently 14Oct2020). And correct, or clarify.</p>
<p>Nov-04-2020 06:34:17 (UTC-08:00) Pacific Time (US & Canada)</p>	<p>ACV0PFEINFP6000</p>	<p>(b)(4),(b)(6)</p>	<p>Query 1: Answered</p>	<p>OK. Thank you. It is very helpful to list the NAME of the eCRF as it is listed in the header. Until the page is opened, you don't see the the actual eCRF name if it is different. (I.E.: DISPOSITION - FOLLOW-UP only shows up as FUP in the header.)</p>
<p>Nov-04-2020 00:33:03 (UTC-08:00) Pacific Time (US & Canada)</p>	<p>ACV0PFEINFP6000</p>	<p>(b)(4),(b)(6)</p>	<p>Query 1: Reissued:Opened</p>	<p>AE start date is after DISPOSITION - TREATMENT date, hence DISPOSITION - FOLLOW-UP under Follow-up (FUP) visit is required. If the Participant, discontinues after the treatment period, select the status accordingly.</p>
<p>Nov-03-2020 05:47:45 (UTC-08:00) Pacific Time (US & Canada)</p>	<p>ACV0PFEINFP6000</p>	<p>(b)(4),(b)(6)</p>	<p>Query 1: Answered</p>	<p>I don't find any forms with the names you list here. However, the EOT page is completed with AE listed as the reason, so this query is incorrect. If there is another page we need to complete, please indicate the actual name of the page.</p>

090177e196ae2fcd\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: 11521476

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

Nov-03-2020 03:46:29 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b)(6)	Query 1: Opened	'Did the adverse event cause the subject to be discontinued from the study?' is Yes but neither DISPOSITION - TREATMENT form nor DISPOSITION - FOLLOW-UP has Status as "ADVERSE EVENT". Please review and update as appropriate.
Oct-29-2020 07:54:49 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Did the adverse event cause the subject to be discontinued from the study?' is Yes but neither DISPOSITION - TREATMENT form nor DISPOSITION - FOLLOW-UP has Status as "ADVERSE EVENT". Please review and update as appropriate.
Oct-29-2020 07:54:49 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b)(6)	<u>Data Entry:</u> YES	New Information
Oct-16-2020 12:15:08 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b)(6)	<u>Data Entry:</u> NO	Initial Entry

090177e196ae2fcd\Final\Final On: 01-Apr-2021 03:52 (GMT)

Header Text: c4591001

Visit: End of Treatment - Unscheduled

Form: DISPOSITION - TREATMENT - eCRF Audit Trail History

Form Version: 15-Sep-2020 21:55

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1152

Site Name: (1152) California Research Foundation

Subject No: 11521476

Subject Initials: ---

Generated By: (b) (4)

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

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I. Date of Completion/Discontinuation/Death :

Date	Location	User	Value	Reason
Nov-13-2020 03:36:35 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Query 3: Closed	Response satisfies query
Nov-12-2020 14:35:25 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 3: Answered	Changed Information
Nov-12-2020 14:35:25 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b)(6)	Data Entry: Oct/15/2020	Changed Information
Nov-12-2020 09:24:40 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Query 3: Opened	EOT DISCONTINUATION DATE must be relative to AE that caused withdrawal of study vaccine & since AE start=14OCT2020 & end=23OCT2020, EOT DISCONTINUATION DATE must be within that time period. Please refer to source related to AE then adjust date accordingly
Nov-12-2020 09:17:33 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Query 2: Closed	Will re-write a clearer query.
Nov-11-2020 06:28:08 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b)(6)	Query 2: Answered	I would be happy to comply if I could.
Nov-10-2020 23:56:58 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Query 1: Closed	Response satisfies query
Nov-10-2020 19:54:23 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Query 2: Opened	The discontinuation date of 25SEP2020 should be relative to the AE causing the the withdrawal of the study vaccine, AE start 14OCT2020 and end

090177e196ae2fcd\Final\Final On: 01-Apr-2021 03:52 (GMT)

Header Text: c4591001

Visit: End of Treatment - Unscheduled

Form: DISPOSITION - TREATMENT - eCRF Audit Trail History

Form Version: 15-Sep-2020 21:55

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1152

Site Name: (1152) California Research Foundation

Subject No: 11521476

Subject Initials: ---

Generated By: (b) (4)

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

				23OCT2020 (date should not be after the AE ended). Please adjust Discontinuation date.
Nov-10-2020 17:43:55 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b)(6)	Query 1: Answered	Well, I can't change this anyway.
Nov-10-2020 15:37:02 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Query 1: Opened	Since Subject discontinued from treatment due to Adverse Event, the date of discontinuation should be between start date and prior to stop date of Adverse Event causing the discontinuation. Please update accordingly.
Oct-29-2020 07:54:04 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b)(6)	Data Entry: Sep/25/2020	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Oct-29-2020 07:54:04 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: VACCINATION	Initial Entry

3. Status:

Date	Location	User	Value	Reason
Nov-12-2020 08:41:39 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Query 2: Closed	Response satisfies query
Nov-11-2020 06:30:13 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b)(6)	Query 2: Answered	I was told to do this for another subject and than was told the FUP form is only completed if the subject discontinues the STUDY. I will not go round and round with this again. I believe this query is

090177e196ae2fcd\Final\Final On: 01-Apr-2021 03:52 (GMT)

Header Text: c4591001

Visit: End of Treatment - Unscheduled

Form: DISPOSITION - TREATMENT - eCRF Audit Trail History

Form Version: 15-Sep-2020 21:55

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1152

Site Name: (1152) California Research Foundation

Subject No: 11521476

Subject Initials: ---

Generated By: (b) (4)

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

				INCORRECT. Please review.
Nov-10-2020 22:24:39 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b)(6)	Query 2: Reissued:Opened	Please confirm if subject treatment is discontinued early due to AE. If yes, kindly updated FUP disposition CRF accordingly. Or clarify.
Nov-10-2020 17:41:58 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b)(6)	Query 2: Answered	Subject did NOT discontinue the study. Only discontinued receiving second vaccine.
Nov-10-2020 15:40:47 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Query 2: Opened	Since Subject discontinued from study per adverse event, the FUP page needs to be completed with the same information then the End of Treatment page (discontinuation date should be between start date and prior to stop date of AE). Thank You!
Oct-29-2020 07:54:49 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Oct-29-2020 07:54:04 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	Status is reported as Adverse Event, but there is no Adverse Event with 'Did the adverse event cause the subject to be discontinued from the study' reported as YES. Please check and correct the data.
Oct-29-2020 07:54:04 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b)(6)	Data Entry: ADVERSE EVENT	Initial Entry

090177e196ae2fcd\Final\Final On: 01-Apr-2021 03:52 (GMT)

Header Text: c4591001

Visit: V201_SURVEIL_CONSENT - Unscheduled **Form:** DATE OF VISIT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen, Verified

Site No: 1152

Site Name: (1152) California Research Foundation

Subject No: 11521476

Subject Initials: ---

Generated By: (b) (4)

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

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I. Date of Visit

Date	Location	User	Value	Reason
Feb-23-2021 09:48:16 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Data Entry: Feb/23/2021	Initial Entry

Header Text: c4591001

Visit: V201_SURVEIL_CONSENT - Unscheduled **Form:** INFORMED CONSENT - ASYMPTOMATIC SURVEILLANCE - eCRF Audit Trail History

Form Version: 14-Jan-2021 02:29

Form Status: Data Complete, Frozen, Verified

Site No: 1152

Site Name: (1152) California Research Foundation

Subject No: 11521476

Subject Initials: ---

Generated By: (b) (4)

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

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I. Consent Was:

Date	Location	User	Value	Reason
Feb-23-2021 09:48:27 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Data Entry: OBTAINED Date Written Consent Obtained Feb/23/2021	Initial Entry

Header Text: c4591001
Visit: V201_SURVEIL_CONSENT - Unscheduled **Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - 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: 11521476 **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
Feb-23-2021 09:48:39 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type				
Date	Location	User	Value	Reason
Feb-23-2021 09:48:39 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SERUM	Initial Entry

3. Sample Collected?				
Date	Location	User	Value	Reason
Feb-23-2021 20:16:51 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Feb-23-2021 09:48:39 (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.
Feb-23-2021 09:48:39 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Data Entry: YES Date of Collection: Feb/23/2021	Initial Entry

5.a				
Date	Location	User	Value	Reason
Feb-23-2021 20:16:51 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: Sample ID: BRCMZZ	Initial Entry

5.a Sample ID				
Date	Location	User	Value	Reason
Feb-23-2021 20:16:51	ACV0PFEINFP6000	(b) (6)	Data Entry:	Initial Entry

Header Text: c4591001

Visit: V201_SURVEIL_CONSENT - Unscheduled **Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - 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: 11521476

Subject Initials: ---

Generated By: (b) (4)

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

(UTC-08:00) Pacific Time (US & Canada)		(b)(4), (b)(6)	BRCMZZ	
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5.b

Date	Location	User	Value	Reason
Feb-23-2021 20:17:05 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: Sample ID: BRCN00	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Feb-23-2021 20:17:05 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: BRCN00	Initial Entry

5.c

Date	Location	User	Value	Reason
Feb-23-2021 20:17:15 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: Sample ID: BS6KWG	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Feb-23-2021 20:17:15 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: BS6KWG	Initial Entry

090177e196ae2fcd\Final\Final On: 01-Apr-2021 03:52 (GMT)

Header Text: c4591001**Visit:** V201_SURVEIL_CONSENT - Unscheduled **Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB - eCRF Audit Trail History**Form Version:** 22-Apr-2020 21:03**Form Status:** Data Complete, Frozen, Verified**Site No:** 1152**Site Name:** (1152) California Research Foundation**Subject No:** 11521476**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 11:56[Back to Form](#)**1. Data Origin**

Date	Location	User	Value	Reason
Feb-23-2021 09:49:00 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Feb-23-2021 09:49:00 (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
Feb-23-2021 20:17:34 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Feb-23-2021 09:49:00 (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.
Feb-23-2021 09:49:00 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Data Entry: YES Date of Collection: Feb/23/2021	Initial Entry

5.a

Date	Location	User	Value	Reason
Feb-23-2021 20:17:34 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: Sample ID: BRMT3M	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Feb-23-2021 20:17:34	ACV0PFEINFP6000	(b) (6)	Data Entry:	Initial Entry

Header Text: c4591001

Visit: V201_SURVEIL_CONSENT - Unscheduled

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1152

Site Name: (1152) California Research Foundation

Subject No: 11521476

Subject Initials: ---

Generated By: (b) (4)

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

(UTC-08:00) Pacific Time
(US & Canada)

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

BRMT3M

Header Text: c4591001**Visit:** Follow-Up - Unscheduled**Form Version:** 15-Sep-2020 21:53**Site No:** 1152**Subject No:** 11521476**Generated By:** (b) (4)**Form:** DISPOSITION - FOLLOW-UP - eCRF Audit Trail History**Form Status:** Incomplete, Verified**Site Name:** (1152) California Research Foundation**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 11:56[Back to Form](#)**1. Date of Completion/Discontinuation/Death :**

Date	Location	User	Value	Reason
Jan-10-2021 22:26:14 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b)(6)	Query 1: Closed	Response satisfies query
Jan-09-2021 12:33:54 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b)(6)	Query 1: Answered	She DID agree to continue in the study.
Jan-07-2021 23:23:17 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b)(6)	Query 1: Opened	DM: Subject discontinued, kindly update as per given guidelines. "If the Participant, discontinues during the treatment period and does not agree to remain in the study for follow-up, report the same status/date as reported on Disposition Treatment form.
Nov-06-2020 07:30:17 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b)(6)	Data Entry:	Changed Information
Nov-04-2020 06:30:42 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b)(6)	Data Entry: Sep/25/2020	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Nov-06-2020 07:30:17 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry:	Changed Information
Nov-04-2020 06:30:42 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: FOLLOW-UP	Initial Entry

3. Status:

Date	Location	User	Value	Reason
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Header Text: c4591001

Visit: Follow-Up - Unscheduled

Form Version: 15-Sep-2020 21:53

Site No: 1152

Subject No: 11521476

Generated By: (b) (4)

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

Form Status: Incomplete, Verified

Site Name: (1152) California Research Foundation

Subject Initials: ---

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

Nov-06-2020 07:30:28 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry:	Changed Information
Nov-04-2020 06:30:42 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: ADVERSE EVENT	Initial Entry

Header Text: c4591001

Visit: V202_SURVEIL_SWAB 1 - Unscheduled
Visit on Mar/10/2021

Form Version: 14-Jan-2021 02:22

Site No: 1152

Subject No: 11521476

Generated By: (b) (4)

Form: DATE OF VISIT - ASYMPTOMATIC SURVEILLANCE - 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

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1. Date of Visit

Date	Location	User	Value	Reason
Mar-12-2021 10:14:13 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Data Entry: Mar/10/2021	Initial Entry

3. COVID-19 Surveillance Visit:

Date	Location	User	Value	Reason
Mar-12-2021 10:14:13 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Data Entry: SSWAB_WEEK2	Initial Entry

Header Text: c4591001**Visit:** V202_SURVEIL_SWAB 1 - Unscheduled
Visit on Mar/10/2021**Form:** ELECTRONIC SAMPLE TRACKING - REPEAT SWAB - eCRF
Audit Trail History**Form Version:** 10-Oct-2020 15:57**Form Status:** Data Complete, Verified**Site No:** 1152**Site Name:** (1152) California Research Foundation**Subject No:** 11521476**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 11:56[Back to Form](#)**1. Data Origin**

Date	Location	User	Value	Reason
Mar-12-2021 10:14:36 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Mar-12-2021 10:14:36 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Data Entry: NASAL_SWAB_SELF	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Mar-12-2021 10:15:00 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Mar-12-2021 10:14:36 (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.
Mar-12-2021 10:14:36 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Data Entry: YES Date of Collection: Mar/10/2021	Initial Entry

5.a

Date	Location	User	Value	Reason
Mar-12-2021 10:15:00 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Data Entry: Sample ID: AA00003	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Mar-12-2021 10:15:00	ACV0PFEINFP6000	(b) (6)	Data Entry:	Initial Entry

Header Text: c4591001

Visit: V202_SURVEIL_SWAB 1 - Unscheduled
Visit on Mar/10/2021

Form Version: 10-Oct-2020 15:57

Site No: 1152

Subject No: 11521476

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - REPEAT SWAB - 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

(UTC-08:00) Pacific Time
(US & Canada)

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

AA00003

Header Text: c4591001

Visit: Potential ReVax Initial Contact - Unscheduled **Form:** DATE OF VISIT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen, Verified

Site No: 1152

Site Name: (1152) California Research Foundation

Subject No: 11521476

Subject Initials: ---

Generated By: (b) (4)

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

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I. Date of Visit

Date	Location	User	Value	Reason
Feb-22-2021 15:23:58 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Data Entry: Feb/19/2021	Initial Entry

Header Text: c4591001

Visit: Potential ReVax Initial Contact - Unscheduled **Form:** FURTHER VACCINATION CONFIRMATION - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:25

Form Status: Data Complete, Frozen

Site No: 1152

Site Name: (1152) California Research Foundation

Subject No: 11521476

Subject Initials: ---

Generated By: (b) (4)

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

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

Date	Location	User	Value	Reason
Feb-22-2021 15:24:12 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Data Entry: Participant is willing to return for Vaccination 3 Participant is: eligible and NOT confirmed to have received only placebo at Vaccination 1/2	Initial Entry

Header Text: c4591001

Visit: Disposition - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1152

Subject No: 11521476

Generated By: (b) (4)

Form: TREATMENT UNBLINDED - 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 Treatment Unblinded :

Date	Location	User	Value	Reason
Feb-22-2021 15:23:37 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Data Entry: Feb/19/2021	Initial Entry

2. Primary Reason for Unblinding:

Date	Location	User	Value	Reason
Feb-22-2021 15:23:37 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Data Entry: ASSESS ELIGIBILITY FOR ADDIT IONAL VACCINATION	Initial Entry

Header Text: c4591001

Visit: Subject Status - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1152

Subject No: 11521476

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

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I. Subject Status

Date	Location	User	Value	Reason
Nov-06-2020 07:30:28 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: DISCONTINUED	Changed Information
Nov-04-2020 06:30:42 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: DISCONTINUED	Initial Entry
Oct-29-2020 07:54:04 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: DISCONTINUED	Initial Entry
Sep-25-2020 15:49:17 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: ENROLLED/RANDOMIZED	Initial Entry
Sep-25-2020 15:27:58 (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-12-2020 14:35:25 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Oct/15/2020	Changed Information
Nov-06-2020 07:30:28 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sep/25/2020	Changed Information
Nov-06-2020 07:30:17 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sep/25/2020	Changed Information
Nov-04-2020 06:30:42 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sep/25/2020	Initial Entry
Oct-29-2020 07:54:04 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sep/25/2020	Initial Entry
Sep-25-2020 15:49:17 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sep/25/2020	Initial Entry

090177e196ae2fcd\Final\Final On: 01-Apr-2021 03:52 (GMT)

Header Text: c4591001

Visit: Subject Status - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1152

Subject No: 11521476

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

Sep-25-2020 15:27:58 (UTC-08:00) Pacific Time (US & Canada)	ACVOPFEINFP6000	auto calc (autocalc)	Data Entry: Sep/25/2020	Initial Entry
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090177e196ae2fcd\Final\Final On: 01-Apr-2021 03:52 (GMT)

Header Text: c4591001

Visit: Investigator Signature - Unscheduled

Form: CASEBOOK SIGNATURE FORM - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Verified

Site No: 1152

Site Name: (1152) California Research Foundation

Subject No: 11521476

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-03-2020 05:44:46 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: Click Here to Enable	Initial Entry