

Header Text: c4591001

Visit: COHORT_SELECTION

Form Version: 10-Dec-2020 02:31

Site No: 1270

Subject No: 12701222

Generated By: (b) (4)

Form: COHORT_SELECTION

Form Status: Data Complete, Frozen, Verified

Site Name: (1270) Kaiser Permanente Sacramento

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

[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	01 DEC 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: 1270

Subject No: 12701222

Generated By: (b) (4)

Form: MAIN INFORMED CONSENT

Form Status: Data Complete, Frozen, Verified

Site Name: (1270) Kaiser Permanente Sacramento

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

[eCRF Audit Trail History](#)

Informed Consent

1.	Consent Was:	OBTAINED Date Written Consent Obtained Dec/18/2020
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Header Text: c4591001

Visit: COHORT_SELECTION

Form Version: 10-Dec-2020 02:26

Site No: 1270

Subject No: 12701222

Generated By: (b) (4)

Form: DEMOGRAPHY

Form Status: Data Complete, Frozen, Verified

Site Name: (1270) Kaiser Permanente Sacramento

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

[eCRF Audit Trail History](#)

Demography

1.	Subject ID	[12701222]
2.	Birth Date:	(b) (6) 2006
3.	Sex:	FEMALE
4.	Ethnicity:	NOT HISPANIC OR LATINO(A) OR OF SPANISH ORIGIN
5.	Race: (Check X all that apply):	WHITE
6.	Racial Designation:	

090177e196ae2e3f\Final\Final On: 01-Apr-2021 03:08 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:02

Site No: 1270

Subject No: 12701222

Generated By: (b) (4)

Form: DATE OF VISIT

Form Status: Data Complete, Frozen, Verified

Site Name: (1270) Kaiser Permanente Sacramento

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

[eCRF Audit Trail History](#)

Date of Visit

1.	Date of Visit	Dec/18/2020
2.	Erroneous Visit	

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 10-Oct-2020 16:00

Site No: 1270

Subject No: 12701222

Generated By: (b) (4)

Form: INCLUSION/EXCLUSION CRITERIA

Form Status: Data Complete, Frozen, Verified

Site Name: (1270) Kaiser Permanente Sacramento

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

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 _____
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090177e196ae2e3f\Final\Final On: 01-Apr-2021 03:08 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 15-Sep-2020 21:52

Site No: 1270

Subject No: 12701222

Generated By: (b) (4)

Form: DISPOSITION - SCREENING

Form Status: Data Complete, Frozen, Verified

Site Name: (1270) Kaiser Permanente Sacramento

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

[eCRF Audit Trail History](#)

Disposition - Screening

1.	Date of Completion/Discontinuation /Death	Dec/18/2020
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:** 1270**Subject No:** 12701222**Generated By:** (b) (4)**Form:** GENERAL MEDICAL HISTORY**Form Status:** Data Complete, Frozen, Verified**Site Name:** (1270) Kaiser Permanente Sacramento**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 18:51[eCRF Audit Trail History](#)**Medical History Details**

1.a	Line/MH Number:	[1]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Anxiety]
	Start Date:	Aug/31/2020
	Ongoing:	YES
1.b	Line/MH Number:	[2]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Attention Deficit Hyperactivity Disorder]
	Start Date:	Jan/UNK/2015
	Ongoing:	YES
1.c	Line/MH Number:	[3]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Right knee pain]
	Start Date:	Jun/19/2020
	Ongoing:	YES
1.d	Line/MH Number:	[4]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Right Forearm Pain]
	Start Date:	Jun/19/2020
	Ongoing:	YES

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1270

Subject No: 12701222

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY

Form Status: Data Complete, Frozen, Verified

Site Name: (1270) Kaiser Permanente Sacramento

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

1.e	Line/MH Number:	[5]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Depression]
	Start Date:	Dec/8/2020
	Ongoing:	YES

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 15-Sep-2020 21:57

Site No: 1270

Subject No: 12701222

Generated By: (b) (4)

Form: HIV STATUS

Form Status: Data Complete, Frozen, Verified

Site Name: (1270) Kaiser Permanente Sacramento

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

[eCRF Audit Trail History](#)

HIV Status

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

Header Text: c4591001**Visit:** V1_DAY1_VAX1_L**Form Version:** 10-Dec-2020 02:29**Site No:** 1270**Subject No:** 12701222**Generated By:** (b) (4)**Form:** VITAL SIGNS - BASELINE**Form Status:** Data Complete, Frozen, Verified**Site Name:** (1270) Kaiser Permanente Sacramento**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 18:51[eCRF Audit Trail History](#)**Vital Signs**

1.	Date:	Dec/18/2020
2.	Weight:	[60.6]
3.	Unit:	kg
4.	Height:	[167.6]
5.	Unit:	cm
6.	Body Mass Index:	[21.6]

Vital Signs Details

7.a	Record Identifier:	1
	Temperature:	[97.8]
	Unit:	F
	Temperature Location:	ORAL CAVITY

Header Text: c4591001**Visit:** V1_DAY1_VAX1_L**Form Version:** 10-Dec-2020 02:23**Site No:** 1270**Subject No:** 12701222**Generated By:** (b) (4)**Form:** LAB URINALYSIS - PREGNANCY TEST**Form Status:** Data Complete, Frozen, Verified**Site Name:** (1270) Kaiser Permanente Sacramento**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 18:51[eCRF Audit Trail History](#)**Lab Urinalysis**

1.	Lab Panel:	URINALYSIS
2.	Lab Sub-Panel:	PREGNANCY
3.	Collection Date:	Dec/18/2020
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: 1270

Subject No: 12701222

Generated By: (b) (4)

Form: RANDOMIZATION

Form Status: Data Complete, Frozen, Verified

Site Name: (1270) Kaiser Permanente Sacramento

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

[eCRF Audit Trail History](#)

Disposition

1.	Randomization Date :	Dec/18/2020
2.	Randomization Number:	[23485]
3.	Randomization Group:	[]

Header Text: c4591001**Visit:** V1_DAY1_VAX1_L**Form:** ELECTRONIC SAMPLE TRACKING -
IMMUNOGENICITY**Form Version:** 22-Apr-2020 21:03**Form Status:** Data Complete, Frozen, Verified**Site No:** 1270**Site Name:** (1270) Kaiser Permanente Sacramento**Subject No:** 12701222**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 18:51[eCRF Audit Trail History](#)**Electronic Sample Tracking**

1.	Data Origin	SITE
2.	Sample Type	SERUM
3.	Sample Collected?	YES Date of Collection: Dec/18/2020
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	[BRFFDS]
5.b	Sample ID	[BRFFDT]
5.c	Sample ID	[BK5M07]

Header Text: c4591001**Visit:** V1_DAY1_VAX1_L**Form Version:** 22-Apr-2020 21:03**Site No:** 1270**Subject No:** 12701222**Generated By:** (b) (4)**Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB**Form Status:** Data Complete, Frozen, Verified**Site Name:** (1270) Kaiser Permanente Sacramento**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 18:51[eCRF Audit Trail History](#)**Electronic Sample Tracking**

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Dec/18/2020
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	[BRFFCZ]
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Header Text: c4591001**Visit:** V1_DAY1_VAX1_L**Form Version:** 10-Dec-2020 02:26**Site No:** 1270**Subject No:** 12701222**Generated By:** (b) (4)**Form:** VACCINATION**Form Status:** Data Complete, Frozen, Verified**Site Name:** (1270) Kaiser Permanente Sacramento**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 18:51[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:	Dec/18/2020 16:30
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

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 06-Jul-2020 21:53

Site No: 1270

Subject No: 12701222

Generated By: (b) (4)

Form: REACTOGENICITY DIARY

Form Status: Data Complete, Frozen, Verified

Site Name: (1270) Kaiser Permanente Sacramento

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

[eCRF Audit Trail History](#)

Reactogenicity Diary

1.	Select appropriate response - Reactogenicity diary collection	YES - REACTOGENICITY E-DIARY COLLECTED FOR THIS SUBJECT
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Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 1270

Subject No: 12701222

Generated By: (b) (4)

Form: DATE OF VISIT

Form Status: Data Complete, Frozen, Verified

Site Name: (1270) Kaiser Permanente Sacramento

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

[eCRF Audit Trail History](#)

Date of Visit

1.	Date of Visit	Jan/8/2021
2.	Erroneous Visit	

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 10-Dec-2020 02:30

Site No: 1270

Subject No: 12701222

Generated By: (b) (4)

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM
RESOLVED DATES

Form Status: Data Complete, Frozen, Verified

Site Name: (1270) Kaiser Permanente Sacramento

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

[eCRF Audit Trail History](#)

Vaccination Symptoms Diary - Symptom Resolved Dates

1.	Were medications to treat fever/pain given on the last day the Subject Diary was completed?	NO
2.a	Symptom:	FEVER
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO
2.b	Symptom:	FATIGUE
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO
2.c	Symptom:	HEADACHE
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO
2.d	Symptom:	CHILLS
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO

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Header Text: c4591001**Visit:** V2_VAX2_L**Form:** VACCINATION SYMPTOMS DIARY - SYMPTOM
RESOLVED DATES**Form Version:** 10-Dec-2020 02:30**Form Status:** Data Complete, Frozen, Verified**Site No:** 1270**Site Name:** (1270) Kaiser Permanente Sacramento**Subject No:** 12701222**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 18:51

2.e	Symptom:	VOMITING
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO
2.f	Symptom:	DIARRHEA
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO
2.g	Symptom:	NEW OR WORSENERED MUSCLE PAIN
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO
2.h	Symptom:	NEW OR WORSENERED JOINT PAIN
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO
3.	Injection Site Location:	DELTOID MUSCLE
4.	Injection Site Body Side:	LEFT
5.a	Injection Site Reaction:	REDNESS
	Were injection site reactions present on the last day the Subject Diary was completed?	NO
5.b	Injection Site Reaction:	SWELLING
	Were injection site reactions present on the last day the Subject Diary was completed?	NO

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 10-Dec-2020 02:30

Site No: 1270

Subject No: 12701222

Generated By: (b) (4)

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM
RESOLVED DATES

Form Status: Data Complete, Frozen, Verified

Site Name: (1270) Kaiser Permanente Sacramento

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

5.c

Injection Site Reaction:

PAIN AT INJECTION SITE

Were injection site reactions
present on the last day the
Subject Diary was completed?

NO

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 10-Dec-2020 02:27

Site No: 1270

Subject No: 12701222

Generated By: (b) (4)

Form: VITAL SIGNS - TEMP

Form Status: Data Complete, Frozen, Verified

Site Name: (1270) Kaiser Permanente Sacramento

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

[eCRF Audit Trail History](#)

Vital Signs

1.	Date:	Jan/8/2021
----	-------	------------

Vital Signs Details

2.a	Record Identifier:	1
	Temperature:	[97.2]
	Unit:	F
	Temperature Location:	ORAL CAVITY

090177e196ae2e3f\Final\Final On: 01-Apr-2021 03:08 (GMT)

Header Text: c4591001**Visit:** V2_VAX2_L**Form Version:** 10-Dec-2020 02:23**Site No:** 1270**Subject No:** 12701222**Generated By:** (b) (4)**Form:** LAB URINALYSIS - PREGNANCY TEST**Form Status:** Data Complete, Frozen, Verified**Site Name:** (1270) Kaiser Permanente Sacramento**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 18:51[eCRF Audit Trail History](#)**Lab Urinalysis**

1.	Lab Panel:	URINALYSIS
2.	Lab Sub-Panel:	PREGNANCY
3.	Collection Date:	Jan/8/2021
4.	Laboratory Name and Address (Derived)	[STUDY SITE]
5.	Specimen Type:	URINE

Lab Result

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

Header Text: c4591001**Visit:** V2_VAX2_L**Form Version:** 22-Apr-2020 21:03**Site No:** 1270**Subject No:** 12701222**Generated By:** (b) (4)**Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB**Form Status:** Data Complete, Frozen, Verified**Site Name:** (1270) Kaiser Permanente Sacramento**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 18:51[eCRF Audit Trail History](#)**Electronic Sample Tracking**

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Jan/8/2021
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[]

Aliquot

Please enter barcode for each aliquot.

5.a	Sample ID	[BR33DD]
-----	-----------	----------

Header Text: c4591001**Visit:** V2_VAX2_L**Form Version:** 10-Dec-2020 02:26**Site No:** 1270**Subject No:** 12701222**Generated By:** (b) (4)**Form:** VACCINATION**Form Status:** Data Complete, Frozen, Verified**Site Name:** (1270) Kaiser Permanente Sacramento**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 18:51[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:	Jan/8/2021 14:18
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

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 1270

Subject No: 12701222

Generated By: (b) (4)

Form: DATE OF VISIT

Form Status: Data Complete, Frozen, Verified

Site Name: (1270) Kaiser Permanente Sacramento

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

[eCRF Audit Trail History](#)

Date of Visit

1.	Date of Visit	Feb/5/2021
2.	Erroneous Visit	

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form Version: 10-Dec-2020 02:30

Site No: 1270

Subject No: 12701222

Generated By: (b) (4)

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM
RESOLVED DATES

Form Status: Data Complete, Frozen, Verified

Site Name: (1270) Kaiser Permanente Sacramento

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

[eCRF Audit Trail History](#)

Vaccination Symptoms Diary - Symptom Resolved Dates

1.	Were medications to treat fever/pain given on the last day the Subject Diary was completed?	NO
2.a	Symptom:	FEVER
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO
2.b	Symptom:	FATIGUE
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO
2.c	Symptom:	HEADACHE
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO
2.d	Symptom:	CHILLS
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO

090177e196ae2e3f\Final\Final On: 01-Apr-2021 03:08 (GMT)

Header Text: c4591001**Visit:** V3_MONTH1_POSTVAX2_L**Form:** VACCINATION SYMPTOMS DIARY - SYMPTOM
RESOLVED DATES**Form Version:** 10-Dec-2020 02:30**Form Status:** Data Complete, Frozen, Verified**Site No:** 1270**Site Name:** (1270) Kaiser Permanente Sacramento**Subject No:** 12701222**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 18:51

2.e	Symptom:	VOMITING
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO
2.f	Symptom:	DIARRHEA
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO
2.g	Symptom:	NEW OR WORSENERED MUSCLE PAIN
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO
2.h	Symptom:	NEW OR WORSENERED JOINT PAIN
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO
3.	Injection Site Location:	DELTOID MUSCLE
4.	Injection Site Body Side:	LEFT
5.a	Injection Site Reaction:	REDNESS
	Were injection site reactions present on the last day the Subject Diary was completed?	NO
5.b	Injection Site Reaction:	SWELLING
	Were injection site reactions present on the last day the Subject Diary was completed?	NO

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM
RESOLVED DATES

Form Version: 10-Dec-2020 02:30

Form Status: Data Complete, Frozen, Verified

Site No: 1270

Site Name: (1270) Kaiser Permanente Sacramento

Subject No: 12701222

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

5.c

Injection Site Reaction:

PAIN AT INJECTION SITE

Were injection site reactions
present on the last day the
Subject Diary was completed?

NO

Header Text: c4591001**Visit:** V3_MONTH1_POSTVAX2_L**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY**Form Version:** 22-Apr-2020 21:03**Form Status:** Data Complete, Frozen, Verified**Site No:** 1270**Site Name:** (1270) Kaiser Permanente Sacramento**Subject No:** 12701222**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 18:51**eCRF Audit Trail History****Electronic Sample Tracking**

1.	Data Origin	SITE
2.	Sample Type	SERUM
3.	Sample Collected?	YES Date of Collection: Feb/5/2021
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[]

Aliquot

Please enter barcode for each aliquot.

5.a	Sample ID	[BRFFHR]
5.b	Sample ID	[BRFFHS]
5.c	Sample ID	[BK5HR5]

Header Text: c4591001

Visit: V4_MONTH6_L

Form Version: 22-Apr-2020 21:02

Site No: 1270

Subject No: 12701222

Generated By: (b) (4)

Form: DATE OF VISIT

Form Status: Not Started

Site Name: (1270) Kaiser Permanente Sacramento

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

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:** 1270**Subject No:** 12701222**Generated By:** (b) (4)**Form:** ELECTRONIC SAMPLE TRACKING -
IMMUNOGENICITY**Form Status:** Not Started**Site Name:** (1270) Kaiser Permanente Sacramento**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 18:51**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: 1270

Subject No: 12701222

Generated By: (b) (4)

Form: DATE OF VISIT

Form Status: Not Started

Site Name: (1270) Kaiser Permanente Sacramento

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

Header Text: c4591001**Visit:** V5_MONTH12_L**Form:** ELECTRONIC SAMPLE TRACKING -
IMMUNOGENICITY**Form Version:** 22-Apr-2020 21:03**Form Status:** Not Started**Site No:** 1270**Site Name:** (1270) Kaiser Permanente Sacramento**Subject No:** 12701222**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 18:51**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:** 1270**Subject No:** 12701222**Generated By:** (b) (4)**Form:** DATE OF VISIT**Form Status:** Not Started**Site Name:** (1270) Kaiser Permanente Sacramento**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 18:51**Date of Visit**

1.	Date of Visit	//
2.	Erroneous Visit	

Header Text: c4591001**Visit:** V6_MONTH24_L**Form:** ELECTRONIC SAMPLE TRACKING -
IMMUNOGENICITY**Form Version:** 22-Apr-2020 21:03**Form Status:** Not Started**Site No:** 1270**Site Name:** (1270) Kaiser Permanente Sacramento**Subject No:** 12701222**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 18:51**Electronic Sample Tracking**

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

Aliquot

Please enter barcode for each aliquot.

5.	Sample ID	[]
----	-----------	-----

Header Text: c4591001

Visit: POT_COVID_ILL - New
Unscheduled Visit

Form Version: 22-Apr-2020 21:03

Site No: 1270

Subject No: 12701222

Generated By: (b) (4)

Form: DATE OF VISIT - ILLNESS ONSET

Form Status: Not Started

Site Name: (1270) Kaiser Permanente Sacramento

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

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:** 1270**Site Name:** (1270) Kaiser Permanente Sacramento**Subject No:** 12701222**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 18:51**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 Version:** 22-Apr-2020 21:03**Site No:** 1270**Subject No:** 12701222**Generated By:** (b) (4)**Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB
SELF**Form Status:** Not Started**Site Name:** (1270) Kaiser Permanente Sacramento**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 18:51**Electronic Sample Tracking**

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

Aliquot

Please enter barcode for each aliquot.

5.	Sample ID	[]
----	-----------	-----

Header Text: c4591001**Visit:** POT_COVID_ILL - New
Unscheduled Visit**Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB**Form Version:** 22-Apr-2020 21:03**Form Status:** Not Started**Site No:** 1270**Site Name:** (1270) Kaiser Permanente Sacramento**Subject No:** 12701222**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 18:51**Electronic Sample Tracking**

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

Aliquot

Please enter barcode for each aliquot.

5.	Sample ID	[]
----	-----------	-----

Header Text: c4591001**Visit:** POT_COVID_ILL - New
Unscheduled Visit**Form Version:** 20-Feb-2021 02:19**Site No:** 1270**Subject No:** 12701222**Generated By:** (b) (4)**Form:** HEALTH CARE UTILIZATION**Form Status:** Not Started**Site Name:** (1270) Kaiser Permanente Sacramento**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 18:51**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 Version: 06-Jul-2020 21:52

Site No: 1270

Subject No: 12701222

Generated By: (b) (4)

Form: ILLNESS DETAILS

Form Status: Not Started

Site Name: (1270) Kaiser Permanente Sacramento

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

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 Version: 22-Apr-2020 21:04

Site No: 1270

Subject No: 12701222

Generated By: (b) (4)

Form: DATE OF VISIT - ILLNESS CONVALESCENT

Form Status: Not Started

Site Name: (1270) Kaiser Permanente Sacramento

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

COVID-19 Illness Visit

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

Header Text: c4591001**Visit:** POT_COVID_CONVA - New
Unscheduled Visit**Form Version:** 22-Apr-2020 21:03**Site No:** 1270**Subject No:** 12701222**Generated By:** (b) (4)**Form:** ELECTRONIC SAMPLE TRACKING -
IMMUNOGENICITY**Form Status:** Not Started**Site Name:** (1270) Kaiser Permanente Sacramento**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 18:51**Electronic Sample Tracking**

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

Aliquot

Please enter barcode for each aliquot.

5.	Sample ID	[]
----	-----------	-----

Header Text: c4591001

Visit: POT_COVID_REPEAT_SWAB -
New Unscheduled Visit

Form: DATE OF VISIT - REPEAT SWAB

Form Version: 10-Oct-2020 15:57

Form Status: Not Started

Site No: 1270

Site Name: (1270) Kaiser Permanente Sacramento

Subject No: 12701222

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

COVID-19 Repeat Swab

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

Header Text: c4591001**Visit:** POT_COVID_REPEAT_SWAB -
New Unscheduled Visit**Form:** ELECTRONIC SAMPLE TRACKING - REPEAT SWAB**Form Version:** 10-Oct-2020 15:57**Form Status:** Not Started**Site No:** 1270**Site Name:** (1270) Kaiser Permanente Sacramento**Subject No:** 12701222**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 18:51**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: Logs

Form: ADVERSE EVENT REPORT

Form Version: 22-Apr-2020 21:02

Site No: 1270

Site Name: (1270) Kaiser Permanente Sacramento

Subject No: 12701222

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

#	Category	AE Identifier	Adverse Event	Start Date	Is the Adverse Event Still Ongoing	Form Instance
1.	ADVERSE EVENT	1	SUICIDAL IDEATION	Feb/16/2021 10:17	YES	Repeating Pages

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1270

Subject No: 12701222

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete

Site Name: (1270) Kaiser Permanente Sacramento

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

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[Form Audit Trail](#)

Adverse Event Report

1.	Category:	ADVERSE EVENT
2.	AE ID:	[1]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[SUICIDAL IDEATION]
4.	Start Date Time:	Feb/16/2021 10:17
5.	Is the adverse event still ongoing?	YES
6.	Toxicity Grade:	3
7.	Is the adverse event serious? If Yes, NOTIFY PFIZER IMMEDIATELY. Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).	YES Is this serious event associated with congenital anomaly or birth defect? Did this serious event result in death? Did this serious event require or prolong hospitalization? YES Did this serious event result in persistent or significant disability/incapacity? Is this serious event life threatening? Other medically important serious event
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

090177e196ae2e3f\Final\Final On: 01-Apr-2021 03:08 (GMT)

Header Text: c4591001**Visit:** Logs - Unscheduled**Form Version:** 22-Apr-2020 21:02**Site No:** 1270**Subject No:** 12701222**Generated By:** (b) (4)**Form:** ADVERSE EVENT REPORT**Form Status:** Data Complete**Site Name:** (1270) Kaiser Permanente Sacramento**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 18:51

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: [PSYCHOSOCIAL ISSUES]
10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE
11.	Was a Concomitant Medication given?	NO
12.	Was a Non-Drug Treatment given?	YES
13.	What was the outcome of this adverse event?:	NOT RECOVERED/NOT RESOLVED
14.	Did the adverse event cause the subject to be discontinued from the study?	NO
15.	Serious Adverse Event Number: For Pfizer Use Only	[2021195810]

Header Text: c4591001

Visit: Logs

Form: MEDICATION ERROR

Form Version: 17-Jul-2020 21:54

Site No: 1270

Site Name: (1270) Kaiser Permanente Sacramento

Subject No: 12701222

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

#	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: 1270

Subject No: 12701222

Generated By: (b) (4)

Form: MEDICATION ERROR

Form Status: Not Started

Site Name: (1270) Kaiser Permanente Sacramento

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

[Back to Form](#)

Medication Error

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

090177e196ae2e3f\Final\Final On: 01-Apr-2021 03:08 (GMT)

Header Text: c4591001

Visit: Logs

Form: CONCOMITANT MEDICATIONS - NON STUDY
VACCINATIONS

Form Version: 22-Apr-2020 21:03

Site No: 1270

Site Name: (1270) Kaiser Permanente Sacramento

Subject No: 12701222

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

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

Header Text: c4591001**Visit:** Logs - Unscheduled**Form:** CONCOMITANT MEDICATIONS - NON STUDY VACCINATIONS**Form Version:** 22-Apr-2020 21:03**Form Status:** Not Started**Site No:** 1270**Site Name:** (1270) Kaiser Permanente Sacramento**Subject No:** 12701222**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 18:51[Back to Form](#)**Concomitant Medications**

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

Header Text: c4591001

Visit: Logs

Form: CONCOMITANT MEDICATIONS - PROHIBITED

Form Version: 22-Apr-2020 21:03

Site No: 1270

Site Name: (1270) Kaiser Permanente Sacramento

Subject No: 12701222

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

#	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:** 1270**Subject No:** 12701222**Generated By:** (b) (4)**Form:** CONCOMITANT MEDICATIONS - PROHIBITED**Form Status:** Not Started**Site Name:** (1270) Kaiser Permanente Sacramento**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 18:51[Back to Form](#)**Concomitant Medications**

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

Header Text: c4591001

Visit: Logs

Form: RADIATION TREATMENT

Form Version: 22-Apr-2020 21:02

Site No: 1270

Site Name: (1270) Kaiser Permanente Sacramento

Subject No: 12701222

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

#	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: 1270

Subject No: 12701222

Generated By: (b) (4)

Form: RADIATION TREATMENT

Form Status: Not Started

Site Name: (1270) Kaiser Permanente Sacramento

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

[Back to Form](#)

Radiation Treatment

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

Header Text: c4591001

Visit: Logs

Form: TRANSFUSIONS

Form Version: 22-Apr-2020 21:03

Site No: 1270

Site Name: (1270) Kaiser Permanente Sacramento

Subject No: 12701222

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

#	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: 1270

Subject No: 12701222

Generated By: (b) (4)

Form: TRANSFUSIONS

Form Status: Not Started

Site Name: (1270) Kaiser Permanente Sacramento

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

[Back to Form](#)

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

Header Text: c4591001

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

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

Site No: 1270 **Site Name:** (1270) Kaiser Permanente Sacramento

Subject No: 12701222 **Subject Initials:** ---

Generated By: (b) (4) **Generated Time (GMT):** 29-Mar-2021 18:51

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: 1270 **Site Name:** (1270) Kaiser Permanente Sacramento

Subject No: 12701222 **Subject Initials:** ---

Generated By: (b) (4) **Generated Time (GMT):** 29-Mar-2021 18:51

Unplanned Assessments

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

Header Text: c4591001

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

Form Version: 22-Apr-2020 21:02

Form Status: Not Started

Site No: 1270

Site Name: (1270) Kaiser Permanente Sacramento

Subject No: 12701222

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

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: 1270

Site Name: (1270) Kaiser Permanente Sacramento

Subject No: 12701222

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

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:** 1270**Site Name:** (1270) Kaiser Permanente Sacramento**Subject No:** 12701222**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 18:51**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:** 1270**Site Name:** (1270) Kaiser Permanente Sacramento**Subject No:** 12701222**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 18:51**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?	

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: 1270

Site Name: (1270) Kaiser Permanente Sacramento

Subject No: 12701222

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

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: 1270

Site Name: (1270) Kaiser Permanente Sacramento

Subject No: 12701222

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

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:** 1270**Site Name:** (1270) Kaiser Permanente Sacramento**Subject No:** 12701222**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 18:51**Date of Visit**

1.	Date of Visit	//
2.	Erroneous Visit	

Header Text: c4591001

Visit: V201_SURVEIL_CONSENT -
Unscheduled

Form Version: 14-Jan-2021 02:29

Site No: 1270

Subject No: 12701222

Generated By: (b) (4)

Form: INFORMED CONSENT - ASYMPTOMATIC
SURVEILLANCE

Form Status: Not Started

Site Name: (1270) Kaiser Permanente Sacramento

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

Informed Consent - Asymptomatic Surveillance

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

Header Text: c4591001**Visit:** V201_SURVEIL_CONSENT -
Unscheduled**Form Version:** 22-Apr-2020 21:03**Site No:** 1270**Subject No:** 12701222**Generated By:** (b) (4)**Form:** ELECTRONIC SAMPLE TRACKING -
IMMUNOGENICITY**Form Status:** Not Started**Site Name:** (1270) Kaiser Permanente Sacramento**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 18:51**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 Version:** 22-Apr-2020 21:03**Site No:** 1270**Subject No:** 12701222**Generated By:** (b) (4)**Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB**Form Status:** Not Started**Site Name:** (1270) Kaiser Permanente Sacramento**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 18:51**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: End of Treatment - Unscheduled

Form Version: 20-Feb-2021 02:26

Site No: 1270

Subject No: 12701222

Generated By: (b) (4)

Form: DISPOSITION - TREATMENT

Form Status: Data Complete, Frozen, Verified

Site Name: (1270) Kaiser Permanente Sacramento

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

[eCRF Audit Trail History](#)

Disposition - Treatment

1.	Date of Completion/Discontinuation/Death :	Feb/5/2021
2.	Phase of Disposition:	VACCINATION
3.	Status:	COMPLETED
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:** 1270**Site Name:** (1270) Kaiser Permanente Sacramento**Subject No:** 12701222**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 18:51**Date of Visit**

1.	Date of Visit	//
2.	Erroneous Visit	

Header Text: c4591001

Visit: Potential ReVax Initial Contact -
Unscheduled

Form Version: 10-Dec-2020 02:25

Site No: 1270

Subject No: 12701222

Generated By: (b) (4)

Form: FURTHER VACCINATION CONFIRMATION

Form Status: Not Started

Site Name: (1270) Kaiser Permanente Sacramento

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

Further Vaccination Confirmation

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

Header Text: c4591001

Visit: Disposition - Unscheduled

Form Version: 10-Dec-2020 02:27

Site No: 1270

Subject No: 12701222

Generated By: (b) (4)

Form: TREATMENT UNBLINDED

Form Status: Not Started

Site Name: (1270) Kaiser Permanente Sacramento

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

Treatment Unblinded

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

Header Text: c4591001

Visit: Disposition - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1270

Subject No: 12701222

Generated By: (b) (4)

Form: WITHDRAWAL OF CONSENT

Form Status: Not Started

Site Name: (1270) Kaiser Permanente Sacramento

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

Withdrawal Of Consent

1.	Withdrawal of Consent Date :	//
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090177e196ae2e3f\Final\Final On: 01-Apr-2021 03:08 (GMT)

Header Text: c4591001

Visit: Disposition - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1270

Subject No: 12701222

Generated By: (b) (4)

Form: DEATH DETAILS CODED

Form Status: Not Started

Site Name: (1270) Kaiser Permanente Sacramento

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

Death Details

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

Cause of Death

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

Header Text: c4591001

Visit: Follow-Up - Unscheduled

Form Version: 15-Sep-2020 21:53

Site No: 1270

Subject No: 12701222

Generated By: (b) (4)

Form: DISPOSITION - FOLLOW-UP

Form Status: Not Started

Site Name: (1270) Kaiser Permanente Sacramento

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

Disposition - Follow-Up

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

Header Text: c4591001

Visit: Subject Status - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1270

Subject No: 12701222

Generated By: (b) (4)

Form: SUBJECT STATUS

Form Status: Data Complete, Verified

Site Name: (1270) Kaiser Permanente Sacramento

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

[eCRF Audit Trail History](#)

Subject Status

1.	Subject Status	FOLLOW-UP
2.	Subject Status Date	Feb/5/2021

Header Text: c4591001

Visit: Investigator Signature - Unscheduled

Form: CASEBOOK SIGNATURE FORM

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Signed, Verified

Site No: 1270

Site Name: (1270) Kaiser Permanente Sacramento

Subject No: 12701222

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

[eCRF Audit Trail History](#)

Casebook Signature Form

1.	Casebook Signature	Click Here to Enable
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090177e196ae2e3f\Final\Final On: 01-Apr-2021 03:08 (GMT)

Header Text: c4591001**Visit:** Investigator Signature - Unscheduled **Form:** CASEBOOK SIGNATURE FORM**Form Version:** 22-Apr-2020 21:04**Form Status:** Data Complete, Signed, Verified**Site No:** 1270**Site Name:** (1270) Kaiser Permanente Sacramento**Subject No:** 12701222**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 18:51[Audit Trail](#)

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

- CRF_Sign

Name	Signature Meaning	Date	Type	Action
Nicola Klein	Approved	Mar-10-2021 14:56:04 (UTC-08:00) Pacific Time (US & Canada)	BOOK	Signed

Affidavit:

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

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

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

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 10-Oct-2020 16:00

Site No: 1270

Subject No: 12701222

Generated By: (b) (4)

Form: INCLUSION/EXCLUSION CRITERIA - Comments

Form Status: Data Complete, Frozen, Verified

Site Name: (1270) Kaiser Permanente Sacramento

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

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Item	Date	User	Comment
Form	Dec-22-2020 13:14:27 (UTC-08:00) Pacific Time (US & Canada)	(b) (4), (b) (6)	N/A
			Not Applicable

Header Text: c4591001

Visit: Investigator Signature - Unscheduled **Form:** CASEBOOK SIGNATURE FORM - Signature History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Signed, Verified

Site No: 1270

Site Name: (1270) Kaiser Permanente Sacramento

Subject No: 12701222

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

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

- CRF_Sign

Name	Signature Meaning	Date	Type	Action
Nicola Klein	Approved	Mar-10-2021 14:56:04 (UTC-08:00) Pacific Time (US & Canada)	BOOK	Signed

Affidavit:

By my dated signature below, I, NicolaKlein, 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.

090177e196ae2e3f\Final\Final On: 01-Apr-2021 03:08 (GMT)

Header Text: c4591001

Visit: COHORT_SELECTION

Form Version: 10-Dec-2020 02:31

Site No: 1270

Subject No: 12701222

Generated By: (b) (4)

Form: COHORT SELECTION - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1270) Kaiser Permanente Sacramento

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

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1. Select appropriate response - Protocol version

Date	Location	User	Value	Reason
Dec-22-2020 13:12:51 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 01 DEC 2020	Initial Entry

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

Date	Location	User	Value	Reason
Dec-22-2020 13:12:51 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: STAGE 3 COHORTS	Initial Entry

090177e196ae2e3f\Final\Final On: 01-Apr-2021 03:08 (GMT)

Header Text: c4591001

Visit: COHORT_SELECTION

Form Version: 22-Apr-2020 21:02

Site No: 1270

Subject No: 12701222

Generated By: (b) (4)

Form: MAIN INFORMED CONSENT - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1270) Kaiser Permanente Sacramento

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

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1. Consent Was:

Date	Location	User	Value	Reason
Dec-22-2020 13:13:37 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> OBTAINED Date Written Consent Obtained Dec/18/2020	Initial Entry

Header Text: c4591001**Visit:** COHORT_SELECTION**Form Version:** 10-Dec-2020 02:26**Site No:** 1270**Subject No:** 12701222**Generated By:** (b) (4)**Form:** DEMOGRAPHY - eCRF Audit Trail History**Form Status:** Data Complete, Frozen, Verified**Site Name:** (1270) Kaiser Permanente Sacramento**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 18:51[Back to Form](#)**1. Subject ID**

Date	Location	User	Value	Reason
Dec-22-2020 13:12:40 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 12701222	Item copied from previous form

2. Birth Date:

Date	Location	User	Value	Reason
Dec-22-2020 13:07:12 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: (b) (6) 2006	Enrollment Entry

3. Sex:

Date	Location	User	Value	Reason
Dec-22-2020 13:13:59 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: FEMALE	Initial Entry

4. Ethnicity:

Date	Location	User	Value	Reason
Dec-22-2020 13:13:59 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NOT HISPANIC OR LATI NO(A) OR OF SPANISH ORIGIN	Initial Entry

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

Date	Location	User	Value	Reason
Dec-22-2020 13:13:59 (UTC-08:00) Pacific	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: WHITE	Initial Entry

Header Text: c4591001

Visit: COHORT_SELECTION

Form Version: 10-Dec-2020 02:26

Site No: 1270

Subject No: 12701222

Generated By: (b) (4)

Form: DEMOGRAPHY - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1270) Kaiser Permanente Sacramento

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

Time (US & Canada)				
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090177e196ae2e3f\Final\Final On: 01-Apr-2021 03:08 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:02

Site No: 1270

Subject No: 12701222

Generated By: (b) (4)

Form: DATE OF VISIT - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1270) Kaiser Permanente Sacramento

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

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1. Date of Visit

Date	Location	User	Value	Reason
Dec-22-2020 13:14:13 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Dec/18/2020	Initial Entry

090177e196ae2e3f\Final\Final On: 01-Apr-2021 03:08 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 15-Sep-2020 21:52

Site No: 1270

Subject No: 12701222

Generated By: (b) (4)

Form: DISPOSITION - SCREENING - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1270) Kaiser Permanente Sacramento

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

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1. Date of Completion/Discontinuation/Death

Date	Location	User	Value	Reason
Dec-22-2020 13:14:52 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Dec/18/2020	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Dec-22-2020 13:14:52 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SCREENING	Initial Entry

3. Status:

Date	Location	User	Value	Reason
Dec-22-2020 13:14:52 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: COMPLETED	Initial Entry

090177e196ae2e3f\Final\Final On: 01-Apr-2021 03:08 (GMT)

Header Text: c4591001**Visit:** V1_DAY1_VAX1_L**Form Version:** 22-Apr-2020 21:03**Site No:** 1270**Subject No:** 12701222**Generated By:** (b) (4)**Form:** GENERAL MEDICAL HISTORY - eCRF Audit Trail History**Form Status:** Data Complete, Frozen, Verified**Site Name:** (1270) Kaiser Permanente Sacramento**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 18:51[Back to Form](#)**I.a**

Date	Location	User	Value	Reason
Dec-22-2020 13:15:14 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: Medical History Term: Start Date: Aug/31/2020 Ongoing: YES	Initial Entry

I.a Line/MH Number:

Date	Location	User	Value	Reason
Dec-22-2020 13:15:14 (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
Dec-22-2020 13:15:14 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Anxiety	Initial Entry

I.a Start Date:

Date	Location	User	Value	Reason
Dec-22-2020 13:15:14 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Aug/31/2020	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1270

Subject No: 12701222

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1270) Kaiser Permanente Sacramento

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

1.a Ongoing:

Date	Location	User	Value	Reason
Dec-22-2020 13:15:14 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

1.b

Date	Location	User	Value	Reason
Dec-22-2020 13:15:26 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH 2 Number: Medical History Term: Attention Deficit Hyperactivity Disorder Start Date: Jan/UNK/2015 Ongoing: YES	Initial Entry

090177e196ae2e3f\Final\Final On: 01-Apr-2021 03:08 (GMT)

Header Text: c4591001**Visit:** V1_DAY1_VAX1_L**Form:** GENERAL MEDICAL HISTORY - eCRF Audit Trail History**Form Version:** 22-Apr-2020 21:03**Form Status:** Data Complete, Frozen, Verified**Site No:** 1270**Site Name:** (1270) Kaiser Permanente Sacramento**Subject No:** 12701222**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 18:51**1.b Line/MH Number:**

Date	Location	User	Value	Reason
Dec-22-2020 13:15:26 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 2	Initial Entry

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

Date	Location	User	Value	Reason
Dec-22-2020 13:15:26 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Attention Deficit Hyperactivity Disorder	Initial Entry

1.b Start Date:

Date	Location	User	Value	Reason
Dec-22-2020 13:15:26 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Jan/UNK/2015	Initial Entry

1.b Ongoing:

Date	Location	User	Value	Reason
Dec-22-2020 13:15:26 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

1.c

Date	Location	User	Value	Reason
Dec-22-2020 13:15:39 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 3	Initial Entry

Header Text: c4591001**Visit:** V1_DAY1_VAX1_L**Form:** GENERAL MEDICAL HISTORY - eCRF Audit Trail History**Form Version:** 22-Apr-2020 21:03**Form Status:** Data Complete, Frozen, Verified**Site No:** 1270**Site Name:** (1270) Kaiser Permanente Sacramento**Subject No:** 12701222**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 18:51

			Medical History Right knee Term: pain Start Date: Jun/19/2020 Ongoing: YES	
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I.c Line/MH Number:

Date	Location	User	Value	Reason
Dec-22-2020 13:15:39 (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
Dec-22-2020 13:15:39 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Right knee pain	Initial Entry

I.c Start Date:

Date	Location	User	Value	Reason
Dec-22-2020 13:15:39 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Jun/19/2020	Initial Entry

I.c Ongoing:

Date	Location	User	Value	Reason
Dec-22-2020 13:15:39 (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: 22-Apr-2020 21:03

Site No: 1270

Subject No: 12701222

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1270) Kaiser Permanente Sacramento

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

I.d

Date	Location	User	Value	Reason
Dec-22-2020 17:15:52 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Line/MH Nu 4 mber: Medical Hist Right Fore ory Term: arm Pain Start Date: Jun/19/202 0 Ongoing: YES	Transcription Error
Dec-22-2020 13:16:11 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Nu 4 mber: Medical Hist Right Fore ory Term: arm Pain Start Date: Jun/19/202 0 Ongoing: YES	Initial Entry

090177e196ae2e3f\Final\Final On: 01-Apr-2021 03:08 (GMT)

Header Text: c4591001**Visit:** V1_DAY1_VAX1_L**Form:** GENERAL MEDICAL HISTORY - eCRF Audit Trail History**Form Version:** 22-Apr-2020 21:03**Form Status:** Data Complete, Frozen, Verified**Site No:** 1270**Site Name:** (1270) Kaiser Permanente Sacramento**Subject No:** 12701222**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 18:51***1.d Line/MH Number:***

Date	Location	User	Value	Reason
Dec-22-2020 13:16:11 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 4	Initial Entry

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

Date	Location	User	Value	Reason
Dec-22-2020 19:30:57 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	PFETMS Oracle (b) (4)	Query 1 : Closed	Discrepancy has been closed.
Dec-22-2020 17:15:52 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1 : Answered	Transcription Error
Dec-22-2020 17:15:52 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Right Forearm Pain	Transcription Error
Dec-22-2020 16:29:24 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	PFETMS Oracle (b) (4)	Query 1 : Opened	Special Characters: Verbatim Term contains embedded non-compliant characters.
Dec-22-2020 13:16:11	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1270

Subject No: 12701222

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1270) Kaiser Permanente Sacramento

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

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

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

Right Forearm
Pain

1.d Start Date:

Date	Location	User	Value	Reason
Dec-22-2020 13:16:11 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Jun/19/2020	Initial Entry

1.d Ongoing:

Date	Location	User	Value	Reason
Dec-22-2020 13:16:11 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

1.e

Date	Location	User	Value	Reason
Mar-03-2021 12:24:09 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number 5 : Medical History T Depression: Start Date: Dec/8/2020 Ongoing: YES	Initial Entry

090177e196ae2e3f\Final\Final On: 01-Apr-2021 03:08 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1270

Subject No: 12701222

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1270) Kaiser Permanente Sacramento

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

I.e Line/MH Number:

Date	Location	User	Value	Reason
Mar-03-2021 12:24:09 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 5	Initial Entry

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

Date	Location	User	Value	Reason
Mar-03-2021 12:24:09 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Depression	Initial Entry

I.e Start Date:

Date	Location	User	Value	Reason
Mar-03-2021 12:24:09 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Dec/8/2020	Initial Entry

I.e Ongoing:

Date	Location	User	Value	Reason
Mar-03-2021 12:24:09 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

090177e196ae2e3f\Final\Final On: 01-Apr-2021 03:08 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 15-Sep-2020 21:57

Site No: 1270

Subject No: 12701222

Generated By: (b) (4)

Form: HIV STATUS - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1270) Kaiser Permanente Sacramento

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

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

Date	Location	User	Value	Reason
Dec-22-2020 13:16:22 (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: 10-Dec-2020 02:29

Site No: 1270

Subject No: 12701222

Generated By: (b) (4)

Form: VITAL SIGNS - BASELINE - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1270) Kaiser Permanente Sacramento

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

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1. Date:

Date	Location	User	Value	Reason
Dec-22-2020 13:16:58 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Dec/18/2020	Initial Entry

2. Weight:

Date	Location	User	Value	Reason
Dec-22-2020 13:16:58 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 60.6	Initial Entry

3. Unit:

Date	Location	User	Value	Reason
Dec-22-2020 13:16:58 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: kg	Initial Entry

4. Height:

Date	Location	User	Value	Reason
Dec-22-2020 13:16:58 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 167.6	Initial Entry

5. Unit:

Date	Location	User	Value	Reason
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090177e196ae2e3f\Final\Final On: 01-Apr-2021 03:08 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 10-Dec-2020 02:29

Site No: 1270

Subject No: 12701222

Generated By: (b) (4)

Form: VITAL SIGNS - BASELINE - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1270) Kaiser Permanente Sacramento

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

Dec-22-2020 13:16:58 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: cm	Initial Entry
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6. Body Mass Index:

Date	Location	User	Value	Reason
Dec-22-2020 13:16:58 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 21.6	Initial Entry

7.a

Date	Location	User	Value	Reason
Dec-22-2020 13:16:58 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Record Identif 1 ier:: Temperature: 97.8 Temperature F Unit: Temperature ORAL C Location:: AVITY	Initial Entry

7.a Record Identifier:

Date	Location	User	Value	Reason
Dec-22-2020 13:16:58 (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
Dec-22-2020 13:16:58 (UTC-08:00) Pacific	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 97.8	Initial Entry

090177e196ae2e3f\Final\Final On: 01-Apr-2021 03:08 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 10-Dec-2020 02:29

Site No: 1270

Subject No: 12701222

Generated By: (b) (4)

Form: VITAL SIGNS - BASELINE - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1270) Kaiser Permanente Sacramento

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

Time (US & Canada)

7.a Unit:

Date	Location	User	Value	Reason
Dec-22-2020 13:16:58 (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
Dec-22-2020 13:16:58 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: ORAL CAVITY	Initial Entry

090177e196ae2e3f\Final\Final On: 01-Apr-2021 03:08 (GMT)

Header Text: c4591001**Visit:** V1_DAY1_VAX1_L**Form:** LAB URINALYSIS - PREGNANCY TEST - eCRF Audit Trail History**Form Version:** 10-Dec-2020 02:23**Form Status:** Data Complete, Frozen, Verified**Site No:** 1270**Site Name:** (1270) Kaiser Permanente Sacramento**Subject No:** 12701222**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 18:51[Back to Form](#)**1. Lab Panel:**

Date	Location	User	Value	Reason
Dec-22-2020 13:17:15 (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
Dec-22-2020 13:17:15 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: PREGNANCY	Initial Entry

3. Collection Date:

Date	Location	User	Value	Reason
Dec-22-2020 13:17:15 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Dec/18/2020	Initial Entry

4. Laboratory Name and Address (Derived)

Date	Location	User	Value	Reason
Dec-22-2020 13:17:15 (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
Dec-22-2020 13:17:15 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: URINE	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 10-Dec-2020 02:23

Site No: 1270

Subject No: 12701222

Generated By: (b) (4)

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

Form Status: Data Complete, Frozen, Verified

Site Name: (1270) Kaiser Permanente Sacramento

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

6.a

Date	Location	User	Value	Reason
Dec-22-2020 13:17:15 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sponsor-Def 113 ined Identifi er: Test:: Choriogonadot ropin Beta_PX 113 Result:: NEGATIVE Not Done::	Initial Entry

6.a Sponsor ID:

Date	Location	User	Value	Reason
Dec-22-2020 13:17:15 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 113	Initial Entry

6.a Test:

Date	Location	User	Value	Reason
Dec-22-2020 13:17:15 (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
Dec-22-2020 13:17:15 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NEGATIVE	Initial Entry

090177e196ae2e3f\Final\Final On: 01-Apr-2021 03:08 (GMT)

Header Text: c4591001**Visit:** V1_DAY1_VAX1_L**Form Version:** 22-Apr-2020 21:03**Site No:** 1270**Subject No:** 12701222**Generated By:** (b) (4)**Form:** RANDOMIZATION - eCRF Audit Trail History**Form Status:** Data Complete, Frozen, Verified**Site Name:** (1270) Kaiser Permanente Sacramento**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 18:51[Back to Form](#)**1. Randomization Date :**

Date	Location	User	Value	Reason
Dec-22-2020 13:19:02 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Dec-22-2020 13:19:02 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Dec/18/2020	Transcription Error
Dec-22-2020 13:17:36 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	Randomization Date 21/Dec/2020 is before or more than 1 day after corresponding Date of Visit 18/Dec/2020. Please review and update as appropriate.
Dec-22-2020 13:17:36 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Dec/21/2020	Initial Entry

2. Randomization Number:

Date	Location	User	Value	Reason
Dec-22-2020 13:17:36 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 23485	Initial Entry

Header Text: c4591001**Visit:** V1_DAY1_VAX1_L**Form Version:** 22-Apr-2020 21:03**Site No:** 1270**Subject No:** 12701222**Generated By:** (b) (4)**Form:** ELECTRONIC SAMPLE TRACKING -
IMMUNOGENICITY - eCRF Audit Trail History**Form Status:** Data Complete, Frozen, Verified**Site Name:** (1270) Kaiser Permanente Sacramento**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 18:51[Back to Form](#)**1. Data Origin**

Date	Location	User	Value	Reason
Dec-22-2020 13:18:08 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Dec-22-2020 13:18:08 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SERUM	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Dec-22-2020 13:18:08 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Collection: Dec/18/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Dec-22-2020 13:17:48 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BRFFDS	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
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Header Text: c4591001**Visit:** V1_DAY1_VAX1_L**Form:** ELECTRONIC SAMPLE TRACKING -
IMMUNOGENICITY - eCRF Audit Trail History**Form Version:** 22-Apr-2020 21:03**Form Status:** Data Complete, Frozen, Verified**Site No:** 1270**Site Name:** (1270) Kaiser Permanente Sacramento**Subject No:** 12701222**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 18:51

Dec-22-2020 13:17:48 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BRFFDS	Initial Entry
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5.b

Date	Location	User	Value	Reason
Dec-22-2020 13:17:54 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BRFFDT	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Dec-22-2020 13:17:54 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BRFFDT	Initial Entry

5.c

Date	Location	User	Value	Reason
Dec-22-2020 13:18:00 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BK5M07	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Dec-22-2020 13:18:00 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BK5M07	Initial Entry

Header Text: c4591001**Visit:** V1_DAY1_VAX1_L**Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB -
eCRF Audit Trail History**Form Version:** 22-Apr-2020 21:03**Form Status:** Data Complete, Frozen, Verified**Site No:** 1270**Site Name:** (1270) Kaiser Permanente Sacramento**Subject No:** 12701222**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 18:51[Back to Form](#)**1. Data Origin**

Date	Location	User	Value	Reason
Dec-22-2020 13:18:27 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Dec-22-2020 13:18:27 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: NASAL_SWAB	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Dec-22-2020 13:18:27 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Collection: Dec/18/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Dec-22-2020 13:18:16 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BRFFCZ	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
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Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1270

Subject No: 12701222

Generated By: (b) (4)

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

Form Status: Data Complete, Frozen, Verified

Site Name: (1270) Kaiser Permanente Sacramento

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

Dec-22-2020 13:18:16 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> BRFFCZ	Initial Entry
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Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 10-Dec-2020 02:26

Site No: 1270

Subject No: 12701222

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1270) Kaiser Permanente Sacramento

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

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1. Was there a temporary delay of vaccination?

Date	Location	User	Value	Reason
Dec-22-2020 13:18:40 (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
Dec-22-2020 13:18:40 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: BLINDED THERAPY	Initial Entry

3. Formulation:

Date	Location	User	Value	Reason
Dec-22-2020 13:18:40 (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
Dec-22-2020 13:18:40 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Dec/18/2020 16:30	Initial Entry

5. Anatomical Location:

Date	Location	User	Value	Reason
Dec-22-2020 13:18:40 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: DELTOID MUSCLE	Initial Entry

090177e196ae2e3f\Final\Final On: 01-Apr-2021 03:08 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 10-Dec-2020 02:26

Site No: 1270

Subject No: 12701222

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1270) Kaiser Permanente Sacramento

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

6. Body Side:

Date	Location	User	Value	Reason
Dec-22-2020 13:18:40 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: LEFT	Initial Entry

7. Route:

Date	Location	User	Value	Reason
Dec-22-2020 13:18:40 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INTRAMUSCULAR	Initial Entry

10. Timeframe Subject Was Observed

Date	Location	User	Value	Reason
Dec-22-2020 13:18:40 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: THE PROTOCOL SPECIFIED OBSERVATION PERIOD	Initial Entry

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

Date	Location	User	Value	Reason
Dec-22-2020 13:18:40 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

090177e196ae2e3f\Final\Final On: 01-Apr-2021 03:08 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 06-Jul-2020 21:53

Site No: 1270

Subject No: 12701222

Generated By: (b) (4)

Form: REACTOGENICITY DIARY - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1270) Kaiser Permanente Sacramento

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

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1. Select appropriate response - Reactogenicity diary collection

Date	Location	User	Value	Reason
Dec-22-2020 13:18:50 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES - REACTOGENICIT Y E-DIARY COLLECTED FOR THIS SUBJECT	Initial Entry

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 1270

Subject No: 12701222

Generated By: (b) (4)

Form: DATE OF VISIT - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1270) Kaiser Permanente Sacramento

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

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1. Date of Visit

Date	Location	User	Value	Reason
Jan-11-2021 13:03:01 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Jan/8/2021	Initial Entry

090177e196ae2e3f\Final\Final On: 01-Apr-2021 03:08 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 10-Dec-2020 02:30

Site No: 1270

Subject No: 12701222

Generated By: (b) (4)

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM
RESOLVED DATES - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1270) Kaiser Permanente Sacramento

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

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1. Were medications to treat fever/pain given on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Jan-11-2021 13:03:16 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2.a

Date	Location	User	Value	Reason
Jan-11-2021 13:03:16 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom:: FE V E R Were fever or system N ic symptoms present O on the last day the Su bject Diary was com pleted?:	Initial Entry

2.a Symptom:

Date	Location	User	Value	Reason
Jan-11-2021 13:03:16 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: FEVER	Initial Entry

2.a Were fever or systemic symptoms present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Jan-11-2021 13:03:16 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

090177e196ae2e3f\Final\On: 01-Apr-2021 03:08 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 10-Dec-2020 02:30

Site No: 1270

Subject No: 12701222

Generated By: (b) (4)

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM
RESOLVED DATES - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1270) Kaiser Permanente Sacramento

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

2.b

Date	Location	User	Value	Reason
Jan-11-2021 13:03:16 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom:: FA TI G UE Were fever or system N ic symptoms present O on the last day the S ubject Diary was co mpleted?:	Initial Entry

2.b Symptom:

Date	Location	User	Value	Reason
Jan-11-2021 13:03:16 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: FATIGUE	Initial Entry

2.b Were fever or systemic symptoms present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Jan-11-2021 13:03:16 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2.c

Date	Location	User	Value	Reason
Jan-11-2021 13:03:16 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom:: HE AD AC HE	Initial Entry

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 10-Dec-2020 02:30

Site No: 1270

Subject No: 12701222

Generated By: (b) (4)

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM
RESOLVED DATES - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1270) Kaiser Permanente Sacramento

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

			Were fever or systemic symptoms present on the last day the Subject Diary was completed?:	
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2.c Symptom:

Date	Location	User	Value	Reason
Jan-11-2021 13:03:16 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: HEADACHE	Initial Entry

2.c Were fever or systemic symptoms present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Jan-11-2021 13:03:16 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2.d

Date	Location	User	Value	Reason
Jan-11-2021 13:03:16 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom:: C HI LL S Were fever or systemic symptoms present on the last day the Subject Diary was completed?: N O	Initial Entry

090177e196ae2e3f\Final\Final On: 01-Apr-2021 03:08 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 10-Dec-2020 02:30

Site No: 1270

Subject No: 12701222

Generated By: (b) (4)

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM
RESOLVED DATES - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1270) Kaiser Permanente Sacramento

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

2.d Symptom:

Date	Location	User	Value	Reason
Jan-11-2021 13:03:16 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: CHILLS	Initial Entry

2.d Were fever or systemic symptoms present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Jan-11-2021 13:03:16 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2.e

Date	Location	User	Value	Reason
Jan-11-2021 13:03:16 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom:: VO MI TIN G Were fever or syste NO mic symptoms prese nt on the last day th e Subject Diary was completed?:	Initial Entry

090177e196ae2e3f\Final\Final On: 01-Apr-2021 03:08 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 10-Dec-2020 02:30

Site No: 1270

Subject No: 12701222

Generated By: (b) (4)

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM
RESOLVED DATES - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1270) Kaiser Permanente Sacramento

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

2.e Symptom:

Date	Location	User	Value	Reason
Jan-11-2021 13:03:16 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: VOMITING	Initial Entry

2.e Were fever or systemic symptoms present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Jan-11-2021 13:03:16 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2.f

Date	Location	User	Value	Reason
Jan-11-2021 13:03:16 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom:: DI AR RH EA Were fever or syste NO mic symptoms prese nt on the last day th e Subject Diary was completed?:	Initial Entry

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 10-Dec-2020 02:30

Site No: 1270

Subject No: 12701222

Generated By: (b) (4)

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM
RESOLVED DATES - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1270) Kaiser Permanente Sacramento

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

2.f Symptom:

Date	Location	User	Value	Reason
Jan-11-2021 13:03:16 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: DIARRHEA	Initial Entry

2.f Were fever or systemic symptoms present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Jan-11-2021 13:03:16 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2.g

Date	Location	User	Value	Reason
Jan-11-2021 13:03:16 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom:: NEW O R WOR SENED MUSC LE PAI N Were fever or sy NO stemic symptom s present on the last day the Sub ject Diary was c ompleted?:	Initial Entry

090177e196ae2e3f\Final\Final On: 01-Apr-2021 03:08 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 10-Dec-2020 02:30

Site No: 1270

Subject No: 12701222

Generated By: (b) (4)

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM
RESOLVED DATES - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1270) Kaiser Permanente Sacramento

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

2.g Symptom:

Date	Location	User	Value	Reason
Jan-11-2021 13:03:16 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NEW OR WORSENER M USCLE PAIN	Initial Entry

2.g Were fever or systemic symptoms present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Jan-11-2021 13:03:16 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2.h

Date	Location	User	Value	Reason
Jan-11-2021 13:03:16 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom:: NEW O R WOR SENER JOINT PAIN Were fever or sy NO stemic symptom s present on the l ast day the Subj ect Diary was co mpleted?:	Initial Entry

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 10-Dec-2020 02:30

Site No: 1270

Subject No: 12701222

Generated By: (b) (4)

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM
RESOLVED DATES - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1270) Kaiser Permanente Sacramento

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

2.h Symptom:

Date	Location	User	Value	Reason
Jan-11-2021 13:03:16 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NEW OR WORSENER JO INT PAIN	Initial Entry

2.h Were fever or systemic symptoms present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Jan-11-2021 13:03:16 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

3. Injection Site Location:

Date	Location	User	Value	Reason
Jan-11-2021 13:03:16 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: DELTOID MUSCLE	Initial Entry

4. Injection Site Body Side:

Date	Location	User	Value	Reason
Jan-11-2021 13:03:16 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: LEFT	Initial Entry

5.a

Date	Location	User	Value	Reason
Jan-11-2021 13:03:16 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Injection Site Reacti RE on:: DN ES S	Initial Entry

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 10-Dec-2020 02:30

Site No: 1270

Subject No: 12701222

Generated By: (b) (4)

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM
RESOLVED DATES - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1270) Kaiser Permanente Sacramento

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

			Were injection site reactions present on the last day the Subject Diary was completed?:	
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5.a Injection Site Reaction:

Date	Location	User	Value	Reason
Jan-11-2021 13:03:16 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: REDNESS	Initial Entry

5.a Were injection site reactions present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Jan-11-2021 13:03:16 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

5.b

Date	Location	User	Value	Reason
Jan-11-2021 13:03:16 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Injection Site Reaction: SWELLING Were injection site reactions present on the last day the Subject Diary was completed?:	Initial Entry

090177e196ae2e3f\Final\Final On: 01-Apr-2021 03:08 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 10-Dec-2020 02:30

Site No: 1270

Subject No: 12701222

Generated By: (b) (4)

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM
RESOLVED DATES - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1270) Kaiser Permanente Sacramento

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

5.b Injection Site Reaction:

Date	Location	User	Value	Reason
Jan-11-2021 13:03:16 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: SWELLING	Initial Entry

5.b Were injection site reactions present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Jan-11-2021 13:03:16 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

5.c

Date	Location	User	Value	Reason
Jan-11-2021 13:03:16 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Injection Site Reaction: PAIN AT IN JECTI ON SI TE Were injection site reactions present on the last day the Subject Diary was completed?: NO	Initial Entry

090177e196ae2e3f\Final\Final On: 01-Apr-2021 03:08 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 10-Dec-2020 02:30

Site No: 1270

Subject No: 12701222

Generated By: (b) (4)

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM
RESOLVED DATES - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1270) Kaiser Permanente Sacramento

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

5.c Injection Site Reaction:

Date	Location	User	Value	Reason
Jan-11-2021 13:03:16 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: PAIN AT INJECTION SIT E	Initial Entry

5.c Were injection site reactions present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Jan-11-2021 13:03:16 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

090177e196ae2e3f\Final\Final On: 01-Apr-2021 03:08 (GMT)

Header Text: c4591001**Visit:** V2_VAX2_L**Form Version:** 10-Dec-2020 02:27**Site No:** 1270**Subject No:** 12701222**Generated By:** (b) (4)**Form:** VITAL SIGNS - TEMP - eCRF Audit Trail History**Form Status:** Data Complete, Frozen, Verified**Site Name:** (1270) Kaiser Permanente Sacramento**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 18:51[Back to Form](#)**1. Date:**

Date	Location	User	Value	Reason
Jan-11-2021 13:03:47 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Jan/8/2021	Initial Entry

2.a

Date	Location	User	Value	Reason
Jan-11-2021 13:03:47 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Record Identifier: Temperature: 97.2 Temperature Unit: F Temperature Location: ORAL CAVITY	Initial Entry

2.a Record Identifier:

Date	Location	User	Value	Reason
Jan-11-2021 13:03:47 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 1	Initial Entry

2.a Temperature:

Date	Location	User	Value	Reason
Jan-11-2021 13:03:47 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 97.2	Initial Entry

2.a Unit:

Date	Location	User	Value	Reason
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Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 10-Dec-2020 02:27

Site No: 1270

Subject No: 12701222

Generated By: (b) (4)

Form: VITAL SIGNS - TEMP - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1270) Kaiser Permanente Sacramento

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

Jan-11-2021 13:03:47
(UTC-08:00) Pacific
Time (US & Canada)

ACV0PFEINFP6000

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

Data Entry:

F

Initial Entry

2.a Temperature Location:

Date

Location

User

Value

Reason

Jan-11-2021 13:03:47
(UTC-08:00) Pacific
Time (US & Canada)

ACV0PFEINFP6000

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

Data Entry:

ORAL CAVITY

Initial Entry

Header Text: c4591001**Visit:** V2_VAX2_L**Form:** LAB URINALYSIS - PREGNANCY TEST - eCRF Audit Trail History**Form Version:** 10-Dec-2020 02:23**Form Status:** Data Complete, Frozen, Verified**Site No:** 1270**Site Name:** (1270) Kaiser Permanente Sacramento**Subject No:** 12701222**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 18:51[Back to Form](#)**1. Lab Panel:**

Date	Location	User	Value	Reason
Jan-11-2021 13:04:32 (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
Jan-11-2021 13:04:32 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: PREGNANCY	Initial Entry

3. Collection Date:

Date	Location	User	Value	Reason
Jan-11-2021 13:04:32 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Jan/8/2021	Initial Entry

4. Laboratory Name and Address (Derived)

Date	Location	User	Value	Reason
Jan-11-2021 13:04:32 (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
Jan-11-2021 13:04:32 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: URINE	Initial Entry

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 10-Dec-2020 02:23

Site No: 1270

Subject No: 12701222

Generated By: (b) (4)

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

Form Status: Data Complete, Frozen, Verified

Site Name: (1270) Kaiser Permanente Sacramento

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

6.a

Date	Location	User	Value	Reason
Jan-11-2021 13:04:32 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sponsor-Def 113 ined Identifi er: Test:: Choriogonadot ropin Beta_PX 113 Result:: NEGATIVE Not Done::	Initial Entry

6.a Sponsor ID:

Date	Location	User	Value	Reason
Jan-11-2021 13:04:32 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 113	Initial Entry

6.a Test:

Date	Location	User	Value	Reason
Jan-11-2021 13:04:32 (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
Jan-11-2021 13:04:32 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NEGATIVE	Initial Entry

090177e196ae2e3f\Final\Final On: 01-Apr-2021 03:08 (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, Frozen, Verified**Site No:** 1270**Site Name:** (1270) Kaiser Permanente Sacramento**Subject No:** 12701222**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 18:51[Back to Form](#)**1. Data Origin**

Date	Location	User	Value	Reason
Jan-11-2021 13:05:07 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Jan-11-2021 13:05:07 (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
Jan-11-2021 13:05:07 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Collection: Jan/8/2021	Initial Entry

5.a

Date	Location	User	Value	Reason
Jan-11-2021 13:04:52 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BR33DD	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Jan-11-2021 13:04:52 (UTC-08:00) Pacific	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BR33DD	Initial Entry

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:03

Site No: 1270

Subject No: 12701222

Generated By: (b) (4)

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

Form Status: Data Complete, Frozen, Verified

Site Name: (1270) Kaiser Permanente Sacramento

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

Time (US & Canada)

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

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 10-Dec-2020 02:26

Site No: 1270

Subject No: 12701222

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1270) Kaiser Permanente Sacramento

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

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1. Was there a temporary delay of vaccination?

Date	Location	User	Value	Reason
Jan-11-2021 13:05:26 (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
Jan-11-2021 13:05:26 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: BLINDED THERAPY	Initial Entry

3. Formulation:

Date	Location	User	Value	Reason
Jan-11-2021 13:05:26 (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
Jan-11-2021 13:05:26 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Jan/8/2021 14:18	Initial Entry

5. Anatomical Location:

Date	Location	User	Value	Reason
Jan-11-2021 13:05:26 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: DELTOID MUSCLE	Initial Entry

090177e196ae2e3f\Final\Final On: 01-Apr-2021 03:08 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 10-Dec-2020 02:26

Site No: 1270

Subject No: 12701222

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1270) Kaiser Permanente Sacramento

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

6. Body Side:

Date	Location	User	Value	Reason
Jan-11-2021 13:05:26 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: LEFT	Initial Entry

7. Route:

Date	Location	User	Value	Reason
Jan-11-2021 13:05:26 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INTRAMUSCULAR	Initial Entry

10. Timeframe Subject Was Observed

Date	Location	User	Value	Reason
Jan-11-2021 13:05:26 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: THE PROTOCOL SPECIFIE D OBSERVATION PERIOD	Initial Entry

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

Date	Location	User	Value	Reason
Jan-11-2021 13:05:26 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

090177e196ae2e3f\Final\Final On: 01-Apr-2021 03:08 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 1270

Subject No: 12701222

Generated By: (b) (4)

Form: DATE OF VISIT - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1270) Kaiser Permanente Sacramento

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

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1. Date of Visit

Date	Location	User	Value	Reason
Feb-24-2021 14:36:58 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Feb/5/2021	Initial Entry

Header Text: c4591001**Visit:** V3_MONTH1_POSTVAX2_L**Form:** VACCINATION SYMPTOMS DIARY - SYMPTOM
RESOLVED DATES - eCRF Audit Trail History**Form Version:** 10-Dec-2020 02:30**Form Status:** Data Complete, Frozen, Verified**Site No:** 1270**Site Name:** (1270) Kaiser Permanente Sacramento**Subject No:** 12701222**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 18:51[Back to Form](#)**1. Were medications to treat fever/pain given on the last day the Subject Diary was completed?**

Date	Location	User	Value	Reason
Feb-24-2021 14:37:19 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2.a

Date	Location	User	Value	Reason
Feb-24-2021 14:37:19 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom:: FE V ER Were fever or systemi N c symptoms present o O n the last day the Subj ect Diary was complet ed?:	Initial Entry

2.a Symptom:

Date	Location	User	Value	Reason
Feb-24-2021 14:37:19 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: FEVER	Initial Entry

2.a Were fever or systemic symptoms present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Feb-24-2021 14:37:19 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2.b

Header Text: c4591001**Visit:** V3_MONTH1_POSTVAX2_L**Form:** VACCINATION SYMPTOMS DIARY - SYMPTOM
RESOLVED DATES - eCRF Audit Trail History**Form Version:** 10-Dec-2020 02:30**Form Status:** Data Complete, Frozen, Verified**Site No:** 1270**Site Name:** (1270) Kaiser Permanente Sacramento**Subject No:** 12701222**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 18:51

Date	Location	User	Value	Reason
Feb-24-2021 14:37:19 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom:: FA TI GU E Were fever or systemi NO c symptoms present o n the last day the Sub ject Diary was comple ted?:	Initial Entry

2.b Symptom:

Date	Location	User	Value	Reason
Feb-24-2021 14:37:19 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: FATIGUE	Initial Entry

2.b Were fever or systemic symptoms present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Feb-24-2021 14:37:19 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2.c

Date	Location	User	Value	Reason
Feb-24-2021 14:37:19 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom:: HE AD AC HE	Initial Entry

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form Version: 10-Dec-2020 02:30

Site No: 1270

Subject No: 12701222

Generated By: (b) (4)

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM
RESOLVED DATES - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1270) Kaiser Permanente Sacramento

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

			Were fever or system NO ic symptoms present on the last day the Su bject Diary was com pleted?:	
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2.c Symptom:

Date	Location	User	Value	Reason
Feb-24-2021 14:37:19 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: HEADACHE	Initial Entry

2.c Were fever or systemic symptoms present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Feb-24-2021 14:37:19 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2.d

Date	Location	User	Value	Reason
Feb-24-2021 14:37:19 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom:: C HI LL S Were fever or systemi N c symptoms present o O n the last day the Subj ect Diary was complet ed?:	Initial Entry

090177e196ae2e3f\Final\Final On: 01-Apr-2021 03:08 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form Version: 10-Dec-2020 02:30

Site No: 1270

Subject No: 12701222

Generated By: (b) (4)

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM
RESOLVED DATES - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1270) Kaiser Permanente Sacramento

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

2.d Symptom:

Date	Location	User	Value	Reason
Feb-24-2021 14:37:19 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: CHILLS	Initial Entry

2.d Were fever or systemic symptoms present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Feb-24-2021 14:37:19 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2.e

Date	Location	User	Value	Reason
Feb-24-2021 14:37:19 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom:: VO MI TIN G Were fever or system NO ic symptoms present on the last day the Su bject Diary was com pleted?:	Initial Entry

090177e196ae2e3f\Final\Final On: 01-Apr-2021 03:08 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form Version: 10-Dec-2020 02:30

Site No: 1270

Subject No: 12701222

Generated By: (b) (4)

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM
RESOLVED DATES - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1270) Kaiser Permanente Sacramento

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

2.e Symptom:

Date	Location	User	Value	Reason
Feb-24-2021 14:37:19 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: VOMITING	Initial Entry

2.e Were fever or systemic symptoms present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Feb-24-2021 14:37:19 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2.f

Date	Location	User	Value	Reason
Feb-24-2021 14:37:19 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom:: DI AR RH EA Were fever or systemi NO c symptoms present o n the last day the Sub ject Diary was compl eted?:	Initial Entry

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form Version: 10-Dec-2020 02:30

Site No: 1270

Subject No: 12701222

Generated By: (b) (4)

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM
RESOLVED DATES - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1270) Kaiser Permanente Sacramento

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

2.f Symptom:

Date	Location	User	Value	Reason
Feb-24-2021 14:37:19 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: DIARRHEA	Initial Entry

2.f Were fever or systemic symptoms present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Feb-24-2021 14:37:19 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2.g

Date	Location	User	Value	Reason
Feb-24-2021 14:37:19 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom:: NEW O R WOR SENE MUSCL E PAIN Were fever or sys NO temic symptoms present on the la st day the Subjec t Diary was com pleted?:	Initial Entry

090177e196ae2e3f\Final\Final On: 01-Apr-2021 03:08 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form Version: 10-Dec-2020 02:30

Site No: 1270

Subject No: 12701222

Generated By: (b) (4)

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM
RESOLVED DATES - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1270) Kaiser Permanente Sacramento

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

2.g Symptom:

Date	Location	User	Value	Reason
Feb-24-2021 14:37:19 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NEW OR WORSENERED SCLE PAIN	Initial Entry

2.g Were fever or systemic symptoms present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Feb-24-2021 14:37:19 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2.h

Date	Location	User	Value	Reason
Feb-24-2021 14:37:19 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom:: NEW O R WOR SENERED JOINT PAIN Were fever or sys NO temic symptoms present on the las t day the Subject Diary was compl eted?:	Initial Entry

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form Version: 10-Dec-2020 02:30

Site No: 1270

Subject No: 12701222

Generated By: (b) (4)

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM
RESOLVED DATES - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1270) Kaiser Permanente Sacramento

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

2.h Symptom:

Date	Location	User	Value	Reason
Feb-24-2021 14:37:19 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NEW OR WORSENER JOINT PAIN	Initial Entry

2.h Were fever or systemic symptoms present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Feb-24-2021 14:37:19 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

3. Injection Site Location:

Date	Location	User	Value	Reason
Feb-24-2021 14:37:19 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: DELTOID MUSCLE	Initial Entry

4. Injection Site Body Side:

Date	Location	User	Value	Reason
Feb-24-2021 14:37:19 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: LEFT	Initial Entry

5.a

Date	Location	User	Value	Reason
Feb-24-2021 14:37:19 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Injection Site Reaction: REDNESS	Initial Entry

Header Text: c4591001**Visit:** V3_MONTH1_POSTVAX2_L**Form:** VACCINATION SYMPTOMS DIARY - SYMPTOM
RESOLVED DATES - eCRF Audit Trail History**Form Version:** 10-Dec-2020 02:30**Form Status:** Data Complete, Frozen, Verified**Site No:** 1270**Site Name:** (1270) Kaiser Permanente Sacramento**Subject No:** 12701222**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 18:51

			Were injection site re NO actions present on the last day the Subject D iary was completed?:	
--	--	--	---	--

5.a Injection Site Reaction:

Date	Location	User	Value	Reason
Feb-24-2021 14:37:19 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: REDNESS	Initial Entry

5.a Were injection site reactions present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Feb-24-2021 14:37:19 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

5.b

Date	Location	User	Value	Reason
Feb-24-2021 14:37:19 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Injection Site Reacti SW on:: ELL ING Were injection site re NO actions present on th e last day the Subject Diary was completed ?:	Initial Entry

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form Version: 10-Dec-2020 02:30

Site No: 1270

Subject No: 12701222

Generated By: (b) (4)

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM
RESOLVED DATES - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1270) Kaiser Permanente Sacramento

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

5.b Injection Site Reaction:

Date	Location	User	Value	Reason
Feb-24-2021 14:37:19 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: SWELLING	Initial Entry

5.b Were injection site reactions present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Feb-24-2021 14:37:19 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

5.c

Date	Location	User	Value	Reason
Feb-24-2021 14:37:19 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Injection Site Reaction: PAIN AT IN JECTI ON SI TE Were injection site reactions present on the last day the Subject Diary was completed?: NO	Initial Entry

090177e196ae2e3f\Final\Final On: 01-Apr-2021 03:08 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form Version: 10-Dec-2020 02:30

Site No: 1270

Subject No: 12701222

Generated By: (b) (4)

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM
RESOLVED DATES - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1270) Kaiser Permanente Sacramento

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

5.c Injection Site Reaction:

Date	Location	User	Value	Reason
Feb-24-2021 14:37:19 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: PAIN AT INJECTION SITE	Initial Entry

5.c Were injection site reactions present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Feb-24-2021 14:37:19 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

Header Text: c4591001**Visit:** V3_MONTH1_POSTVAX2_L**Form Version:** 22-Apr-2020 21:03**Site No:** 1270**Subject No:** 12701222**Generated By:** (b) (4)**Form:** ELECTRONIC SAMPLE TRACKING -
IMMUNOGENICITY - eCRF Audit Trail History**Form Status:** Data Complete, Frozen, Verified**Site Name:** (1270) Kaiser Permanente Sacramento**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 18:51[Back to Form](#)**1. Data Origin**

Date	Location	User	Value	Reason
Feb-24-2021 14:37:32 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Feb-24-2021 14:37:32 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SERUM	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Feb-24-2021 14:37:42 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Feb-24-2021 14:37:32 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Feb-24-2021 14:37:32 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry: YES Date of Collection: Feb/5/2021	Initial Entry

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form Version: 22-Apr-2020 21:03

Site No: 1270

Subject No: 12701222

Generated By: (b) (4)

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

Form Status: Data Complete, Frozen, Verified

Site Name: (1270) Kaiser Permanente Sacramento

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

5.a

Date	Location	User	Value	Reason
Feb-24-2021 14:37:42 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BRFFHR	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Feb-24-2021 14:37:42 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BRFFHR	Initial Entry

5.b

Date	Location	User	Value	Reason
Feb-24-2021 14:37:50 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BRFFHS	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Feb-24-2021 14:37:50 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BRFFHS	Initial Entry

5.c

Date	Location	User	Value	Reason
Feb-24-2021 14:37:57 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BK5HR5	Initial Entry

090177e196ae2e3f\Final\Final On: 01-Apr-2021 03:08 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form Version: 22-Apr-2020 21:03

Site No: 1270

Subject No: 12701222

Generated By: (b) (4)

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

Form Status: Data Complete, Frozen, Verified

Site Name: (1270) Kaiser Permanente Sacramento

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

5.c Sample ID

Date	Location	User	Value	Reason
Feb-24-2021 14:37:57 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BK5HR5	Initial Entry

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1270

Subject No: 12701222

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - Audit Trail

Form Status:

Site Name: (1270) Kaiser Permanente Sacramento

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

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Date	Location	User	Value	Reason
Feb-23-2021 10:50:54 (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: 1270

Subject No: 12701222

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete

Site Name: (1270) Kaiser Permanente Sacramento

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

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1. Category:

Date	Location	User	Value	Reason
Feb-23-2021 10:50:54 (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 10:50:54 (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
Mar-08-2021 14:38:41 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Giselle Castillo (b) (4)	Query 3: Clo sed	Ok. thanks
Mar-04-2021 09:17:16 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: An swe red	Query already asked and answered regarding follow up SAE, which has been submitted (03MAR2021)
Mar-04-2021 04:48:59 (UTC-08:00) Pacific Time (US &	ACV0PFEINFP6000	Giselle Castillo (b) (4)	Query 3: Rei ssued: Open ed	Thank you for confirming. This information is missing in the safety report

Header Text: c4591001**Visit:** Logs - Unscheduled**Form Version:** 22-Apr-2020 21:02**Site No:** 1270**Subject No:** 12701222**Generated By:** (b) (4)**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History**Form Status:** Data Complete**Site Name:** (1270) Kaiser Permanente Sacramento**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 18:51

Canada)				(AER# 2021195810), kindly submit a FU letter to the information is added to the SAE report. Thanks.
Mar-03-2021 14:13:44 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 5: Closed	Medhx Record amended. Thank you!
Mar-03-2021 12:24:23 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 5: Answered	DONE
Mar-03-2021 11:34:42 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 5: Reissued: Opened	MedHx form is unfrozen until 8Mar201. please review and amend as needed ASAP. Thank you
Mar-02-2021 15:27:50 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 5: Answered	MH is frozen and data cannot be updated
Mar-02-2021 08:32:55 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 5: Opened	GPD Clin: if diagnosis of depressive disorder has new onset post-study enrollment,

Header Text: c4591001**Visit:** Logs - Unscheduled**Form Version:** 22-Apr-2020 21:02**Site No:** 1270**Subject No:** 12701222**Generated By:** (b) (4)**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History**Form Status:** Data Complete**Site Name:** (1270) Kaiser Permanente Sacramento**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 18:51

				please add as AE with assessment of causal factors and onset date. else include in medhx with date of onset. Thank you.
Feb-28-2021 16:35:55 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Closed	Response satisfies query
Feb-26-2021 12:04:53 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 4: Closed	Response satisfies query
Feb-26-2021 11:17:36 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 4: Answered	No past history of depression or suicidal ideation
Feb-26-2021 11:16:51 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Answered	Depressive disorder and management with medication Sertraline (Zoloft) 50mg oral every morning. Diphenhydramine (Banophen) 25mg at bedtime for insomnia and individual, family

Header Text: c4591001**Visit:** Logs - Unscheduled**Form Version:** 22-Apr-2020 21:02**Site No:** 1270**Subject No:** 12701222**Generated By:** (b) (4)**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History**Form Status:** Data Complete**Site Name:** (1270) Kaiser Permanente Sacramento**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 18:51

				and group therapy.
Feb-26-2021 11:14:18 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Query 2: Answered	No history of substance use/abuse
Feb-26-2021 07:29:15 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Query 4: Opened	clinical: please confirm no past history of depression or suicidal ideation. Thanks.
Feb-25-2021 09:27:48 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Giselle Castillo (b) (4) [REDACTED]	Query 3: Opened	Medical Monitor_ Pls advice if there were additional conditions diagnosed on discharge and the management. Thanks
Feb-24-2021 15:23:43 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Query 2: Opened	GPD Clin: please confirm if there was past or recent history of substance use/abuse.
Feb-24-2021 14:50:11 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	PFETMS Oracle (b) (4) [REDACTED]	Query 1: Closed	Discrepancy has been closed.
Feb-24-2021 11:04:09	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Transcription Error

Header Text: c4591001**Visit:** Logs - Unscheduled**Form Version:** 22-Apr-2020 21:02**Site No:** 1270**Subject No:** 12701222**Generated By:** (b) (4)**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History**Form Status:** Data Complete**Site Name:** (1270) Kaiser Permanente Sacramento**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 18:51

(UTC-08:00) Pacific Time (US & Canada)			swere d	
Feb-24-2021 11:04:09 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry: : SUCIDAL IDEATION	Transcription Error
Feb-23-2021 16:05:31 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	PFETMS Oracle (b) (4)	Query 1: Opened	Clarify SUCIDAL IDEATION as follows...Should the spelling be SUICIDAL IDEATION? If so, edit. Otherwise clarify. Thank you.
Feb-23-2021 10:50:54 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry: : SUCIDAL IDEATION	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason
Feb-23-2021 10:50:54 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry: Feb/16/2021 10:17	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
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Header Text: c4591001

Visit: Logs - Unscheduled

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Subject No: 12701222

Generated By: (b) (4)

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Feb-23-2021 10:50:54 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry
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6. Toxicity Grade:

Date	Location	User	Value	Reason
Feb-23-2021 10:50:54 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 3	Initial Entry

7. Is the adverse event serious?

If Yes, NOTIFY PFIZER IMMEDIATELY.

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

Date	Location	User	Value	Reason
Feb-26-2021 02:00:34 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Deleted	Query can be addressed internally
Feb-24-2021 11:04:09 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	For AE SUICIDAL IDEATION: Response to "Is the adverse event serious?" is 'Yes' but "Serious Adverse Event Number" is blank.
Feb-24-2021 00:10:28 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Closed	Prolonged hospitalization is checked
Feb-23-2021	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Answered	Please clarify

Header Text: c4591001**Visit:** Logs - Unscheduled**Form Version:** 22-Apr-2020 21:02**Site No:** 1270**Subject No:** 12701222**Generated By:** (b) (4)**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History**Form Status:** Data Complete**Site Name:** (1270) Kaiser Permanente Sacramento**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 18:51

10:52:20 (UTC-08:00) Pacific Time (US & Canada)		(b) (4), (b) (6)		query - Prolonged hospitalization is checked
Feb-23-2021 10:51:15 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Opened	Is this adverse event serious?' is reported 'Yes', but at least one seriousness criteria is missing. Please review and update as appropriate.
Feb-23-2021 10:51:15 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	For AE SUCIDAL IDEATION: Response to "Is the adverse event serious?" is 'Yes' but "Serious Adverse Event Number" is blank.
Feb-23-2021 10:51:15 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Did this serious event require or prolong hospitalization? YES	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 10:50:54 (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:

Header Text: c4591001**Visit:** Logs - Unscheduled**Form Version:** 22-Apr-2020 21:02**Site No:** 1270**Subject No:** 12701222**Generated By:** (b) (4)**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History**Form Status:** Data Complete**Site Name:** (1270) Kaiser Permanente Sacramento**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 18:51

Date	Location	User	Value	Reason
Mar-03-2021 14:17:22 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Closed	Response satisfies query
Mar-03-2021 12:21:00 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NOT RELATED If Not Related to study tr eatment(s), this event is d ue to: OTHER <i>If Other, specify:</i> PSYCHOSOCIAL I SSUES	Changed Information
Mar-02-2021 15:30:13 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Answered	SAE changed to correlate with AE - SAE will be sent in one the signed by the PI
Mar-01-2021 13:54:38 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Reissued:Opened	GPD Clin: Per SAE report SUICIDAL IDEATION was assessed as related to recent changes in ADHD medications. Please review and harmonize alternative causality between SAE report and AE CRF as appropriate.

Header Text: c4591001**Visit:** Logs - Unscheduled**Form Version:** 22-Apr-2020 21:02**Site No:** 1270**Subject No:** 12701222**Generated By:** (b) (4)**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History**Form Status:** Data Complete**Site Name:** (1270) Kaiser Permanente Sacramento**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 18:51

Feb-26-2021 11:18:39 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Answered	Please clarify query
Feb-24-2021 15:47:27 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Opened	GPD Clin: per SAE report, investigator assessed SI as related to new concomitant medication. Please review and amend item 9. per SAE report as appropriate
Feb-24-2021 15:29:32 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Closed	GPD Clin: per SAE report, investigator assessed SI as related to new concomitant medication. Please review and amend item 9. per SAE report as appropriate
Feb-24-2021 15:28:02 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	issuing revised query
Feb-24-2021 15:19:07 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Opened	GPD Clin: please confirm if patient had any of the following precipitating factors - new school or social stressors, significant life

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				changes, other stressful triggers, etc.
Feb-24-2021 15:17:35 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	GPD Clin: please confirm if patient had pas med history of suicidal ideation or depression.
Feb-23-2021 10:50:54 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NOT RELATED If Not Related to study treatment(s), this event is due to: OTHER <i>If Other, specify:</i> UNKNOWN	Initial Entry

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Feb-23-2021 10:50:54 (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 10:50:54 (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
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Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

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Site Name: (1270) Kaiser Permanente Sacramento

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Feb-23-2021 10:50:54
(UTC-08:00) Pacific
Time (US & Canada)

ACV0PFEINFP6000

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

Data Entry:
YES

Initial Entry

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

Date	Location	User	Value	Reason
Feb-23-2021 10:50:54 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NOT RECOVERED/NOT R ESOLVED	Initial Entry

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

Date	Location	User	Value	Reason
Feb-23-2021 10:50:54 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

090177e196ae2e3f\Final\Final On: 01-Apr-2021 03:08 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1270

Subject No: 12701222

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete

Site Name: (1270) Kaiser Permanente Sacramento

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

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15. Serious Adverse Event Number: For Pfizer Use Only

Date	Location	User	Value	Reason
Feb-28-2021 23:57:26 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 2021195810	Initial Entry

Header Text: c4591001

Visit: End of Treatment - Unscheduled

Form Version: 20-Feb-2021 02:26

Site No: 1270

Subject No: 12701222

Generated By: (b) (4)

Form: DISPOSITION - TREATMENT - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1270) Kaiser Permanente Sacramento

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

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1. Date of Completion/Discontinuation/Death :

Date	Location	User	Value	Reason
Feb-24-2021 14:38:09 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Feb/5/2021	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Feb-24-2021 14:38:09 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: VACCINATION	Initial Entry

3. Status:

Date	Location	User	Value	Reason
Feb-24-2021 14:38:09 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: COMPLETED	Initial Entry

090177e196ae2e3f\Final\Final On: 01-Apr-2021 03:08 (GMT)

Header Text: c4591001**Visit:** Subject Status - Unscheduled**Form Version:** 22-Apr-2020 21:03**Site No:** 1270**Subject No:** 12701222**Generated By:** (b) (4)**Form:** SUBJECT STATUS - eCRF Audit Trail History**Form Status:** Data Complete, Verified**Site Name:** (1270) Kaiser Permanente Sacramento**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 18:51[Back to Form](#)**1. Subject Status**

Date	Location	User	Value	Reason
Feb-24-2021 14:38:09 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: FOLLOW-UP	Initial Entry
Dec-22-2020 13:19:02 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: ENROLLED/RANDOMIZE D	Transcription Error
Dec-22-2020 13:17:36 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: ENROLLED/RANDOMIZE D	Initial Entry
Dec-22-2020 13:14:52 (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 14:38:09 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Feb/5/2021	Initial Entry
Dec-22-2020 13:19:02 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Dec/18/2020	Transcription Error
Dec-22-2020 13:17:36 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Dec/21/2020	Initial Entry
Dec-22-2020 13:14:52 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Dec/18/2020	Initial Entry

Header Text: c4591001

Visit: Investigator Signature - Unscheduled **Form:** CASEBOOK SIGNATURE FORM - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Signed, Verified

Site No: 1270

Site Name: (1270) Kaiser Permanente Sacramento

Subject No: 12701222

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

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1. Casebook Signature

Date	Location	User	Value	Reason
Mar-10-2021 12:05:38 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Click Here to Enable	Initial Entry