

Header Text: c4591001

Visit: COHORT_SELECTION

Form Version: 15-Sep-2020 21:55

Site No: 1152

Subject No: 11521450

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 Version: 22-Apr-2020 21:02

Site No: 1152

Subject No: 11521450

Generated By: (b) (4)

Form: MAIN INFORMED CONSENT

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1152) California Research Foundation

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Informed Consent

1.	Consent Was:	OBTAINED Date Written Consent Obtained Sep/16/2020
----	--------------	--

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: 11521450

Subject Initials: ---

Generated By: (b) (4)

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

[eCRF Audit Trail History](#)

Demography

1.	Subject ID	[11521450]
2.	Birth Date:	(b) (6)/1992
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: 11521450

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/16/2020
2.	Erroneous Visit	

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 15-Sep-2020 21:53

Site No: 1152

Subject No: 11521450

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: 11521450

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/16/2020
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: 11521450

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:	[hypercholesterolemia]
	Start Date:	UNK/UNK/2018
	Ongoing:	NO End Date: UNK/UNK/2019
1.b	Line/MH Number:	[2]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[diarrhea, occasional (spicy food induced)]
	Start Date:	UNK/UNK/2017
	Ongoing:	YES
1.c	Line/MH Number:	[3]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[smoker's cough]
	Start Date:	Mar/UNK/2019
	Ongoing:	YES

090177e196ae2fcb\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: 11521450

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: 11521450

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/16/2020
2.	Weight:	[190.4]
3.	Unit:	LB
4.	Height:	[60.5]
5.	Unit:	in
6.	Body Mass Index:	[36.6]

Vital Signs Details

7.a	Record Identifier:	1
	Temperature:	[98.7]
	Unit:	F
	Temperature Location:	ORAL CAVITY

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 15-Sep-2020 21:51

Site No: 1152

Subject No: 11521450

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:	URINALYSIS
2.	Lab Sub-Panel:	PREGNANCY
3.	Collection Date:	Sep/16/2020
4.	Laboratory Name and Address (Derived)	[STUDY SITE]
5.	Specimen Type:	URINE

Lab Result

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

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1152

Subject No: 11521450

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/16/2020
2.	Randomization Number:	[91854]
3.	Randomization Group:	[]

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1152

Subject No: 11521450

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/16/2020
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	[BP9K5W]
5.b	Sample ID	[BP9K5X]
5.c	Sample ID	[BNWJX9]

090177e196ae2fcb\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: 11521450

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/16/2020
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	[BPOSBR]
-----	-----------	----------

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:04

Site No: 1152

Subject No: 11521450

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/16/2020 15:50
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

090177e196ae2fcb\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: 11521450

Generated By: (b) (4)

Form: REACTOGENICITY DIARY

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1152) California Research Foundation

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Reactogenicity Diary

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

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 1152

Subject No: 11521450

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/9/2020
2.	Erroneous Visit	

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 15-Sep-2020 21:54

Site No: 1152

Subject No: 11521450

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/9/2020
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Vital Signs Details

2.a	Record Identifier:	1
	Temperature:	[98.3]
	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: 11521450

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:	URINALYSIS
2.	Lab Sub-Panel:	PREGNANCY
3.	Collection Date:	Oct/9/2020
4.	Laboratory Name and Address (Derived)	[STUDY SITE]
5.	Specimen Type:	URINE

Lab Result

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

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:03

Site No: 1152

Subject No: 11521450

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/9/2020
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	[BPOSMJ]
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090177e196ae2fcb\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: 11521450

Generated By: (b) (4)

Form: VACCINATION

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1152) California Research Foundation

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Vaccination		
1.	Was there a temporary delay of vaccination?	NO
2.	Treatment Name	[BLINDED THERAPY]
3.	Formulation:	INJECTION
4.	Dose Date Time:	Oct/9/2020 13:31
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

090177e196ae2fcb\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: 11521450

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	Nov/20/2020
2.	Erroneous Visit	

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form Version: 22-Apr-2020 21:03

Site No: 1152

Subject No: 11521450

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: Nov/20/2020
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[]

Aliquot

Please enter barcode for each aliquot.

5.a	Sample ID	[BRJH1Z]
5.b	Sample ID	[BRJH20]
5.c	Sample ID	[BS6K4N]

090177e196ae2fcb\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: 11521450

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: 11521450

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: 11521450

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: 11521450

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: 11521450

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: 11521450

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: 11521450

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: 11521450 **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: 11521450

Subject Initials: ---

Generated By: (b) (4)

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

Electronic Sample Tracking

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

Aliquot

Please enter barcode for each aliquot.

5.	Sample ID	[]
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Header Text: c4591001

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

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1152

Site Name: (1152) California Research Foundation

Subject No: 11521450

Subject Initials: ---

Generated By: (b) (4)

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

Electronic Sample Tracking

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

Aliquot

Please enter barcode for each aliquot.

5.	Sample ID	[]
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Header Text: c4591001

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

Form Version: 20-Feb-2021 02:19 **Form Status:** Not Started

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

Subject No: 11521450 **Subject Initials:** ---

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

Health Care Utilization

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

Health Care Utilization Other

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

Health Care Utilization

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

Header Text: c4591001

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

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

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

Subject No: 11521450 **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: 11521450

Subject Initials: ---

Generated By: (b) (4)

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

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

COVID-19 Illness Visit

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

Header Text: c4591001

Visit: POT_COVID_CONVA - New Unscheduled Visit

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1152

Site Name: (1152) California Research Foundation

Subject No: 11521450

Subject Initials: ---

Generated By: (b) (4)

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

Electronic Sample Tracking

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

Aliquot

Please enter barcode for each aliquot.

5.	Sample ID	[]
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Header Text: c4591001

Visit: POT_COVID_REPEAT_SWAB - New
Unscheduled Visit

Form: DATE OF VISIT - REPEAT SWAB

Form Version: 10-Oct-2020 15:57

Form Status: Not Started

Site No: 1152

Site Name: (1152) California Research Foundation

Subject No: 11521450

Subject Initials: ---

Generated By: (b) (4)

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

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

COVID-19 Repeat Swab

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

Visit: POT_COVID_REPEAT_SWAB - New
Unscheduled Visit

Form: ELECTRONIC SAMPLE TRACKING - REPEAT SWAB

Form Version: 10-Oct-2020 15:57

Form Status: Not Started

Site No: 1152

Site Name: (1152) California Research Foundation

Subject No: 11521450

Subject Initials: ---

Generated By: (b) (4)

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

Electronic Sample Tracking

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

Aliquot

Please enter barcode for each aliquot.

5.	Sample ID	[]
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Header Text: c4591001

Visit: Unplanned - New Unscheduled Visit

Form: DATE OF VISIT

Form Version: 22-Apr-2020 21:02

Form Status: Not Started

Site No: 1152

Site Name: (1152) California Research Foundation

Subject No: 11521450

Subject Initials: ---

Generated By: (b) (4)

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

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

Header Text: c4591001

Visit: Unplanned - New Unscheduled Visit

Form: UNPLANNED VISIT

Form Version: 22-Apr-2020 21:04

Form Status: Not Started

Site No: 1152

Site Name: (1152) California Research Foundation

Subject No: 11521450

Subject Initials: ---

Generated By: (b) (4)

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

Unplanned Assessments

1.	Assessments	
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Header Text: c4591001

Visit: Logs

Form: ADVERSE EVENT REPORT

Form Version: 22-Apr-2020 21:02

Site No: 1152

Site Name: (1152) California Research Foundation

Subject No: 11521450

Subject Initials: ---

Generated By: (b) (4)

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

#	Category	AE Identifier	Adverse Event	Start Date	Is the Adverse Event Still Ongoing	Form Instance
1.	ADVERSE EVENT	1	Fatigue	Oct/9/2020 18:00	NO End Date Time: Oct/11/2020 UNK:UNK	Repeating Pages
2.	ADVERSE EVENT	2	Headache	Oct/10/2020 UNK:UNK	NO End Date Time: Oct/12/2020 UNK:UNK	Repeating Pages
3.	ADVERSE EVENT	3	Body Aches	Oct/10/2020 UNK:UNK	NO End Date Time: Oct/11/2020 UNK:UNK	Repeating Pages
4.	ADVERSE EVENT	4	Diarrhea	Oct/12/2020 UNK:UNK	NO End Date Time: Oct/12/2020 UNK:UNK	Repeating Pages
5.	ADVERSE EVENT	5	Exposure during pregnancy	Dec/26/2020 UNK:UNK	YES	Repeating Pages

090177e196ae2fcb\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: 11521450

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Frozen

Site Name: (1152) California Research Foundation

Subject Initials: ---

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

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Adverse Event Report

1.	Category:	ADVERSE EVENT
2.	AE ID:	[1]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[Fatigue]
4.	Start Date Time:	Oct/9/2020 18:00
5.	Is the adverse event still ongoing?	NO End Date Time: Oct/11/2020 UNK:UNK
6.	Toxicity Grade:	2
7.	Is the adverse event serious? If Yes, NOTIFY PFIZER IMMEDIATELY. Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).	NO
8.	Is this adverse event the result of a study Medication Error? If Yes, record the type of medication error on the Medication Error Log.	NO
9.	Is this event related to study treatment:	RELATED
10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE
11.	Was a Concomitant Medication given?	YES
12.	Was a Non-Drug Treatment given?	NO
13.	What was the outcome of this adverse event?:	RECOVERED/RESOLVED
14.	Did the adverse event cause the subject to be discontinued from the study?	NO

090177e196ae2fcb\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: 11521450

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

15.	Serious Adverse Event Number: For Pfizer Use Only	[]
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090177e196ae2fcb\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: 11521450

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Frozen

Site Name: (1152) California Research Foundation

Subject Initials: ---

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

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Adverse Event Report

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

090177e196ae2fcb\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: 11521450

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 - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1152

Subject No: 11521450

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Frozen

Site Name: (1152) California Research Foundation

Subject Initials: ---

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

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Adverse Event Report

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

090177e196ae2fcb\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: 11521450

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 - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1152

Subject No: 11521450

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Frozen

Site Name: (1152) California Research Foundation

Subject Initials: ---

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

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Adverse Event Report

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

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Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1152

Subject No: 11521450

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	[]

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Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1152

Subject No: 11521450

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Queries

Site Name: (1152) California Research Foundation

Subject Initials: ---

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

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Adverse Event Report

1.	Category:	ADVERSE EVENT	
2.	AE ID:	[5]	
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[Exposure during pregnancy]	
4.	Start Date Time:	Dec/26/2020 UNK:UNK	
5.	Is the adverse event still ongoing?	YES	
6.	Toxicity Grade:	3	Comments
7.	Is the adverse event serious? If Yes, NOTIFY PFIZER IMMEDIATELY. Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).	NO	
8.	Is this adverse event the result of a study Medication Error? If Yes, record the type of medication error on the Medication Error Log.	NO	
9.	Is this event related to study treatment:	NOT RELATED If Not Related to study treatment(s), this event is due to: OTHER If Other, specify: [Did not use birth control]	
10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE	
11.	Was a Concomitant Medication given?	NO	
12.	Was a Non-Drug Treatment given?	NO	
13.	What was the outcome of this adverse event?:	NOT RECOVERED/NOT RESOLVED	

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Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1152

Subject No: 11521450

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Queries

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: 11521450

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: 11521450

Generated By: (b) (4)

Form: MEDICATION ERROR

Form Status: Not Started

Site Name: (1152) California Research Foundation

Subject Initials: ---

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

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Medication Error

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

090177e196ae2fcb\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: 11521450

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: 11521450

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

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Concomitant Medications

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

090177e196ae2fcb\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: 11521450

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: 11521450

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?	

090177e196ae2fcb\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: 11521450

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: 11521450

Generated By: (b) (4)

Form: RADIATION TREATMENT

Form Status: Not Started

Site Name: (1152) California Research Foundation

Subject Initials: ---

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

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Radiation Treatment

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

Header Text: c4591001

Visit: Logs

Form: TRANSFUSIONS

Form Version: 22-Apr-2020 21:03

Site No: 1152

Site Name: (1152) California Research Foundation

Subject No: 11521450

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: 11521450

Generated By: (b) (4)

Form: TRANSFUSIONS

Form Status: Not Started

Site Name: (1152) California Research Foundation

Subject Initials: ---

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

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

Header Text: c4591001

Visit: End of Treatment - Unscheduled

Form: DISPOSITION - TREATMENT

Form Version: 15-Sep-2020 21:55

Form Status: Data Complete, Frozen, Verified

Site No: 1152

Site Name: (1152) California Research Foundation

Subject No: 11521450

Subject Initials: ---

Generated By: (b) (4)

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

[eCRF Audit Trail History](#)

Disposition - Treatment

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

Header Text: c4591001

Visit: Unplanned Vaccination - Unscheduled

Form: DATE OF VISIT

Form Version: 22-Apr-2020 21:02

Form Status: Not Started

Site No: 1152

Site Name: (1152) California Research Foundation

Subject No: 11521450

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: 11521450

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: 11521450

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:	

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: 11521450

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?	

090177e196ae2fcb\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: 11521450

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: 11521450 **Subject Initials:** ---
Generated By: (b) (4) **Generated Time (GMT):** 29-Mar-2021 11:56

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

Header Text: c4591001

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

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

Site No: 1152

Site Name: (1152) California Research Foundation

Subject No: 11521450

Subject Initials: ---

Generated By: (b) (4)

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

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

Header Text: c4591001

Visit: V201_SURVEIL_CONSENT - Unscheduled

Form: INFORMED CONSENT - ASYMPTOMATIC SURVEILLANCE

Form Version: 14-Jan-2021 02:29

Form Status: Not Started

Site No: 1152

Site Name: (1152) California Research Foundation

Subject No: 11521450

Subject Initials: ---

Generated By: (b) (4)

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

Informed Consent - Asymptomatic Surveillance

1.	Consent Was:	
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Header Text: c4591001

Visit: V201_SURVEIL_CONSENT - Unscheduled

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1152

Site Name: (1152) California Research Foundation

Subject No: 11521450

Subject Initials: ---

Generated By: (b) (4)

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

Electronic Sample Tracking

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

Aliquot

Please enter barcode for each aliquot.

5.	Sample ID	[]
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Header Text: c4591001

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

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1152

Site Name: (1152) California Research Foundation

Subject No: 11521450

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: Follow-Up - Unscheduled

Form Version: 15-Sep-2020 21:53

Site No: 1152

Subject No: 11521450

Generated By: (b) (4)

Form: DISPOSITION - FOLLOW-UP

Form Status: Not Started

Site Name: (1152) California Research Foundation

Subject Initials: ---

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

Disposition - Follow-Up

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

Header Text: c4591001

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

Form Version: 22-Apr-2020 21:02

Form Status: Not Started

Site No: 1152

Site Name: (1152) California Research Foundation

Subject No: 11521450

Subject Initials: ---

Generated By: (b) (4)

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

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

Header Text: c4591001

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

Form Version: 10-Dec-2020 02:25

Form Status: Not Started

Site No: 1152

Site Name: (1152) California Research Foundation

Subject No: 11521450

Subject Initials: ---

Generated By: (b) (4)

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

Further Vaccination Confirmation

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

Header Text: c4591001

Visit: Disposition - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1152

Subject No: 11521450

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:	OTHER If other, specify: [Subject is pregnant.]

Header Text: c4591001

Visit: Disposition - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1152

Subject No: 11521450

Generated By: (b) (4)

Form: WITHDRAWAL OF CONSENT

Form Status: Not Started

Site Name: (1152) California Research Foundation

Subject Initials: ---

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

Withdrawal Of Consent

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

090177e196ae2fcb\Final\Final On: 01-Apr-2021 03:52 (GMT)

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: 11521450

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: 11521450

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	FOLLOW-UP
2.	Subject Status Date	Nov/20/2020

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: 11521450

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 Version: 22-Apr-2020 21:04

Site No: 1152

Subject No: 11521450

Generated By: (b) (4)

Form: CASEBOOK SIGNATURE FORM

Form Status: Data Complete, Verified

Site Name: (1152) California Research Foundation

Subject Initials: ---

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

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 15-Sep-2020 21:53

Site No: 1152

Subject No: 11521450

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-16-2020 16:44:06 (UTC-08:00) Pacific Time (US & Canada)	(b)(4),(b)(6)	Not Applicable

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1152

Subject No: 11521450

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - Comments

Form Status: Data Complete, Frozen

Site Name: (1152) California Research Foundation

Subject Initials: ---

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

[Back to Form](#)

Item	Date	User	Comment
6	Feb-23-2021 03:07:53 (UTC-08:00) Pacific Time (US & Canada)	(b)(4),(b)(6)	
6	Feb-23-2021 03:05:41 (UTC-08:00) Pacific Time (US & Canada)	(b)(4),(b)(6)	Not Applicable

090177e196ae2fcb\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: 11521450

Subject Initials: ---

Generated By: (b) (4)

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

[Back to Form](#)

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

- CRF_Sign
- CRF_Sign_1

Name	Signature Meaning	Date	Type	Action
(b) (6)	N/A	Feb-23-2021 03:01:30 (UTC-08:00) Pacific Time (US & Canada)		Edit - All signatures invalidated

Affidavit:

N/A

Donald Brandon	Approved	Nov-24-2020 20:15:46 (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	Nov-20-2020 13:44:53 (UTC-08:00) Pacific Time (US & Canada)		Edit - All signatures invalidated
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Affidavit:

N/A

Donald Brandon	Approved	Nov-06-2020 08:51:09 (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.

090177e196ae2fcb\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: 11521450

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

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1. Select appropriate response - Protocol version

Date	Location	User	Value	Reason
Sep-16-2020 16:42:47 (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-16-2020 16:42:47 (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: 11521450

Generated By: (b) (4)

Form: MAIN INFORMED CONSENT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1152) California Research Foundation

Subject Initials: ---

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

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I. Consent Was:

Date	Location	User	Value	Reason
Sep-16-2020 16:43:19 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4, (b)(6) [REDACTED]	Data Entry: OBTAINED Date Written Consent Obtained Sep/16/2020	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: 11521450

Subject Initials: ---

Generated By: (b) (4)

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

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1. Subject ID

Date	Location	User	Value	Reason
Sep-16-2020 16:42:21 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> 11521450	Item copied from previous form

2. Birth Date:

Date	Location	User	Value	Reason
Sep-16-2020 16:41:37 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> (b) (6) /1992	Enrollment Entry

3. Sex:

Date	Location	User	Value	Reason
Sep-16-2020 16:43:40 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4, (b)(6)	<u>Data Entry:</u> FEMALE	Initial Entry

4. Ethnicity:

Date	Location	User	Value	Reason
Sep-16-2020 16:43:40 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4, (b)(6)	<u>Data Entry:</u> HISPANIC OR LATINO(A) OR OF S PANISH ORIGIN	Initial Entry

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

Date	Location	User	Value	Reason
Sep-16-2020 16:43:40 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4, (b)(6)	<u>Data Entry:</u> WHITE	Initial Entry

090177e196ae2fcb\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: 11521450

Generated By: (b) (4)

Form: DATE OF VISIT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1152) California Research Foundation

Subject Initials: ---

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

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1. Date of Visit

Date	Location	User	Value	Reason
Sep-16-2020 16:43:54 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: Sep/16/2020	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 15-Sep-2020 21:52

Site No: 1152

Subject No: 11521450

Generated By: (b) (4)

Form: DISPOSITION - SCREENING - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1152) California Research Foundation

Subject Initials: ---

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

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1. Date of Completion/Discontinuation/Death

Date	Location	User	Value	Reason
Sep-16-2020 16:44:36 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4, (b)(6)	Data Entry: Sep/16/2020	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Sep-16-2020 16:44:36 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SCREENING	Initial Entry

3. Status:

Date	Location	User	Value	Reason
Sep-16-2020 16:44:36 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4, (b)(6)	Data Entry: COMPLETED	Initial Entry

090177e196ae2fcb\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: 11521450

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1152) California Research Foundation

Subject Initials: ---

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

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I.a

Date	Location	User	Value	Reason
Sep-16-2020 16:45:14 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 1 Medical History Term: hypercholesterolemia Start Date: UNK/UNK/2018 Ongoing: NO End Date: UNK/UNK/2019	Initial Entry

I.a Line/MH Number:

Date	Location	User	Value	Reason
Sep-16-2020 16:45:14 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 1	Initial Entry

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

Date	Location	User	Value	Reason
Sep-16-2020 16:45:14 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: hypercholesterolemia	Initial Entry

I.a Start Date:

Date	Location	User	Value	Reason
Sep-16-2020 16:45:14 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: UNK/UNK/2018	Initial Entry

I.a Ongoing:

Date	Location	User	Value	Reason
Sep-16-2020 16:45:14 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: NO End Date: UNK/UNK/2019	Initial Entry

090177e196ae2fcb\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: 11521450

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-16-2020 16:46:58 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Nu 2 mber: Medical History Term: diarrhea, occasional (spicy food induced) Start Date: UNK/UNK/2017 Ongoing: YES	Initial Entry

I.b Line/MH Number:

Date	Location	User	Value	Reason
Sep-16-2020 16:46:58 (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-16-2020 16:46:58 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4, (b)(6)	Data Entry: diarrhea, occasional (spicy food induced)	Initial Entry

I.b Start Date:

Date	Location	User	Value	Reason
Sep-16-2020 16:46:58 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4, (b)(6)	Data Entry: UNK/UNK/2017	Initial Entry

I.b Ongoing:

Date	Location	User	Value	Reason
Sep-16-2020 16:46:58 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4, (b)(6)	Data Entry: YES	Initial Entry

I.c

Date	Location	User	Value	Reason
Sep-16-2020 16:47:29 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 3 Medical History Term: smoker's cough	Initial Entry

090177e196ae2fcb\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: 11521450

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:	Mar/UNK/2019	
			Ongoing:	YES	

I.c Line/MH Number:

Date	Location	User	Value	Reason
Sep-16-2020 16:47:29 (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-16-2020 16:47:29 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4, (b)(6)	Data Entry: smoker's cough	Initial Entry

I.c Start Date:

Date	Location	User	Value	Reason
Sep-16-2020 16:47:29 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4, (b)(6)	Data Entry: Mar/UNK/2019	Initial Entry

I.c Ongoing:

Date	Location	User	Value	Reason
Sep-16-2020 16:47:29 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4, (b)(6)	Data Entry: YES	Initial Entry

090177e196ae2fcb\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: 11521450

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-16-2020 16:48:52 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: The subject is NOT known to be HIV POSITIVE	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 15-Sep-2020 21:56

Site No: 1152

Subject No: 11521450

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-16-2020 16:51:01 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4, (b)(6)	<u>Data Entry:</u> Sep/16/2020	Initial Entry

2. Weight:

Date	Location	User	Value	Reason
Sep-16-2020 16:51:01 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4, (b)(6)	<u>Data Entry:</u> 190.4	Initial Entry

3. Unit:

Date	Location	User	Value	Reason
Sep-16-2020 16:51:01 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4, (b)(6)	<u>Data Entry:</u> LB	Initial Entry

4. Height:

Date	Location	User	Value	Reason
Sep-16-2020 16:51:01 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4, (b)(6)	<u>Data Entry:</u> 60.5	Initial Entry

5. Unit:

Date	Location	User	Value	Reason
Sep-16-2020 16:51:01 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4, (b)(6)	<u>Data Entry:</u> in	Initial Entry

6. Body Mass Index:

Date	Location	User	Value	Reason
Sep-16-2020 16:51:01 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> 36.6	Initial Entry

7.a

Date	Location	User	Value	Reason
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090177e196ae2fcb\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: 11521450

Subject Initials: ---

Generated By: (b) (4)

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

Sep-16-2020 16:51:01 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4, (b)(6)	Data Entry: Record Identifier:: 1 Temperature: 98.7 Temperature Unit: F Temperature Location:: ORAL CAVITY	Initial Entry
---	-----------------	------------------	---	---------------

7.a Record Identifier:

Date	Location	User	Value	Reason
Sep-16-2020 16:51:01 (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-16-2020 16:51:01 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4, (b)(6)	Data Entry: 98.7	Initial Entry

7.a Unit:

Date	Location	User	Value	Reason
Sep-16-2020 16:51:01 (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-16-2020 16:51:01 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4, (b)(6)	Data Entry: ORAL CAVITY	Initial Entry

090177e196ae2fcb\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: 11521450

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
Sep-16-2020 16:51:10 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: URINALYSIS	Initial Entry

2. Lab Sub-Panel:

Date	Location	User	Value	Reason
Sep-16-2020 16:51:10 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: PREGNANCY	Initial Entry

3. Collection Date:

Date	Location	User	Value	Reason
Sep-16-2020 16:51:10 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4, (b)(6)	Data Entry: Sep/16/2020	Initial Entry

4. Laboratory Name and Address (Derived)

Date	Location	User	Value	Reason
Sep-16-2020 16:51:10 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: STUDY SITE	Initial Entry

5. Specimen Type:

Date	Location	User	Value	Reason
Sep-16-2020 16:51:10 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: URINE	Initial Entry

6.a

Date	Location	User	Value	Reason
Sep-16-2020 16:51:10 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sponsor-Defined 113 Identifier: Test:: Choriogonadotropin Beta_PX113 Result:: NEGATIVE	Initial Entry

090177e196ae2fcb\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: 11521450

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

			Not Done::	
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6.a Sponsor ID:

Date	Location	User	Value	Reason
Sep-16-2020 16:51:10 (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-16-2020 16:51:10 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4, (b)(6)	Data Entry: Choriogonadotropin Beta_PX113	Initial Entry

6.a Result:

Date	Location	User	Value	Reason
Sep-16-2020 16:51:10 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4, (b)(6)	Data Entry: NEGATIVE	Initial Entry

090177e196ae2fcb\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: 11521450

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-16-2020 16:51:54 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4, (b)(6)	Data Entry: Sep/16/2020	Initial Entry

2. Randomization Number:

Date	Location	User	Value	Reason
Sep-16-2020 16:51:54 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4, (b)(6)	Data Entry: 91854	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:** 11521450**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-16-2020 16:52:10 (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-16-2020 16:52:10 (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-16-2020 18:14:11 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Sep-16-2020 16:52:10 (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-16-2020 16:52:10 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4, (b)(6)	Data Entry: YES Date of Collection: Sep/16/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Sep-16-2020 18:14:11 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4,(b)(6)	Data Entry: Sample ID: BP9K5W	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Sep-16-2020 18:14:11 (UTC-08:00) Pacific Time	ACV0PFEINFP6000	(b) (6)	Data Entry: BP9K5W	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: 11521450

Subject Initials: ---

Generated By: (b) (4)

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

(US & Canada)		(b) (4)	
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5.b

Date	Location	User	Value	Reason
Sep-16-2020 18:14:24 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b)(6)	Data Entry: Sample ID: BP9K5X	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Sep-16-2020 18:14:24 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b)(6)	Data Entry: BP9K5X	Initial Entry

5.c

Date	Location	User	Value	Reason
Sep-16-2020 18:14:34 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b)(6)	Data Entry: Sample ID: BNWJX9	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Sep-16-2020 18:14:34 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b)(6)	Data Entry: BNWJX9	Initial Entry

090177e196ae2fcb\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:** 11521450**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-16-2020 16:52:20 (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-16-2020 16:52:20 (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-16-2020 17:59:10 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Sep-16-2020 16:52:20 (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-16-2020 16:52:20 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4, (b)(6)	Data Entry: YES Date of Collection: Sep/16/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Sep-16-2020 17:59:50 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4,(b)(6)	Data Entry: Sample ID: BPOSBR	Transcription Error
Sep-16-2020 17:59:10 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4,(b)(6)	Data Entry: Sample ID: BPOSB	Initial Entry

5.a Sample ID

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: 11521450

Subject Initials: ---

Generated By: (b) (4)

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

Date	Location	User	Value	Reason
Sep-16-2020 17:59:50 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Sep-16-2020 17:59:50 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b)(6)	Data Entry: BPOSBR	Transcription Error
Sep-16-2020 17:59:10 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	Barcode is not 6 characters in length. Please review and correct as appropriate.
Sep-16-2020 17:59:10 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b)(6)	Data Entry: BPOSB	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:04

Site No: 1152

Subject No: 11521450

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-16-2020 16:52:39 (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-16-2020 16:52:39 (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-16-2020 16:52:39 (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-16-2020 16:52:39 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: Sep/16/2020 15:50	Initial Entry

5. Anatomical Location:

Date	Location	User	Value	Reason
Sep-16-2020 16:52:39 (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-16-2020 16:52:39 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: LEFT	Initial Entry

7. Route:

Date	Location	User	Value	Reason
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090177e196ae2fcb\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: 11521450

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

Sep-16-2020 16:52:39 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INTRAMUSCULAR	Initial Entry
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10. Timeframe Subject Was Observed

Date	Location	User	Value	Reason
Sep-16-2020 16:52:39 (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-16-2020 16:52:39 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4, (b)(6)	Data Entry: YES	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 06-Jul-2020 21:53

Site No: 1152

Subject No: 11521450

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-16-2020 17:09:06 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6) [REDACTED]	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: 11521450

Generated By: (b) (4)

Form: DATE OF VISIT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1152) California Research Foundation

Subject Initials: ---

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

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1. Date of Visit

Date	Location	User	Value	Reason
Oct-09-2020 15:08:38 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: Oct/9/2020	Initial Entry

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 15-Sep-2020 21:54

Site No: 1152

Subject No: 11521450

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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1. Date:

Date	Location	User	Value	Reason
Oct-09-2020 15:08:57 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4, (b)(6)	<u>Data Entry:</u> Oct/9/2020	Initial Entry

2.a

Date	Location	User	Value	Reason
Oct-09-2020 15:08:57 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4, (b)(6)	<u>Data Entry:</u> Record Identifier:: 1 Temperature: 98.3 Temperature Unit: F Temperature Location:: ORAL CAVITY	Initial Entry

2.a Record Identifier:

Date	Location	User	Value	Reason
Oct-09-2020 15:08:57 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4, (b)(6)	<u>Data Entry:</u> 1	Initial Entry

2.a Temperature:

Date	Location	User	Value	Reason
Oct-09-2020 15:08:57 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4, (b)(6)	<u>Data Entry:</u> 98.3	Initial Entry

2.a Unit:

Date	Location	User	Value	Reason
Oct-09-2020 15:08:57 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4, (b)(6)	<u>Data Entry:</u> F	Initial Entry

2.a Temperature Location:

Date	Location	User	Value	Reason
Oct-09-2020 15:08:57 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4, (b)(6)	<u>Data Entry:</u> ORAL CAVITY	Initial Entry

090177e196ae2fcb\Final\Final On: 01-Apr-2021 03:52 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 15-Sep-2020 21:51

Site No: 1152

Subject No: 11521450

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-09-2020 15:09:12 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: URINALYSIS	Initial Entry

2. Lab Sub-Panel:

Date	Location	User	Value	Reason
Oct-09-2020 15:09:12 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: PREGNANCY	Initial Entry

3. Collection Date:

Date	Location	User	Value	Reason
Oct-09-2020 15:09:12 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4, (b)(6)	Data Entry: Oct/9/2020	Initial Entry

4. Laboratory Name and Address (Derived)

Date	Location	User	Value	Reason
Oct-09-2020 15:09:12 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: STUDY SITE	Initial Entry

5. Specimen Type:

Date	Location	User	Value	Reason
Oct-09-2020 15:09:12 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: URINE	Initial Entry

6.a

Date	Location	User	Value	Reason
Oct-09-2020 15:09:12 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sponsor-Defined 113 Identifier: Test:: Choriogonadotropin Beta_PX113 Result:: NEGATIVE	Initial Entry

090177e196ae2fcb\Final\Final On: 01-Apr-2021 03:52 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 15-Sep-2020 21:51

Site No: 1152

Subject No: 11521450

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

			Not Done::	
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6.a Sponsor ID:

Date	Location	User	Value	Reason
Oct-09-2020 15:09:12 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> 113	Initial Entry

6.a Test:

Date	Location	User	Value	Reason
Oct-09-2020 15:09:12 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4, (b)(6)	<u>Data Entry:</u> Choriogonadotropin Beta_PX113	Initial Entry

6.a Result:

Date	Location	User	Value	Reason
Oct-09-2020 15:09:12 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4, (b)(6)	<u>Data Entry:</u> NEGATIVE	Initial Entry

090177e196ae2fcb\Final\Final On: 01-Apr-2021 03:52 (GMT)

Header Text: c4591001**Visit:** V2_VAX2_L**Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB - eCRF Audit Trail History**Form Version:** 22-Apr-2020 21:03**Form Status:** Data Complete, Locked, Frozen, Verified**Site No:** 1152**Site Name:** (1152) California Research Foundation**Subject No:** 11521450**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
Oct-09-2020 15:09:20 (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-09-2020 15:09:20 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: NASAL_SWAB	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Oct-09-2020 21:16:41 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Oct-09-2020 15:09:20 (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-09-2020 15:09:20 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4, (b)(6)	Data Entry: YES Date of Collection: Oct/9/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Oct-09-2020 21:16:41 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b)(6)	Data Entry: Sample ID: BP0SMJ	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Oct-09-2020 21:16:41 (UTC-08:00) Pacific Time	ACV0PFEINFP6000	(b) (6)	Data Entry: BP0SMJ	Initial Entry

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: 11521450

Subject Initials: ---

Generated By: (b) (4)

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

(US & Canada)

(b) (4)

090177e196ae2fcb\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: 11521450

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-09-2020 15:09:49 (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
Oct-09-2020 15:09:49 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: BLINDED THERAPY	Initial Entry

3. Formulation:

Date	Location	User	Value	Reason
Oct-09-2020 15:09:49 (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
Oct-09-2020 15:09:49 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4, (b)(6)	Data Entry: Oct/9/2020 13:31	Initial Entry

5. Anatomical Location:

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

7. Route:

Date	Location	User	Value	Reason
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090177e196ae2fcb\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: 11521450

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

Oct-09-2020 15:09:49 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INTRAMUSCULAR	Initial Entry
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10. Timeframe Subject Was Observed

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

090177e196ae2fcb\Final\Final On: 01-Apr-2021 03:52 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 1152

Subject No: 11521450

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
Feb-24-2021 04:43:58 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b)(6)	Query 2: Clo sed	Closed per data updated by site.
Feb-23-2021 03:09:10 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b)(6)	Query 2: Ans wered	Completed
Feb-23-2021 00:08:50 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b)(6)	Query 2: Op ened	IVRS Reconciliation: As per Impala, Blind Broken is Yes; however, TREATMENT UNBLINDED CRF is blank. Please review and update data as appropriate.
Nov-23-2020 21:34:37 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b)(6)	Query 1: Clo sed	Closed per SITE response, added to PD tracker for Clinicals review
Nov-23-2020 07:38:56 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b)(6)	Query 1: Ans wered	Yes, this is out of window.
Nov-23-2020 00:16:22 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	PFE SDQ PROD (b) (4)	Query 1: Op ened	PDQ: Date of visit at V3_MONTH1_POSTVAX2_L is out of window for 7 days from V2_VAX2_L DOV or V2 Vaccination date. Please verify and update. Else, confirm in query response appropriately. (b) (4)
Nov-20-2020	ACV0PFEINFP6000	(b) (6)	Data	Initial Entry

090177e196ae2fcb\Final\Final On: 01-Apr-2021 03:52 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 1152

Subject No: 11521450

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

13:44:53 (UTC-08:00) Pacific Time (US & Canada)	(b) (4)	<u>Entry</u> : Nov/2 0/202 0
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090177e196ae2fcb\Final\Final On: 01-Apr-2021 03:52 (GMT)

Header Text: c4591001**Visit:** V3_MONTH1_POSTVAX2_L**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF
Audit Trail History**Form Version:** 22-Apr-2020 21:03**Form Status:** Data Complete, Frozen, Verified**Site No:** 1152**Site Name:** (1152) California Research Foundation**Subject No:** 11521450**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
Nov-20-2020 13:45:01 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Nov-20-2020 13:45:01 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SERUM	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Nov-20-2020 14:31:13 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Nov-20-2020 13:45:01 (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.
Nov-20-2020 13:45:01 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4, (b)(6)	Data Entry: YES Date of Collection: Nov/20/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Nov-20-2020 14:31:13 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b)(6)	Data Entry: Sample ID: BRJH1Z	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Nov-20-2020 14:31:13 (UTC-08:00) Pacific Time	ACV0PFEINFP6000	(b) (6)	Data Entry: BRJH1Z	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: 11521450

Subject Initials: ---

Generated By: (b) (4)

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

(US & Canada)		(b) (4)	
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5.b

Date	Location	User	Value	Reason
Nov-20-2020 14:31:23 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b)(6)	Data Entry: Sample ID: BRJH20	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Nov-20-2020 14:31:23 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b)(6)	Data Entry: BRJH20	Initial Entry

5.c

Date	Location	User	Value	Reason
Nov-20-2020 14:31:36 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b)(6)	Data Entry: Sample ID: BS6K4N	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Nov-20-2020 14:31:36 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b)(6)	Data Entry: BS6K4N	Initial Entry

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Header Text: c4591001

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Form Version: 22-Apr-2020 21:02

Site No: 1152

Subject No: 11521450

Generated By: (b) (4)

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Form Status:

Site Name: (1152) California Research Foundation

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Date	Location	User	Value	Reason
Nov-24-2020 13:24:17 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Form Created	

Header Text: c4591001

Visit: Logs - Unscheduled

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Site No: 1152

Subject No: 11521450

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - Audit Trail

Form Status:

Site Name: (1152) California Research Foundation

Subject Initials: ---

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Date	Location	User	Value	Reason
Nov-24-2020 13:39:45 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Form Created	

090177e196ae2fcb\Final\Final On: 01-Apr-2021 03:52 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

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Site No: 1152

Subject No: 11521450

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - Audit Trail

Form Status:

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Date	Location	User	Value	Reason
Nov-24-2020 13:40:53 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Form Created	

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1152

Subject No: 11521450

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - Audit Trail

Form Status:

Site Name: (1152) California Research Foundation

Subject Initials: ---

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Date	Location	User	Value	Reason
Nov-24-2020 13:41:41 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Form Created	

Header Text: c4591001

Visit: Logs - Unscheduled

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Site No: 1152

Subject No: 11521450

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - Audit Trail

Form Status:

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Date	Location	User	Value	Reason
Feb-23-2021 03:05:25 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b) (6)	Form Created	

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1152

Subject No: 11521450

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: ---

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1. Category:

Date	Location	User	Value	Reason
Nov-24-2020 13:24:17 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: ADVERSE EVENT	Initial Entry

2. AE ID:

Date	Location	User	Value	Reason
Nov-24-2020 13:24:17 (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
Nov-24-2020 13:24:17 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4, (b)(6)	Data Entry: Fatigue	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason
Nov-24-2020 13:24:17 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4, (b)(6)	Data Entry: Oct/9/2020 18:00	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Nov-24-2020 13:24:17 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4, (b)(6)	Data Entry: NO End Date Time: Oct/11/2020 UNK:UNK	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
Nov-24-2020 13:24:17 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4, (b)(6)	Data Entry: 2	Initial Entry

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Site No: 1152

Subject No: 11521450

Generated By: (b) (4)

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Form Status: Data Complete, Frozen

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

7. Is the adverse event serious?

If Yes, NOTIFY PFIZER IMMEDIATELY.

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

Date	Location	User	Value	Reason
Nov-24-2020 13:24:17 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4, (b)(6)	<u>Data Entry:</u> NO	Initial Entry

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

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

Date	Location	User	Value	Reason
Nov-24-2020 13:24:17 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4, (b)(6)	<u>Data Entry:</u> NO	Initial Entry

9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Nov-24-2020 13:24:17 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4, (b)(6)	<u>Data Entry:</u> RELATED	Initial Entry

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Nov-24-2020 13:24:17 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4, (b)(6)	<u>Data Entry:</u> NOT APPLICABLE	Initial Entry

11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
Nov-24-2020 13:24:17 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4, (b)(6)	<u>Data Entry:</u> YES	Initial Entry

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Nov-24-2020 13:24:17 (UTC-08:00) Pacific Time	ACV0PFEINFP6000	(b) (6)	<u>Data Entry:</u> NO	Initial Entry

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Site No: 1152

Subject No: 11521450

Generated By: (b) (4)

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Form Status: Data Complete, Frozen

Site Name: (1152) California Research Foundation

Subject Initials: ---

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

(US & Canada)

(b) (4)

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

Date	Location	User	Value	Reason
Nov-24-2020 13:24:17 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4, (b)(6)	Data Entry: RECOVERED/RESOLVED	Initial Entry

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

Date	Location	User	Value	Reason
Nov-24-2020 13:24:17 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4, (b)(6)	Data Entry: NO	Initial Entry

Header Text: c4591001**Visit:** Logs - Unscheduled**Form Version:** 22-Apr-2020 21:02**Site No:** 1152**Subject No:** 11521450**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[Back to Form](#)**1. Category:**

Date	Location	User	Value	Reason
Nov-24-2020 13:39:45 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: ADVERSE EVENT	Initial Entry

2. AE ID:

Date	Location	User	Value	Reason
Nov-24-2020 13:39:45 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 2	Initial Entry

3. Adverse Event:*(If possible specify diagnosis, not individual symptoms)*

Date	Location	User	Value	Reason
Nov-24-2020 13:39:45 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4, (b)(6)	Data Entry: Headache	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason
Nov-24-2020 13:39:45 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4, (b)(6)	Data Entry: Oct/10/2020 UNK:UNK	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Nov-24-2020 13:39:45 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4, (b)(6)	Data Entry: NO End Date Time: Oct/12/2020 UNK:UNK	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
Nov-24-2020 13:39:45 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4, (b)(6)	Data Entry: 2	Initial Entry

Header Text: c4591001

Visit: Logs - Unscheduled

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Site No: 1152

Subject No: 11521450

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

7. Is the adverse event serious?

If Yes, NOTIFY PFIZER IMMEDIATELY.

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

Date	Location	User	Value	Reason
Nov-24-2020 13:39:45 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4, (b)(6)	<u>Data Entry:</u> NO	Initial Entry

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

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

Date	Location	User	Value	Reason
Nov-24-2020 13:39:45 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4, (b)(6)	<u>Data Entry:</u> NO	Initial Entry

9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Nov-24-2020 13:39:45 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4, (b)(6)	<u>Data Entry:</u> RELATED	Initial Entry

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Nov-24-2020 13:39:45 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4, (b)(6)	<u>Data Entry:</u> NOT APPLICABLE	Initial Entry

11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
Nov-24-2020 13:39:45 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4, (b)(6)	<u>Data Entry:</u> YES	Initial Entry

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Nov-24-2020 13:39:45 (UTC-08:00) Pacific Time	ACV0PFEINFP6000	(b) (6)	<u>Data Entry:</u> NO	Initial Entry

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Site No: 1152

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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: ---

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(US & Canada)

(b) (4)

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

Date	Location	User	Value	Reason
Nov-24-2020 13:39:45 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4, (b)(6)	Data Entry: RECOVERED/RESOLVED	Initial Entry

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

Date	Location	User	Value	Reason
Nov-24-2020 13:39:45 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4, (b)(6)	Data Entry: NO	Initial Entry

Header Text: c4591001

Visit: Logs - Unscheduled

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Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Frozen

Site Name: (1152) California Research Foundation

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1. Category:

Date	Location	User	Value	Reason
Nov-24-2020 13:40:53 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: ADVERSE EVENT	Initial Entry

2. AE ID:

Date	Location	User	Value	Reason
Nov-24-2020 13:40:53 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 3	Initial Entry

3. Adverse Event:

(If possible specify diagnosis, not individual symptoms)

Date	Location	User	Value	Reason
Nov-24-2020 13:40:53 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4, (b)(6)	Data Entry: Body Aches	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason
Nov-24-2020 13:40:53 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4, (b)(6)	Data Entry: Oct/10/2020 UNK:UNK	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Nov-24-2020 13:40:53 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4, (b)(6)	Data Entry: NO End Date Time: Oct/11/2020 UNK:UNK	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
Nov-24-2020 13:40:53 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4, (b)(6)	Data Entry: 2	Initial Entry

090177e196ae2fcb\Final\Final On: 01-Apr-2021 03:52 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

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Site No: 1152

Subject No: 11521450

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: ---

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7. Is the adverse event serious?

If Yes, NOTIFY PFIZER IMMEDIATELY.

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

Date	Location	User	Value	Reason
Nov-24-2020 13:40:53 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4, (b)(6)	<u>Data Entry:</u> NO	Initial Entry

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

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

Date	Location	User	Value	Reason
Nov-24-2020 13:40:53 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4, (b)(6)	<u>Data Entry:</u> NO	Initial Entry

9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Nov-24-2020 13:40:53 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4, (b)(6)	<u>Data Entry:</u> RELATED	Initial Entry

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Nov-24-2020 13:40:53 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4, (b)(6)	<u>Data Entry:</u> NOT APPLICABLE	Initial Entry

11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
Nov-24-2020 13:40:53 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4, (b)(6)	<u>Data Entry:</u> YES	Initial Entry

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Nov-24-2020 13:40:53 (UTC-08:00) Pacific Time	ACV0PFEINFP6000	(b) (6)	<u>Data Entry:</u> NO	Initial Entry

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Header Text: c4591001

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Subject No: 11521450

Generated By: (b) (4)

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Form Status: Data Complete, Frozen

Site Name: (1152) California Research Foundation

Subject Initials: ---

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(US & Canada)

(b) (4)

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

Date	Location	User	Value	Reason
Nov-24-2020 13:40:53 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4, (b)(6)	Data Entry: RECOVERED/RESOLVED	Initial Entry

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

Date	Location	User	Value	Reason
Nov-24-2020 13:40:53 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4, (b)(6)	Data Entry: NO	Initial Entry

Header Text: c4591001

Visit: Logs - Unscheduled

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Site No: 1152

Subject No: 11521450

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Frozen

Site Name: (1152) California Research Foundation

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1. Category:

Date	Location	User	Value	Reason
Nov-24-2020 13:41:41 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: ADVERSE EVENT	Initial Entry

2. AE ID:

Date	Location	User	Value	Reason
Nov-24-2020 13:41:41 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 4	Initial Entry

3. Adverse Event:

(If possible specify diagnosis, not individual symptoms)

Date	Location	User	Value	Reason
Dec-02-2020 09:43:39 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Salim Bouguermouh (b) (4)	Query 3: Closed	Response satisfies query
Dec-02-2020 09:43:39 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Salim Bouguermouh (b) (4)	Query 2: Closed	Response satisfies query
Dec-02-2020 08:36:25 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b)(6)	Query 3: Answered	But this was only 3 days after the second vaccination. Thus it is a reactogenicity sx, not a COVID sx, correct?
Dec-02-2020 08:35:04 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b)(6)	Query 2: Answered	AE occurred only 3 days after vaccination = reactogenicity sx, NOT COVID sx.
Dec-01-2020 11:43:16	ACV0PFEINFP6000	Salim Bouguermouh (b) (4)	Query 3: Opened	Clin: Despite a telehealth visit

090177e196ae2fcb\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: 11521450

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

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Subject Initials: ---

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

(UTC-08:00) Pacific Time (US & Canada)				was not done, please complete the potential COVID-19 Illness Visit CRF forms with all information available. Should be captured only on the SOD CRF form and a NASAL SWAB will not be collected
Dec-01-2020 11:42:35 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Salim Bouguermouh (b) (4)	Query 2: Opened	Clin: Per protocol section 8.1., COVID-19 listed symptom DIARRHEA should have please triggered a potential COVID Illness Visit irrespective of perceived etiology or clinical significance. A SWAB will not be collected and captured on the SOD form only
Nov-30-2020 23:10:31 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b)(6)	Query 1: Closed	Response satisfies query
Nov-30-2020 16:30:40 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b)(6)	Query 1: Answered	It is not a worsening. It is different in that it was not induced by spicy food.
Nov-26-2020 00:15:18 (UTC-08:00) Pacific Time (US	ACV0PFEINFP6000.InFormAdapter.Discrepancy	PFE SDQ PROD (b) (4)	Query 1: Opened	The AE Diarrhea was reported but is also listed in Medical History.

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Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1152

Subject No: 11521450

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

& Canada)				Please clarify if this is a worsening of the baseline condition, and if so, please consider adding "worsening" to the AE term. AE as baseline conditions should only be reported as AEs if they worsen. (b) (4)
Nov-24-2020 13:41:41 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b)(6)	Data Entry: Diarrhea	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason
Nov-24-2020 13:41:41 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b)(6)	Data Entry: Oct/12/2020 UNK:UNK	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Nov-24-2020 13:41:41 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b)(6)	Data Entry: NO End Date Time: Oct/12/2020 UNK:UNK	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
Nov-24-2020 13:41:41 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b)(6)	Data Entry: 2	Initial Entry

7. Is the adverse event serious?

If Yes, NOTIFY PFIZER IMMEDIATELY.

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Header Text: c4591001

Visit: Logs - Unscheduled

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Site No: 1152

Site Name: (1152) California Research Foundation

Subject No: 11521450

Subject Initials: ---

Generated By: (b) (4)

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

Date	Location	User	Value	Reason
Nov-24-2020 13:41:41 (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.

Date	Location	User	Value	Reason
Nov-24-2020 13:41:41 (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
Nov-24-2020 13:41:41 (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
Nov-24-2020 13:41:41 (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
Nov-24-2020 13:41:41 (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
Nov-24-2020 13:41:41 (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?:

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Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1152

Subject No: 11521450

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

Date	Location	User	Value	Reason
Nov-24-2020 13:41:41 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4, (b)(6)	Data Entry: RECOVERED/RESOLVED	Initial Entry

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

Date	Location	User	Value	Reason
Nov-24-2020 13:41:41 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4, (b)(6)	Data Entry: NO	Initial Entry

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1152

Subject No: 11521450

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Queries

Site Name: (1152) California Research Foundation

Subject Initials: ---

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

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1. Category:

Date	Location	User	Value	Reason
Feb-23-2021 03:05:25 (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
Feb-23-2021 03:05:25 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 5	Initial Entry

3. Adverse Event:

(If possible specify diagnosis, not individual symptoms)

Date	Location	User	Value	Reason
Mar-09-2021 15:15:57 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4, (b)(6)	Query 1: Opened	ClinQuery: If Exposure During Pregnancy occurs in a subject or subject's partner, the investigator must report this to Pfizer Safety on the Vaccines SAE report Form & an EDP supplemental form. Please confirm the SAE & EDP supplemental forms were completed
Feb-23-2021 03:05:25 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b)(6)	Data Entry: Exposure during pregnancy	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason
Feb-23-2021 03:05:25 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b)(6)	Data Entry: Dec/26/2020 UNK:UNK	Initial Entry

5. Is the adverse event still ongoing?

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Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Queries

Site No: 1152

Site Name: (1152) California Research Foundation

Subject No: 11521450

Subject Initials: ---

Generated By: (b) (4)

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

Date	Location	User	Value	Reason
Feb-23-2021 03:05:25 (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
Feb-23-2021 03:08:07 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b)(6)	Data Entry: 3	Initial Entry
Feb-23-2021 03:07:53 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b)(6)	Data Entry:	Initial Entry
Feb-23-2021 03:05:41 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b)(6)	Data Entry: Not Applicable	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
Feb-23-2021 03:05:25 (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.

Date	Location	User	Value	Reason
Feb-23-2021 03:05:25 (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
Feb-23-2021 03:05:25 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b)(6)	Data Entry: NOT RELATED If Not Related to study treatment(s), this event is due to:	Initial Entry

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Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1152

Subject No: 11521450

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Queries

Site Name: (1152) California Research Foundation

Subject Initials: ---

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			OTHER	
			<i>If Other, specify:</i>	
			Did not use birth control	

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Feb-23-2021 03:05:25 (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
Feb-23-2021 03:05:25 (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
Feb-23-2021 03:05:25 (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
Feb-23-2021 03:06:33 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b)(6)	Data Entry: NOT RECOVERED/NOT RESOLVE D	Initial Entry

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

Date	Location	User	Value	Reason
Feb-23-2021 03:05:25 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b)(6)	Data Entry: NO	Initial Entry

090177e196ae2fcb\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, Frozen, Verified

Site No: 1152

Site Name: (1152) California Research Foundation

Subject No: 11521450

Subject Initials: ---

Generated By: (b) (4)

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

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1. Date of Completion/Discontinuation/Death :

Date	Location	User	Value	Reason
Nov-20-2020 13:47:19 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4, (b)(6)	Data Entry: Nov/20/2020	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Nov-20-2020 13:47:19 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: VACCINATION	Initial Entry

3. Status:

Date	Location	User	Value	Reason
Nov-20-2020 13:47:19 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4, (b)(6)	Data Entry: COMPLETED	Initial Entry

090177e196ae2fcb\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: 11521450

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-23-2021 03:01:30 (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-23-2021 03:01:30 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b)(6)	Data Entry: OTHER <i>If other, specify:</i> Subject is pregnant.	Initial Entry

090177e196ae2fcb\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: 11521450

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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1. Subject Status

Date	Location	User	Value	Reason
Nov-20-2020 13:47:19 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: FOLLOW-UP	Initial Entry
Sep-16-2020 16:51:54 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: ENROLLED/RANDOMIZED	Initial Entry
Sep-16-2020 16:44:36 (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
Feb-24-2021 11:38:41 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b)(6)	Query 1: Closed	Response satisfies query
Feb-23-2021 03:08:43 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4, (b)(6)	Query 1: Answered	AE CRF completed
Feb-16-2021 12:33:03 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b)(6)	Query 1: Opened	SAE RECON:AER#2021146306 Non serious AE of Exposure during pregnancy was reported in Safety database but missing in AE CRF. Please confirm and update CRF. If safety update is required, submit a follow-up SAE Form.
Nov-20-2020 13:47:19 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Nov/20/2020	Initial Entry
Sep-16-2020 16:51:54 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sep/16/2020	Initial Entry
Sep-16-2020 16:44:36 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sep/16/2020	Initial Entry

090177e196ae2fcb\Final\Final On: 01-Apr-2021 03:52 (GMT)

Header Text: c4591001

Visit: Investigator Signature - Unscheduled

Form Version: 22-Apr-2020 21:04

Site No: 1152

Subject No: 11521450

Generated By: (b) (4)

Form: CASEBOOK SIGNATURE FORM - 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. Casebook Signature

Date	Location	User	Value	Reason
Nov-06-2020 07:42:36 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: Click Here to Enable	Initial Entry