

**Header Text:** c4591001

**Visit:** COHORT\_SELECTION

**Form Version:** 10-Dec-2020 02:31

**Site No:** 1126

**Subject No:** 11261268

**Generated By:** (b) (4)

**Form:** COHORT\_SELECTION

**Form Status:** Data Complete, Frozen, Verified

**Site Name:** (1126) Kaiser Permanente Santa Clara

**Subject Initials:** ---

**Generated Time (GMT):** 06-Apr-2021 15:36

[eCRF Audit Trail History](#)

**Cohort Selection**

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

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

**Header Text:** c4591001

**Visit:** COHORT\_SELECTION

**Form Version:** 22-Apr-2020 21:02

**Site No:** 1126

**Subject No:** 11261268

**Generated By:** (b) (4)

**Form:** MAIN INFORMED CONSENT

**Form Status:** Data Complete, Frozen, Verified

**Site Name:** (1126) Kaiser Permanente Santa Clara

**Subject Initials:** ---

**Generated Time (GMT):** 06-Apr-2021 15:36

[eCRF Audit Trail History](#)

**Informed Consent**

1.	Consent Was:	OBTAINED Date Written Consent Obtained Dec/14/2020
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**Header Text:** c4591001

**Visit:** COHORT\_SELECTION

**Form Version:** 10-Dec-2020 02:26

**Site No:** 1126

**Subject No:** 11261268

**Generated By:** (b) (4)

**Form:** DEMOGRAPHY

**Form Status:** Data Complete, Frozen, Verified

**Site Name:** (1126) Kaiser Permanente Santa Clara

**Subject Initials:** ---

**Generated Time (GMT):** 06-Apr-2021 15:36

[eCRF Audit Trail History](#)

**Demography**

1.	Subject ID	[11261268]
2.	Birth Date:	(b) (6) 2007
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:	

**Header Text:** c4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form Version:** 22-Apr-2020 21:02

**Site No:** 1126

**Subject No:** 11261268

**Generated By:** (b) (4)

**Form:** DATE OF VISIT

**Form Status:** Data Complete, Frozen, Verified

**Site Name:** (1126) Kaiser Permanente Santa Clara

**Subject Initials:** ---

**Generated Time (GMT):** 06-Apr-2021 15:36

[eCRF Audit Trail History](#)

**Date of Visit**

1.	Date of Visit	Dec/14/2020
2.	Erroneous Visit	

**Header Text:** c4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form Version:** 10-Oct-2020 16:00

**Site No:** 1126

**Subject No:** 11261268

**Generated By:** (b) (4)

**Form:** INCLUSION/EXCLUSION CRITERIA

**Form Status:** Data Complete, Frozen, Verified

**Site Name:** (1126) Kaiser Permanente Santa Clara

**Subject Initials:** ---

**Generated Time (GMT):** 06-Apr-2021 15:36

[Form Comments](#)

**Inclusion Criteria Not Met**

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

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

**Visit:** V1\_DAY1\_VAX1\_L

**Form Version:** 15-Sep-2020 21:52

**Site No:** 1126

**Subject No:** 11261268

**Generated By:** (b) (4)

**Form:** DISPOSITION - SCREENING

**Form Status:** Data Complete, Frozen, Verified

**Site Name:** (1126) Kaiser Permanente Santa Clara

**Subject Initials:** ---

**Generated Time (GMT):** 06-Apr-2021 15:36

[eCRF Audit Trail History](#)

**Disposition - Screening**

1.	Date of Completion/Discontinuation /Death	Dec/14/2020
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:** 1126**Subject No:** 11261268**Generated By:** (b) (4)**Form:** GENERAL MEDICAL HISTORY**Form Status:** Data Complete, Frozen, Verified**Site Name:** (1126) Kaiser Permanente Santa Clara**Subject Initials:** ---**Generated Time (GMT):** 06-Apr-2021 15:36[eCRF Audit Trail History](#)**Medical History Details**

1.a	Line/MH Number:	[1]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Verruca Vulgaris]
	Start Date:	Nov/9/2017
	Ongoing:	YES
1.b	Line/MH Number:	[2]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Left Proximal Radius Fracture]
	Start Date:	Jul/27/2012
	Ongoing:	NO End Date: Aug/22/2012
1.c	Line/MH Number:	[3]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Juvenile Osteochondrosis of Right Tarsal]
	Start Date:	Jun/25/2020
	Ongoing:	YES
1.d	Line/MH Number:	[4]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Right Hip Flexor Strain]
	Start Date:	Nov/12/2020
	Ongoing:	YES

**Header Text:** c4591001**Visit:** V1\_DAY1\_VAX1\_L**Form Version:** 22-Apr-2020 21:03**Site No:** 1126**Subject No:** 11261268**Generated By:** (b) (4)**Form:** GENERAL MEDICAL HISTORY**Form Status:** Data Complete, Frozen, Verified**Site Name:** (1126) Kaiser Permanente Santa Clara**Subject Initials:** ---**Generated Time (GMT):** 06-Apr-2021 15:36

1.e	Line/MH Number:	[5]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Urticaria, No Known Triggers]
	Start Date:	Oct/7/2010
	Ongoing:	YES
1.f	Line/MH Number:	[6]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Allergy to Bee Venom]
	Start Date:	Oct/7/2010
	Ongoing:	YES
1.g	Line/MH Number:	[7]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Premenarchal]
	Start Date:	(b) (6) 2007
	Ongoing:	YES



**Header Text:** c4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form Version:** 15-Sep-2020 21:57

**Site No:** 1126

**Subject No:** 11261268

**Generated By:** (b) (4)

**Form:** HIV STATUS

**Form Status:** Data Complete, Frozen, Verified

**Site Name:** (1126) Kaiser Permanente Santa Clara

**Subject Initials:** ---

**Generated Time (GMT):** 06-Apr-2021 15:36

[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:** 1126**Subject No:** 11261268**Generated By:** (b) (4)**Form:** VITAL SIGNS - BASELINE**Form Status:** Data Complete, Frozen, Verified**Site Name:** (1126) Kaiser Permanente Santa Clara**Subject Initials:** ---**Generated Time (GMT):** 06-Apr-2021 15:36[eCRF Audit Trail History](#)**Vital Signs**

1.	Date:	Dec/14/2020
2.	Weight:	[33.0]
3.	Unit:	kg
4.	Height:	[140.6]
5.	Unit:	cm
6.	Body Mass Index:	[16.7]

**Vital Signs Details**

7.a	Record Identifier:	1
	Temperature:	[96.6]
	Unit:	F
	Temperature Location:	ORAL CAVITY

**Header Text:** c4591001**Visit:** V1\_DAY1\_VAX1\_L**Form Version:** 10-Dec-2020 02:23**Site No:** 1126**Subject No:** 11261268**Generated By:** (b) (4)**Form:** LAB URINALYSIS - PREGNANCY TEST**Form Status:** Data Complete, Frozen, Verified**Site Name:** (1126) Kaiser Permanente Santa Clara**Subject Initials:** ---**Generated Time (GMT):** 06-Apr-2021 15:36[Form Comments](#)[eCRF Audit Trail History](#)**Lab Urinalysis**

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

**Lab Result**

6.a	Sponsor ID:	Not Applicable _____ [ ]	<a href="#">Comments</a>
	Test:	Not Applicable _____ Choriogonadotropin Beta_PX113	
	Result:	Not Applicable _____	<a href="#">Comments</a>
	Not Done:	Not Applicable _____	<a href="#">Comments</a>

**Header Text:** c4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1126

**Subject No:** 11261268

**Generated By:** (b) (4)

**Form:** RANDOMIZATION

**Form Status:** Data Complete, Frozen, Verified

**Site Name:** (1126) Kaiser Permanente Santa Clara

**Subject Initials:** ---

**Generated Time (GMT):** 06-Apr-2021 15:36

[eCRF Audit Trail History](#)

**Disposition**

1.	Randomization Date :	Dec/14/2020
2.	Randomization Number:	[22343]
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:** 1126**Site Name:** (1126) Kaiser Permanente Santa Clara**Subject No:** 11261268**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 06-Apr-2021 15:36**eCRF Audit Trail History****Electronic Sample Tracking**

1.	Data Origin	SITE
2.	Sample Type	SERUM
3.	Sample Collected?	YES Date of Collection: Dec/14/2020
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	[BPZZ2L]
5.b	Sample ID	[BPZZ2M]
5.c	Sample ID	[BS7VG6]

**Header Text:** c4591001**Visit:** V1\_DAY1\_VAX1\_L**Form Version:** 22-Apr-2020 21:03**Site No:** 1126**Subject No:** 11261268**Generated By:** (b) (4)**Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB**Form Status:** Data Complete, Frozen, Verified**Site Name:** (1126) Kaiser Permanente Santa Clara**Subject Initials:** ---**Generated Time (GMT):** 06-Apr-2021 15:36[eCRF Audit Trail History](#)**Electronic Sample Tracking**

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Dec/14/2020
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	[BP28ZG]
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**Header Text:** c4591001**Visit:** V1\_DAY1\_VAX1\_L**Form Version:** 10-Dec-2020 02:26**Site No:** 1126**Subject No:** 11261268**Generated By:** (b) (4)**Form:** VACCINATION**Form Status:** Data Complete, Frozen, Verified**Site Name:** (1126) Kaiser Permanente Santa Clara**Subject Initials:** ---**Generated Time (GMT):** 06-Apr-2021 15:36[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/14/2020 11:08
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:** 1126**Subject No:** 11261268**Generated By:** (b) (4)**Form:** REACTOGENICITY DIARY**Form Status:** Data Complete, Frozen, Verified**Site Name:** (1126) Kaiser Permanente Santa Clara**Subject Initials:** ---**Generated Time (GMT):** 06-Apr-2021 15:36[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:** 1126

**Subject No:** 11261268

**Generated By:** (b) (4)

**Form:** DATE OF VISIT

**Form Status:** Data Complete, Frozen, Verified

**Site Name:** (1126) Kaiser Permanente Santa Clara

**Subject Initials:** ---

**Generated Time (GMT):** 06-Apr-2021 15:36

[eCRF Audit Trail History](#)

**Date of Visit**

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

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

**Form Version:** 10-Dec-2020 02:30

**Site No:** 1126

**Subject No:** 11261268

**Generated By:** (b) (4)

**Form:** VACCINATION SYMPTOMS DIARY - SYMPTOM  
RESOLVED DATES

**Form Status:** Data Complete, Frozen, Verified

**Site Name:** (1126) Kaiser Permanente Santa Clara

**Subject Initials:** ---

**Generated Time (GMT):** 06-Apr-2021 15:36

[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
2.e	Symptom:	VOMITING
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO

090177e196b72785\Final\Final On: 06-Apr-2021 19:12 (GMT)

**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:** 1126

**Site Name:** (1126) Kaiser Permanente Santa Clara

**Subject No:** 11261268

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 06-Apr-2021 15:36

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 WORSENER MUSCLE PAIN
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO
2.h	Symptom:	NEW OR WORSENER 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
5.c	Injection Site Reaction:	PAIN AT INJECTION SITE
	Were injection site reactions present on the last day the Subject Diary was completed?	NO

090177e196b72785\Final\On: 06-Apr-2021 19:12 (GMT)

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

**Form Version:** 10-Dec-2020 02:27

**Site No:** 1126

**Subject No:** 11261268

**Generated By:** (b) (4)

**Form:** VITAL SIGNS - TEMP

**Form Status:** Data Complete, Frozen, Verified

**Site Name:** (1126) Kaiser Permanente Santa Clara

**Subject Initials:** ---

**Generated Time (GMT):** 06-Apr-2021 15:36

[eCRF Audit Trail History](#)

**Vital Signs**

1.	Date:	Jan/5/2021
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**Vital Signs Details**

2.a	Record Identifier:	1
	Temperature:	[98.9]
	Unit:	F
	Temperature Location:	ORAL CAVITY

**Header Text:** c4591001**Visit:** V2\_VAX2\_L**Form Version:** 10-Dec-2020 02:23**Site No:** 1126**Subject No:** 11261268**Generated By:** (b) (4)**Form:** LAB URINALYSIS - PREGNANCY TEST**Form Status:** Data Complete, Frozen, Verified**Site Name:** (1126) Kaiser Permanente Santa Clara**Subject Initials:** ---**Generated Time (GMT):** 06-Apr-2021 15:36[Form Comments](#)[eCRF Audit Trail History](#)**Lab Urinalysis**

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

**Lab Result**

6.a	Sponsor ID:	Not Applicable _____ [ ]	<a href="#">Comments</a>
	Test:	Not Applicable _____ Choriogonadotropin Beta_PX113	
	Result:	Not Applicable _____	<a href="#">Comments</a>
	Not Done:	Not Applicable _____	<a href="#">Comments</a>

**Header Text:** c4591001**Visit:** V2\_VAX2\_L**Form Version:** 22-Apr-2020 21:03**Site No:** 1126**Subject No:** 11261268**Generated By:** (b) (4)**Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB**Form Status:** Data Complete, Frozen, Verified**Site Name:** (1126) Kaiser Permanente Santa Clara**Subject Initials:** ---**Generated Time (GMT):** 06-Apr-2021 15:36[eCRF Audit Trail History](#)**Electronic Sample Tracking**

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Jan/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	[BP293X]
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**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

**Form Version:** 10-Dec-2020 02:26

**Site No:** 1126

**Subject No:** 11261268

**Generated By:** (b) (4)

**Form:** VACCINATION

**Form Status:** Data Complete, Frozen, Verified

**Site Name:** (1126) Kaiser Permanente Santa Clara

**Subject Initials:** ---

**Generated Time (GMT):** 06-Apr-2021 15:36

[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/5/2021 16:05
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

090177e196b72785\Final\Final On: 06-Apr-2021 19:12 (GMT)

**Header Text:** c4591001

**Visit:** V3\_MONTH1\_POSTVAX2\_L

**Form Version:** 22-Apr-2020 21:02

**Site No:** 1126

**Subject No:** 11261268

**Generated By:** (b) (4)

**Form:** DATE OF VISIT

**Form Status:** Data Complete, Frozen, Verified

**Site Name:** (1126) Kaiser Permanente Santa Clara

**Subject Initials:** ---

**Generated Time (GMT):** 06-Apr-2021 15:36

[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:** VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES**Form Version:** 10-Dec-2020 02:30**Form Status:** Data Complete, Frozen, Verified**Site No:** 1126**Site Name:** (1126) Kaiser Permanente Santa Clara**Subject No:** 11261268**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 06-Apr-2021 15:36[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
2.e	Symptom:	VOMITING
	Were fever or systemic symptoms 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:** 1126**Site Name:** (1126) Kaiser Permanente Santa Clara**Subject No:** 11261268**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 06-Apr-2021 15:36

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 WORSENER MUSCLE PAIN
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO
2.h	Symptom:	NEW OR WORSENER 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
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:** 1126**Site Name:** (1126) Kaiser Permanente Santa Clara**Subject No:** 11261268**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 06-Apr-2021 15:36[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	[BR7Z7H]
5.b	Sample ID	[BR7Z7J]
5.c	Sample ID	[BS7VRM]

**Header Text:** c4591001**Visit:** V4\_MONTH6\_L**Form Version:** 22-Apr-2020 21:02**Site No:** 1126**Subject No:** 11261268**Generated By:** (b) (4)**Form:** DATE OF VISIT**Form Status:** Not Started**Site Name:** (1126) Kaiser Permanente Santa Clara**Subject Initials:** ---**Generated Time (GMT):** 06-Apr-2021 15:36**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:** 1126**Subject No:** 11261268**Generated By:** (b) (4)**Form:** ELECTRONIC SAMPLE TRACKING -  
IMMUNOGENICITY**Form Status:** Not Started**Site Name:** (1126) Kaiser Permanente Santa Clara**Subject Initials:** ---**Generated Time (GMT):** 06-Apr-2021 15:36**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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<b>Header Text:</b> c4591001		
<b>Visit:</b> V5_MONTH12_L		<b>Form:</b> DATE OF VISIT
<b>Form Version:</b> 22-Apr-2020 21:02		<b>Form Status:</b> Not Started
<b>Site No:</b> 1126		<b>Site Name:</b> (1126) Kaiser Permanente Santa Clara
<b>Subject No:</b> 11261268		<b>Subject Initials:</b> ---
<b>Generated By:</b> (b) (4)		<b>Generated Time (GMT):</b> 06-Apr-2021 15:36

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:** 1126**Site Name:** (1126) Kaiser Permanente Santa Clara**Subject No:** 11261268**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 06-Apr-2021 15:36**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:** 1126**Subject No:** 11261268**Generated By:** (b) (4)**Form:** DATE OF VISIT**Form Status:** Not Started**Site Name:** (1126) Kaiser Permanente Santa Clara**Subject Initials:** ---**Generated Time (GMT):** 06-Apr-2021 15:36**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:** 1126**Site Name:** (1126) Kaiser Permanente Santa Clara**Subject No:** 11261268**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 06-Apr-2021 15:36**Electronic Sample Tracking**

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

**Aliquot**

Please enter barcode for each aliquot.

5.	Sample ID	[ ]
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**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL - New Unscheduled **Form:** DATE OF VISIT - ILLNESS ONSET Visit

**Form Version:** 22-Apr-2020 21:03

**Form Status:** Not Started

**Site No:** 1126

**Site Name:** (1126) Kaiser Permanente Santa Clara

**Subject No:** 11261268

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 06-Apr-2021 15:36

**Date of Visit**

1.	Date of Visit	//
2.	Erroneous Visit	

**COVID-19 Illness Visit**

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

**Header Text:** c4591001**Visit:** POT\_COVID\_ILL - New Unscheduled **Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 Visit**Form Version:** 20-Feb-2021 02:17**Form Status:** Not Started**Site No:** 1126**Site Name:** (1126) Kaiser Permanente Santa Clara**Subject No:** 11261268**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 06-Apr-2021 15:36**Signs and Symptoms**

1.	Date of Assessment:	//
2.	Date of First Symptom Started:	//
3.	Symptoms Ongoing?	

**Symptoms**

4.	Symptoms:	
	Was symptom present?	

**Symptoms - Other**

5.	Symptoms - Other Text:	[ ]
----	------------------------	-----

**Header Text:** c4591001**Visit:** POT\_COVID\_ILL - New Unscheduled Visit**Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB SELF**Form Version:** 22-Apr-2020 21:03**Form Status:** Not Started**Site No:** 1126**Site Name:** (1126) Kaiser Permanente Santa Clara**Subject No:** 11261268**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 06-Apr-2021 15:36**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 **Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB Visit**Form Version:** 22-Apr-2020 21:03**Form Status:** Not Started**Site No:** 1126**Site Name:** (1126) Kaiser Permanente Santa Clara**Subject No:** 11261268**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 06-Apr-2021 15:36**Electronic Sample Tracking**

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

**Aliquot**

Please enter barcode for each aliquot.

5.	Sample ID	[ ]
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**Header Text:** c4591001**Visit:** POT\_COVID\_ILL - New Unscheduled **Form:** HEALTH CARE UTILIZATION  
Visit**Form Version:** 20-Feb-2021 02:19**Form Status:** Not Started**Site No:** 1126**Site Name:** (1126) Kaiser Permanente Santa Clara**Subject No:** 11261268**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 06-Apr-2021 15:36**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 **Form:** ILLNESS DETAILS  
Visit

**Form Version:** 06-Jul-2020 21:52

**Form Status:** Not Started

**Site No:** 1126

**Site Name:** (1126) Kaiser Permanente Santa Clara

**Subject No:** 11261268

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 06-Apr-2021 15:36

**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:** 1126

**Subject No:** 11261268

**Generated By:** (b) (4)

**Form:** DATE OF VISIT - ILLNESS CONVALESCENT

**Form Status:** Not Started

**Site Name:** (1126) Kaiser Permanente Santa Clara

**Subject Initials:** ---

**Generated Time (GMT):** 06-Apr-2021 15:36

**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:** 1126**Subject No:** 11261268**Generated By:** (b) (4)**Form:** ELECTRONIC SAMPLE TRACKING -  
IMMUNOGENICITY**Form Status:** Not Started**Site Name:** (1126) Kaiser Permanente Santa Clara**Subject Initials:** ---**Generated Time (GMT):** 06-Apr-2021 15:36**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 **Form:** DATE OF VISIT - REPEAT SWAB  
Unscheduled Visit

**Form Version:** 10-Oct-2020 15:57

**Form Status:** Not Started

**Site No:** 1126

**Site Name:** (1126) Kaiser Permanente Santa Clara

**Subject No:** 11261268

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 06-Apr-2021 15:36

**Date of Visit**

1.	Date of Visit	//
2.	Erroneous Visit	

**COVID-19 Repeat Swab**

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

**Header Text:** c4591001**Visit:** POT\_COVID\_REPEAT\_SWAB - New **Form:** ELECTRONIC SAMPLE TRACKING - REPEAT SWAB  
Unscheduled Visit**Form Version:** 10-Oct-2020 15:57**Form Status:** Not Started**Site No:** 1126**Site Name:** (1126) Kaiser Permanente Santa Clara**Subject No:** 11261268**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 06-Apr-2021 15:36**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:** Logs

**Form:** ADVERSE EVENT REPORT

**Form Version:** 22-Apr-2020 21:02

**Site No:** 1126

**Site Name:** (1126) Kaiser Permanente Santa Clara

**Subject No:** 11261268

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 06-Apr-2021 15:36

#	Category	AE Identifier	Adverse Event	Start Date	Is the Adverse Event Still Ongoing	Form Instance
1.	ADVERSE EVENT	1	Facial Urticaria, worsening	Dec/18/2020 UNK:UNK	NO End Date Time:  Dec/31/2020 UNK :UNK	<a href="#">Repeating Pages</a>
2.	ADVERSE EVENT	2	Juvenile Osteochondrosis of bi lateral fifth metatarsals	Dec/28/2020 UNK:UNK	YES	<a href="#">Repeating Pages</a>

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

**Form Version:** 22-Apr-2020 21:02

**Site No:** 1126

**Subject No:** 11261268

**Generated By:** (b) (4)

**Form:** ADVERSE EVENT REPORT

**Form Status:** Data Complete, Frozen

**Site Name:** (1126) Kaiser Permanente Santa Clara

**Subject Initials:** ---

**Generated Time (GMT):** 06-Apr-2021 15:36

[Back to Form](#)

[eCRF Audit Trail History](#)

[Form Audit Trail](#)

**Adverse Event Report**

1.	Category:	ADVERSE EVENT
2.	AE ID:	[1]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[Facial Urticaria, worsening]
4.	Start Date Time:	Dec/18/2020 UNK:UNK
5.	Is the adverse event still ongoing?	NO End Date Time: Dec/31/2020 UNK:UNK
6.	Toxicity Grade:	1
7.	Is the adverse event serious?  If Yes, NOTIFY PFIZER IMMEDIATELY.  Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).	NO
8.	Is this adverse event the result of a study Medication Error? If Yes, record the type of medication error on the Medication Error Log.	NO

090177e196b72785\Final\Final On: 06-Apr-2021 19:12 (GMT)

**Header Text:** c4591001**Visit:** Logs - Unscheduled**Form Version:** 22-Apr-2020 21:02**Site No:** 1126**Subject No:** 11261268**Generated By:** (b) (4)**Form:** ADVERSE EVENT REPORT**Form Status:** Data Complete, Frozen**Site Name:** (1126) Kaiser Permanente Santa Clara**Subject Initials:** ---**Generated Time (GMT):** 06-Apr-2021 15:36

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

**Header Text:** c4591001**Visit:** Logs - Unscheduled**Form Version:** 22-Apr-2020 21:02**Site No:** 1126**Subject No:** 11261268**Generated By:** (b) (4)**Form:** ADVERSE EVENT REPORT**Form Status:** Data Complete**Site Name:** (1126) Kaiser Permanente Santa Clara**Subject Initials:** ---**Generated Time (GMT):** 06-Apr-2021 15:36[Back to Form](#)[eCRF Audit Trail History](#)[Form Audit Trail](#)**Adverse Event Report**

1.	Category:	ADVERSE EVENT
2.	AE ID:	[2]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[Juvenile Osteochondrosis of bilateral fifth metatarsals]
4.	Start Date Time:	Dec/28/2020 UNK:UNK
5.	Is the adverse event still ongoing?	YES
6.	Toxicity Grade:	2
7.	Is the adverse event serious?  If Yes, NOTIFY PFIZER IMMEDIATELY.  Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).	NO
8.	Is this adverse event the result of a study Medication Error? If Yes, record the type of medication error on the Medication Error Log.	NO

**Header Text:** c4591001**Visit:** Logs - Unscheduled**Form Version:** 22-Apr-2020 21:02**Site No:** 1126**Subject No:** 11261268**Generated By:** (b) (4)**Form:** ADVERSE EVENT REPORT**Form Status:** Data Complete**Site Name:** (1126) Kaiser Permanente Santa Clara**Subject Initials:** ---**Generated Time (GMT):** 06-Apr-2021 15:36

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



**Header Text:** c4591001

**Visit:** Logs

**Form:** MEDICATION ERROR

**Form Version:** 17-Jul-2020 21:54

**Site No:** 1126

**Site Name:** (1126) Kaiser Permanente Santa Clara

**Subject No:** 11261268

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 06-Apr-2021 15:36

#	Category	Medication Error	Start Date	Is the medication error Still Ongoing	Study Medication Errors Action	Form Instance
1.						<a href="#">Repeating Pages</a>

**Header Text:** c4591001**Visit:** Logs - Unscheduled**Form Version:** 17-Jul-2020 21:54**Site No:** 1126**Subject No:** 11261268**Generated By:** (b) (4)**Form:** MEDICATION ERROR**Form Status:** Not Started**Site Name:** (1126) Kaiser Permanente Santa Clara**Subject Initials:** ---**Generated Time (GMT):** 06-Apr-2021 15:36[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	[ ]

**Header Text:** c4591001

**Visit:** Logs

**Form:** CONCOMITANT MEDICATIONS - NON STUDY  
VACCINATIONS

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1126

**Site Name:** (1126) Kaiser Permanente Santa Clara

**Subject No:** 11261268

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 06-Apr-2021 15:36

#	Sponsor-Defined Identifier	Category for Medication	Concomitant Medications Pre-specified	Name of Medication	Start Date	Form Instance
1.						<a href="#">Repeating Pages</a>

**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:** 1126**Site Name:** (1126) Kaiser Permanente Santa Clara**Subject No:** 11261268**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 06-Apr-2021 15:36[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:** 1126

**Site Name:** (1126) Kaiser Permanente Santa Clara

**Subject No:** 11261268

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 06-Apr-2021 15:36

#	Sponsor-Defined Identifier	Category for Medication	Concomitant Medications Pre-specified	Name of Medication	Dose Description	Form Instance
1.						<a href="#">Repeating Pages</a>

**Header Text:** c4591001**Visit:** Logs - Unscheduled**Form Version:** 22-Apr-2020 21:03**Site No:** 1126**Subject No:** 11261268**Generated By:** (b) (4)**Form:** CONCOMITANT MEDICATIONS - PROHIBITED**Form Status:** Not Started**Site Name:** (1126) Kaiser Permanente Santa Clara**Subject Initials:** ---**Generated Time (GMT):** 06-Apr-2021 15:36[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:** 1126

**Site Name:** (1126) Kaiser Permanente Santa Clara

**Subject No:** 11261268

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 06-Apr-2021 15:36

#	Category	Treatment Identifier	Con Non-Drug Treatments Pre-specified	Treatment	Start Date	Form Instance
1.						<a href="#">Repeating Pages</a>

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

**Form Version:** 22-Apr-2020 21:02

**Site No:** 1126

**Subject No:** 11261268

**Generated By:** (b) (4)

**Form:** RADIATION TREATMENT

**Form Status:** Not Started

**Site Name:** (1126) Kaiser Permanente Santa Clara

**Subject Initials:** ---

**Generated Time (GMT):** 06-Apr-2021 15:36

[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:** 1126

**Site Name:** (1126) Kaiser Permanente Santa Clara

**Subject No:** 11261268

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 06-Apr-2021 15:36

#	Transfusion Type	Date of Transfusion	Form Instance
1.			<a href="#">Repeating Pages</a>

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1126

**Subject No:** 11261268

**Generated By:** (b) (4)

**Form:** TRANSFUSIONS

**Form Status:** Not Started

**Site Name:** (1126) Kaiser Permanente Santa Clara

**Subject Initials:** ---

**Generated Time (GMT):** 06-Apr-2021 15:36

[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:** 1126

**Site Name:** (1126) Kaiser Permanente Santa Clara

**Subject No:** 11261268

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 06-Apr-2021 15:36

**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:** 1126

**Site Name:** (1126) Kaiser Permanente Santa Clara

**Subject No:** 11261268

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 06-Apr-2021 15:36

**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:** 1126    **Site Name:** (1126) Kaiser Permanente Santa Clara

**Subject No:** 11261268    **Subject Initials:** ---

**Generated By:** (b) (4)    **Generated Time (GMT):** 06-Apr-2021 15:36

**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:** 1126

**Site Name:** (1126) Kaiser Permanente Santa Clara

**Subject No:** 11261268

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 06-Apr-2021 15:36

**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:** 1126**Site Name:** (1126) Kaiser Permanente Santa Clara**Subject No:** 11261268**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 06-Apr-2021 15:36**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:** 1126**Site Name:** (1126) Kaiser Permanente Santa Clara**Subject No:** 11261268**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 06-Apr-2021 15:36**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:** 1126

**Site Name:** (1126) Kaiser Permanente Santa Clara

**Subject No:** 11261268

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 06-Apr-2021 15:36

**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:** 1126

**Site Name:** (1126) Kaiser Permanente Santa Clara

**Subject No:** 11261268

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 06-Apr-2021 15:36

**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:** 1126

**Site Name:** (1126) Kaiser Permanente Santa Clara

**Subject No:** 11261268

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 06-Apr-2021 15:36

**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:** 1126

**Subject No:** 11261268

**Generated By:** (b) (4)

**Form:** INFORMED CONSENT - ASYMPTOMATIC  
SURVEILLANCE

**Form Status:** Not Started

**Site Name:** (1126) Kaiser Permanente Santa Clara

**Subject Initials:** ---

**Generated Time (GMT):** 06-Apr-2021 15:36

**Informed Consent - Asymptomatic Surveillance**

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

**Header Text:** c4591001**Visit:** V201\_SURVEIL\_CONSENT -  
Unscheduled**Form Version:** 22-Apr-2020 21:03**Site No:** 1126**Subject No:** 11261268**Generated By:** (b) (4)**Form:** ELECTRONIC SAMPLE TRACKING -  
IMMUNOGENICITY**Form Status:** Not Started**Site Name:** (1126) Kaiser Permanente Santa Clara**Subject Initials:** ---**Generated Time (GMT):** 06-Apr-2021 15:36**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:** V201\_SURVEIL\_CONSENT -  
Unscheduled**Form Version:** 22-Apr-2020 21:03**Site No:** 1126**Subject No:** 11261268**Generated By:** (b) (4)**Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB**Form Status:** Not Started**Site Name:** (1126) Kaiser Permanente Santa Clara**Subject Initials:** ---**Generated Time (GMT):** 06-Apr-2021 15:36**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:** End of Treatment - Unscheduled

**Form Version:** 10-Dec-2020 02:29

**Site No:** 1126

**Subject No:** 11261268

**Generated By:** (b) (4)

**Form:** DISPOSITION - TREATMENT

**Form Status:** Data Complete, Frozen, Verified

**Site Name:** (1126) Kaiser Permanente Santa Clara

**Subject Initials:** ---

**Generated Time (GMT):** 06-Apr-2021 15:36

[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:** 1126**Site Name:** (1126) Kaiser Permanente Santa Clara**Subject No:** 11261268**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 06-Apr-2021 15:36**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:** 1126

**Subject No:** 11261268

**Generated By:** (b) (4)

**Form:** FURTHER VACCINATION CONFIRMATION

**Form Status:** Not Started

**Site Name:** (1126) Kaiser Permanente Santa Clara

**Subject Initials:** ---

**Generated Time (GMT):** 06-Apr-2021 15:36

**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:** 1126

**Subject No:** 11261268

**Generated By:** (b) (4)

**Form:** TREATMENT UNBLINDED

**Form Status:** Not Started

**Site Name:** (1126) Kaiser Permanente Santa Clara

**Subject Initials:** ---

**Generated Time (GMT):** 06-Apr-2021 15:36

**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:** 1126

**Subject No:** 11261268

**Generated By:** (b) (4)

**Form:** WITHDRAWAL OF CONSENT

**Form Status:** Not Started

**Site Name:** (1126) Kaiser Permanente Santa Clara

**Subject Initials:** ---

**Generated Time (GMT):** 06-Apr-2021 15:36

**Withdrawal Of Consent**

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

**Header Text:** c4591001

**Visit:** Disposition - Unscheduled

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1126

**Subject No:** 11261268

**Generated By:** (b) (4)

**Form:** DEATH DETAILS CODED

**Form Status:** Not Started

**Site Name:** (1126) Kaiser Permanente Santa Clara

**Subject Initials:** ---

**Generated Time (GMT):** 06-Apr-2021 15:36

**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:** 1126

**Subject No:** 11261268

**Generated By:** (b) (4)

**Form:** DISPOSITION - FOLLOW-UP

**Form Status:** Not Started

**Site Name:** (1126) Kaiser Permanente Santa Clara

**Subject Initials:** ---

**Generated Time (GMT):** 06-Apr-2021 15:36

**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:** 1126

**Subject No:** 11261268

**Generated By:** (b) (4)

**Form:** SUBJECT STATUS

**Form Status:** Data Complete, Verified

**Site Name:** (1126) Kaiser Permanente Santa Clara

**Subject Initials:** ---

**Generated Time (GMT):** 06-Apr-2021 15:36

[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:** 1126

**Site Name:** (1126) Kaiser Permanente Santa Clara

**Subject No:** 11261268

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 06-Apr-2021 15:36

[eCRF Audit Trail History](#)

**Casebook Signature Form**

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

**Header Text:** c4591001**Visit:** Investigator Signature - Unscheduled**Form:** CASEBOOK SIGNATURE FORM**Form Version:** 22-Apr-2020 21:04**Form Status:** Data Complete, Signed, Verified**Site No:** 1126**Site Name:** (1126) Kaiser Permanente Santa Clara**Subject No:** 11261268**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 06-Apr-2021 15:36[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-11-2021 15:00:20 (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:** 1126

**Subject No:** 11261268

**Generated By:** (b) (4)

**Form:** INCLUSION/EXCLUSION CRITERIA - Comments

**Form Status:** Data Complete, Frozen, Verified

**Site Name:** (1126) Kaiser Permanente Santa Clara

**Subject Initials:** ---

**Generated Time (GMT):** 06-Apr-2021 15:36

[Back to Form](#)

Item	Date	User	Comment
Form	Dec-15-2020 09:46:28 (UTC-08:00) Pacific Time (US & Canada)	Charlie Chao (b) (4)	N/A Not Applicable

**Header Text:** c4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form Version:** 10-Dec-2020 02:23

**Site No:** 1126

**Subject No:** 11261268

**Generated By:** (b) (4)

**Form:** LAB URINALYSIS - PREGNANCY TEST - Comments

**Form Status:** Data Complete, Frozen, Verified

**Site Name:** (1126) Kaiser Permanente Santa Clara

**Subject Initials:** ---

**Generated Time (GMT):** 06-Apr-2021 15:36

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Item	Date	User	Comment
Form	Dec-15-2020 09:50:31 (UTC-08:00) Pacific Time (US & Canada)	Charlie Chao (b) (4)	N/A Not Applicable

**Header Text:** c4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form Version:** 10-Dec-2020 02:23

**Site No:** 1126

**Subject No:** 11261268

**Generated By:** (b) (4)

**Form:** LAB URINALYSIS - PREGNANCY TEST - Comments

**Form Status:** Data Complete, Frozen, Verified

**Site Name:** (1126) Kaiser Permanente Santa Clara

**Subject Initials:** ---

**Generated Time (GMT):** 06-Apr-2021 15:36

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Item	Date	User	Comment
1	Dec-15-2020 09:50:31 (UTC-08:00) Pacific Time (US & Canada)	Charlie Chao (b) (4)	N/A Not Applicable

**Header Text:** c4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form Version:** 10-Dec-2020 02:23

**Site No:** 1126

**Subject No:** 11261268

**Generated By:** (b) (4)

**Form:** LAB URINALYSIS - PREGNANCY TEST - Comments

**Form Status:** Data Complete, Frozen, Verified

**Site Name:** (1126) Kaiser Permanente Santa Clara

**Subject Initials:** ---

**Generated Time (GMT):** 06-Apr-2021 15:36

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Item	Date	User	Comment
2	Dec-15-2020 09:50:31 (UTC-08:00) Pacific Time (US & Canada)	Charlie Chao (b) (4)	N/A Not Applicable

**Header Text:** c4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form Version:** 10-Dec-2020 02:23

**Site No:** 1126

**Subject No:** 11261268

**Generated By:** (b) (4)

**Form:** LAB URINALYSIS - PREGNANCY TEST - Comments

**Form Status:** Data Complete, Frozen, Verified

**Site Name:** (1126) Kaiser Permanente Santa Clara

**Subject Initials:** ---

**Generated Time (GMT):** 06-Apr-2021 15:36

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Item	Date	User	Comment
3	Dec-15-2020 09:50:31 (UTC-08:00) Pacific Time (US & Canada)	Charlie Chao (b) (4)	N/A _____ Not Applicable

**Header Text:** c4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form Version:** 10-Dec-2020 02:23

**Site No:** 1126

**Subject No:** 11261268

**Generated By:** (b) (4)

**Form:** LAB URINALYSIS - PREGNANCY TEST - Comments

**Form Status:** Data Complete, Frozen, Verified

**Site Name:** (1126) Kaiser Permanente Santa Clara

**Subject Initials:** ---

**Generated Time (GMT):** 06-Apr-2021 15:36

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Item	Date	User	Comment
4	Dec-15-2020 09:50:31 (UTC-08:00) Pacific Time (US & Canada)	Charlie Chao (b) (4)	N/A Not Applicable

**Header Text:** c4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form Version:** 10-Dec-2020 02:23

**Site No:** 1126

**Subject No:** 11261268

**Generated By:** (b) (4)

**Form:** LAB URINALYSIS - PREGNANCY TEST - Comments

**Form Status:** Data Complete, Frozen, Verified

**Site Name:** (1126) Kaiser Permanente Santa Clara

**Subject Initials:** ---

**Generated Time (GMT):** 06-Apr-2021 15:36

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Item	Date	User	Comment
5	Dec-15-2020 09:50:31 (UTC-08:00) Pacific Time (US & Canada)	Charlie Chao (b) (4)	N/A Not Applicable

**Header Text:** c4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form Version:** 10-Dec-2020 02:23

**Site No:** 1126

**Subject No:** 11261268

**Generated By:** (b) (4)

**Form:** LAB URINALYSIS - PREGNANCY TEST - Comments

**Form Status:** Data Complete, Frozen, Verified

**Site Name:** (1126) Kaiser Permanente Santa Clara

**Subject Initials:** ---

**Generated Time (GMT):** 06-Apr-2021 15:36

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Item	Date	User	Comment
6.a	Dec-15-2020 09:50:31 (UTC-08:00) Pacific Time (US & Canada)	Charlie Chao (b) (4)	N/A _____ Not Applicable



**Header Text:** c4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form Version:** 10-Dec-2020 02:23

**Site No:** 1126

**Subject No:** 11261268

**Generated By:** (b) (4)

**Form:** LAB URINALYSIS - PREGNANCY TEST - Comments

**Form Status:** Data Complete, Frozen, Verified

**Site Name:** (1126) Kaiser Permanente Santa Clara

**Subject Initials:** ---

**Generated Time (GMT):** 06-Apr-2021 15:36

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Item	Date	User	Comment
6.a	Dec-15-2020 09:50:31 (UTC-08:00) Pacific Time (US & Canada)	Charlie Chao (b) (4)	N/A _____ Not Applicable

**Header Text:** c4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form Version:** 10-Dec-2020 02:23

**Site No:** 1126

**Subject No:** 11261268

**Generated By:** (b) (4)

**Form:** LAB URINALYSIS - PREGNANCY TEST - Comments

**Form Status:** Data Complete, Frozen, Verified

**Site Name:** (1126) Kaiser Permanente Santa Clara

**Subject Initials:** ---

**Generated Time (GMT):** 06-Apr-2021 15:36

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Item	Date	User	Comment
6.a	Dec-15-2020 09:50:31 (UTC-08:00) Pacific Time (US & Canada)	Charlie Chao (b) (4)	N/A Not Applicable

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

**Form Version:** 10-Dec-2020 02:23

**Site No:** 1126

**Subject No:** 11261268

**Generated By:** (b) (4)

**Form:** LAB URINALYSIS - PREGNANCY TEST - Comments

**Form Status:** Data Complete, Frozen, Verified

**Site Name:** (1126) Kaiser Permanente Santa Clara

**Subject Initials:** ---

**Generated Time (GMT):** 06-Apr-2021 15:36

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Item	Date	User	Comment
Form	Jan-07-2021 08:39:34 (UTC-08:00) Pacific Time (US & Canada)	Charlie Chao (b) (4)	N/A Not Applicable

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

**Form Version:** 10-Dec-2020 02:23

**Site No:** 1126

**Subject No:** 11261268

**Generated By:** (b) (4)

**Form:** LAB URINALYSIS - PREGNANCY TEST - Comments

**Form Status:** Data Complete, Frozen, Verified

**Site Name:** (1126) Kaiser Permanente Santa Clara

**Subject Initials:** ---

**Generated Time (GMT):** 06-Apr-2021 15:36

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Item	Date	User	Comment
1	Jan-07-2021 08:39:34 (UTC-08:00) Pacific Time (US & Canada)	Charlie Chao (b) (4)	N/A Not Applicable

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

**Form Version:** 10-Dec-2020 02:23

**Site No:** 1126

**Subject No:** 11261268

**Generated By:** (b) (4)

**Form:** LAB URINALYSIS - PREGNANCY TEST - Comments

**Form Status:** Data Complete, Frozen, Verified

**Site Name:** (1126) Kaiser Permanente Santa Clara

**Subject Initials:** ---

**Generated Time (GMT):** 06-Apr-2021 15:36

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Item	Date	User	Comment
2	Jan-07-2021 08:39:34 (UTC-08:00) Pacific Time (US & Canada)	Charlie Chao (b) (4)	N/A Not Applicable

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

**Form Version:** 10-Dec-2020 02:23

**Site No:** 1126

**Subject No:** 11261268

**Generated By:** (b) (4)

**Form:** LAB URINALYSIS - PREGNANCY TEST - Comments

**Form Status:** Data Complete, Frozen, Verified

**Site Name:** (1126) Kaiser Permanente Santa Clara

**Subject Initials:** ---

**Generated Time (GMT):** 06-Apr-2021 15:36

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Item	Date	User	Comment
3	Jan-07-2021 08:39:34 (UTC-08:00) Pacific Time (US & Canada)	Charlie Chao (b) (4)	N/A Not Applicable

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

**Form Version:** 10-Dec-2020 02:23

**Site No:** 1126

**Subject No:** 11261268

**Generated By:** (b) (4)

**Form:** LAB URINALYSIS - PREGNANCY TEST - Comments

**Form Status:** Data Complete, Frozen, Verified

**Site Name:** (1126) Kaiser Permanente Santa Clara

**Subject Initials:** ---

**Generated Time (GMT):** 06-Apr-2021 15:36

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Item	Date	User	Comment
4	Jan-07-2021 08:39:34 (UTC-08:00) Pacific Time (US & Canada)	Charlie Chao (b) (4)	N/A Not Applicable

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

**Form Version:** 10-Dec-2020 02:23

**Site No:** 1126

**Subject No:** 11261268

**Generated By:** (b) (4)

**Form:** LAB URINALYSIS - PREGNANCY TEST - Comments

**Form Status:** Data Complete, Frozen, Verified

**Site Name:** (1126) Kaiser Permanente Santa Clara

**Subject Initials:** ---

**Generated Time (GMT):** 06-Apr-2021 15:36

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Item	Date	User	Comment
5	Jan-07-2021 08:39:34 (UTC-08:00) Pacific Time (US & Canada)	Charlie Chao (b) (4)	N/A Not Applicable



**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

**Form Version:** 10-Dec-2020 02:23

**Site No:** 1126

**Subject No:** 11261268

**Generated By:** (b) (4)

**Form:** LAB URINALYSIS - PREGNANCY TEST - Comments

**Form Status:** Data Complete, Frozen, Verified

**Site Name:** (1126) Kaiser Permanente Santa Clara

**Subject Initials:** ---

**Generated Time (GMT):** 06-Apr-2021 15:36

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Item	Date	User	Comment
6.a	Jan-07-2021 08:39:34 (UTC-08:00) Pacific Time (US & Canada)	Charlie Chao (b) (4)	N/A Not Applicable

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

**Form Version:** 10-Dec-2020 02:23

**Site No:** 1126

**Subject No:** 11261268

**Generated By:** (b) (4)

**Form:** LAB URINALYSIS - PREGNANCY TEST - Comments

**Form Status:** Data Complete, Frozen, Verified

**Site Name:** (1126) Kaiser Permanente Santa Clara

**Subject Initials:** ---

**Generated Time (GMT):** 06-Apr-2021 15:36

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Item	Date	User	Comment
6.a	Jan-07-2021 08:39:34 (UTC-08:00) Pacific Time (US & Canada)	Charlie Chao (b) (4)	N/A Not Applicable

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

**Form Version:** 10-Dec-2020 02:23

**Site No:** 1126

**Subject No:** 11261268

**Generated By:** (b) (4)

**Form:** LAB URINALYSIS - PREGNANCY TEST - Comments

**Form Status:** Data Complete, Frozen, Verified

**Site Name:** (1126) Kaiser Permanente Santa Clara

**Subject Initials:** ---

**Generated Time (GMT):** 06-Apr-2021 15:36

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Item	Date	User	Comment
6.a	Jan-07-2021 08:39:34 (UTC-08:00) Pacific Time (US & Canada)	Charlie Chao (b) (4)	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:** 1126

**Site Name:** (1126) Kaiser Permanente Santa Clara

**Subject No:** 11261268

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 06-Apr-2021 15:36

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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-11-2021 15:00:20 (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.

090177e196b72785\Final\Final On: 06-Apr-2021 19:12 (GMT)

**Header Text:** c4591001

**Visit:** COHORT\_SELECTION

**Form Version:** 10-Dec-2020 02:31

**Site No:** 1126

**Subject No:** 11261268

**Generated By:** (b) (4)

**Form:** COHORT SELECTION - eCRF Audit Trail History

**Form Status:** Data Complete, Frozen, Verified

**Site Name:** (1126) Kaiser Permanente Santa Clara

**Subject Initials:** ---

**Generated Time (GMT):** 06-Apr-2021 15:36

[Back to Form](#)

**1. Select appropriate response - Protocol version**

Date	Location	User	Value	Reason
Dec-15-2020 09:44:55 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Charlie Chao (b) (4)	<b>Data Entry:</b> 06 OCT 2020	Initial Entry

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

Date	Location	User	Value	Reason
Dec-15-2020 09:44:55 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Charlie Chao (b) (4)	<b>Data Entry:</b> STAGE 3 COHORTS	Initial Entry

090177e196b72785\Final\Final On: 06-Apr-2021 19:12 (GMT)

**Header Text:** c4591001

**Visit:** COHORT\_SELECTION

**Form Version:** 22-Apr-2020 21:02

**Site No:** 1126

**Subject No:** 11261268

**Generated By:** (b) (4)

**Form:** MAIN INFORMED CONSENT - eCRF Audit Trail History

**Form Status:** Data Complete, Frozen, Verified

**Site Name:** (1126) Kaiser Permanente Santa Clara

**Subject Initials:** ---

**Generated Time (GMT):** 06-Apr-2021 15:36

[Back to Form](#)

***I. Consent Was:***

Date	Location	User	Value	Reason
Dec-15-2020 09:45:04 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Charlie Chao (b) (4)	<b>Data Entry:</b> OBTAINED Date Written Consent Obtain ed  Dec/14/2020	Initial Entry

**Header Text:** c4591001

**Visit:** COHORT\_SELECTION

**Form Version:** 10-Dec-2020 02:26

**Site No:** 1126

**Subject No:** 11261268

**Generated By:** (b) (4)

**Form:** DEMOGRAPHY - eCRF Audit Trail History

**Form Status:** Data Complete, Frozen, Verified

**Site Name:** (1126) Kaiser Permanente Santa Clara

**Subject Initials:** ---

**Generated Time (GMT):** 06-Apr-2021 15:36

[Back to Form](#)

**1. Subject ID**

Date	Location	User	Value	Reason
Dec-15-2020 09:44:41 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 11261268	Item copied from previous form

**2. Birth Date:**

Date	Location	User	Value	Reason
Dec-15-2020 09:44:38 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> (b) (6) 2007	Enrollment Entry

**3. Sex:**

Date	Location	User	Value	Reason
Dec-15-2020 09:45:59 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Charlie Chao (b) (4)	<b>Data Entry:</b> FEMALE	Initial Entry

**4. Ethnicity:**

Date	Location	User	Value	Reason
Dec-15-2020 09:45:59 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Charlie Chao (b) (4)	<b>Data Entry:</b> NOT HISPANIC OR LATINO(A) OR OF SPANISH ORIGIN	Initial Entry

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

Date	Location	User	Value	Reason
Dec-15-2020 09:45:59 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Charlie Chao (b) (4)	<b>Data Entry:</b> WHITE	Initial Entry

090177e196b72785\Final\Final On: 06-Apr-2021 19:12 (GMT)

**Header Text:** c4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form Version:** 22-Apr-2020 21:02

**Site No:** 1126

**Subject No:** 11261268

**Generated By:** (b) (4)

**Form:** DATE OF VISIT - eCRF Audit Trail History

**Form Status:** Data Complete, Frozen, Verified

**Site Name:** (1126) Kaiser Permanente Santa Clara

**Subject Initials:** ---

**Generated Time (GMT):** 06-Apr-2021 15:36

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*I. Date of Visit*

Date	Location	User	Value	Reason
Dec-15-2020 09:46:09 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Charlie Chao (b) (4)	<b>Data Entry:</b> Dec/14/2020	Initial Entry



**Header Text:** c4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form Version:** 15-Sep-2020 21:52

**Site No:** 1126

**Subject No:** 11261268

**Generated By:** (b) (4)

**Form:** DISPOSITION - SCREENING - eCRF Audit Trail History

**Form Status:** Data Complete, Frozen, Verified

**Site Name:** (1126) Kaiser Permanente Santa Clara

**Subject Initials:** ---

**Generated Time (GMT):** 06-Apr-2021 15:36

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**1. Date of Completion/Discontinuation/Death**

Date	Location	User	Value	Reason
Dec-15-2020 09:46:42 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Charlie Chao (b) (4)	<b>Data Entry:</b> Dec/14/2020	Initial Entry

**2. Phase of Disposition:**

Date	Location	User	Value	Reason
Dec-15-2020 09:46:42 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SCREENING	Initial Entry

**3. Status:**

Date	Location	User	Value	Reason
Dec-15-2020 09:46:42 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Charlie Chao (b) (4)	<b>Data Entry:</b> COMPLETED	Initial Entry

090177e196b72785\Final\Final On: 06-Apr-2021 19:12 (GMT)

**Header Text:** c4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1126

**Subject No:** 11261268

**Generated By:** (b) (4)

**Form:** GENERAL MEDICAL HISTORY - eCRF Audit Trail History

**Form Status:** Data Complete, Frozen, Verified

**Site Name:** (1126) Kaiser Permanente Santa Clara

**Subject Initials:** ---

**Generated Time (GMT):** 06-Apr-2021 15:36

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*I.a*

Date	Location	User	Value	Reason
Dec-15-2020 09:47:11 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Line/MH Number:</b> <b>Medical History</b> Verruca Vulgaris <b>Term:</b> <b>Start Date:</b> Nov/9/2017 <b>Ongoing:</b> YES	Initial Entry

*I.a Line/MH Number:*

Date	Location	User	Value	Reason
Dec-15-2020 09:47:11 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 1	Initial Entry

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

Date	Location	User	Value	Reason
Dec-15-2020 09:47:11 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Charlie Chao (b) (4)	<b>Data Entry:</b> Verruca Vulgaris	Initial Entry

*I.a Start Date:*

Date	Location	User	Value	Reason
Dec-15-2020 09:47:11 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Charlie Chao (b) (4)	<b>Data Entry:</b> Nov/9/2017	Initial Entry

*I.a Ongoing:*

Date	Location	User	Value	Reason
Dec-15-2020 09:47:11 (UTC-08:00) Pacific	ACV0PFEINFP6000	Charlie Chao	<b>Data Entry:</b> YES	Initial Entry

**Header Text:** c4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1126

**Subject No:** 11261268

**Generated By:** (b) (4)

**Form:** GENERAL MEDICAL HISTORY - eCRF Audit Trail History

**Form Status:** Data Complete, Frozen, Verified

**Site Name:** (1126) Kaiser Permanente Santa Clara

**Subject Initials:** ---

**Generated Time (GMT):** 06-Apr-2021 15:36

Time (US & Canada)

(b) (4)

*1.b*

Date	Location	User	Value	Reason
Dec-15-2020 09:47:47 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Line/MH N 2</b> <b>umber:</b> <b>Medical His</b> Left Proximal Ra <b>tory Term:</b> dius Fracture <b>Start Date:</b> Jul/27/2012 <b>Ongoing:</b> NO End Date: Aug/22/2012	Initial Entry

090177e196b72785\Final\Final On: 06-Apr-2021 19:12 (GMT)

**Header Text:** c4591001**Visit:** V1\_DAY1\_VAX1\_L**Form Version:** 22-Apr-2020 21:03**Site No:** 1126**Subject No:** 11261268**Generated By:** (b) (4)**Form:** GENERAL MEDICAL HISTORY - eCRF Audit Trail History**Form Status:** Data Complete, Frozen, Verified**Site Name:** (1126) Kaiser Permanente Santa Clara**Subject Initials:** ---**Generated Time (GMT):** 06-Apr-2021 15:36***1.b Line/MH Number:***

Date	Location	User	Value	Reason
Dec-15-2020 09:47:47 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 2	Initial Entry

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

Date	Location	User	Value	Reason
Dec-15-2020 09:47:47 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Charlie Chao (b) (4)	<b>Data Entry:</b> Left Proximal Radius Fracture	Initial Entry

***1.b Start Date:***

Date	Location	User	Value	Reason
Dec-15-2020 09:47:47 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Charlie Chao (b) (4)	<b>Data Entry:</b> Jul/27/2012	Initial Entry

***1.b Ongoing:***

Date	Location	User	Value	Reason
Dec-15-2020 09:47:47 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Charlie Chao (b) (4)	<b>Data Entry:</b> NO End Date:  Aug/22/2012	Initial Entry

***1.c***

Date	Location	User	Value	Reason
Dec-15-2020 09:48:24 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Line/MH</b> 3 <b>Number:</b> <b>Medical Hi</b> Juvenile Osteocho <b>story Term</b> ndrosis of Right T : arsal <b>Start Date:</b> Jun/25/2020	Initial Entry

**Header Text:** c4591001**Visit:** V1\_DAY1\_VAX1\_L**Form Version:** 22-Apr-2020 21:03**Site No:** 1126**Subject No:** 11261268**Generated By:** (b) (4)**Form:** GENERAL MEDICAL HISTORY - eCRF Audit Trail History**Form Status:** Data Complete, Frozen, Verified**Site Name:** (1126) Kaiser Permanente Santa Clara**Subject Initials:** ---**Generated Time (GMT):** 06-Apr-2021 15:36**Ongoing:** YES***I.c Line/MH Number:***

Date	Location	User	Value	Reason
Dec-15-2020 09:48:24 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 3	Initial Entry

***I.c Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:***

Date	Location	User	Value	Reason
Dec-15-2020 09:48:24 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Charlie Chao (b) (4)	<b>Data Entry:</b> Juvenile Osteochondrosis of Ri ght Tarsal	Initial Entry

***I.c Start Date:***

Date	Location	User	Value	Reason
Dec-15-2020 09:48:24 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Charlie Chao (b) (4)	<b>Data Entry:</b> Jun/25/2020	Initial Entry

***I.c Ongoing:***

Date	Location	User	Value	Reason
Dec-15-2020 09:48:24 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Charlie Chao (b) (4)	<b>Data Entry:</b> YES	Initial Entry

***I.d***

Date	Location	User	Value	Reason
Dec-15-2020 09:48:46 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Line/MH Num 4</b> <b>ber:</b> <b>Medical Histo</b> Right Hip Flex <b>ry Term:</b> or Strain <b>Start Date:</b> Nov/12/2020	Initial Entry

**Header Text:** c4591001**Visit:** V1\_DAY1\_VAX1\_L**Form Version:** 22-Apr-2020 21:03**Site No:** 1126**Subject No:** 11261268**Generated By:** (b) (4)**Form:** GENERAL MEDICAL HISTORY - eCRF Audit Trail History**Form Status:** Data Complete, Frozen, Verified**Site Name:** (1126) Kaiser Permanente Santa Clara**Subject Initials:** ---**Generated Time (GMT):** 06-Apr-2021 15:36

			<b>Ongoing:</b> YES	
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***1.d Line/MH Number:***

Date	Location	User	Value	Reason
Dec-15-2020 09:48:46 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 4	Initial Entry

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

Date	Location	User	Value	Reason
Dec-15-2020 09:48:46 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Charlie Chao (b) (4)	<b>Data Entry:</b> Right Hip Flexor Strain	Initial Entry

***1.d Start Date:***

Date	Location	User	Value	Reason
Dec-15-2020 09:48:46 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Charlie Chao (b) (4)	<b>Data Entry:</b> Nov/12/2020	Initial Entry

***1.d Ongoing:***

Date	Location	User	Value	Reason
Dec-15-2020 09:48:46 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Charlie Chao (b) (4)	<b>Data Entry:</b> YES	Initial Entry

***1.e***

Date	Location	User	Value	Reason
Dec-15-2020 09:49:04 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Line/MH Nu</b> 5 <b>mber:</b> <b>Medical Hist</b> Urticaria, No Kn <b>ory Term:</b> own Triggers <b>Start Date:</b> Oct/7/2010	Initial Entry

**Header Text:** c4591001**Visit:** V1\_DAY1\_VAX1\_L**Form Version:** 22-Apr-2020 21:03**Site No:** 1126**Subject No:** 11261268**Generated By:** (b) (4)**Form:** GENERAL MEDICAL HISTORY - eCRF Audit Trail History**Form Status:** Data Complete, Frozen, Verified**Site Name:** (1126) Kaiser Permanente Santa Clara**Subject Initials:** ---**Generated Time (GMT):** 06-Apr-2021 15:36**Ongoing:** YES***I.e Line/MH Number:***

Date	Location	User	Value	Reason
Dec-15-2020 09:49:04 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 5	Initial Entry

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

Date	Location	User	Value	Reason
Dec-15-2020 09:49:04 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Charlie Chao (b) (4)	<b>Data Entry:</b> Urticaria, No Known Triggers	Initial Entry

***I.e Start Date:***

Date	Location	User	Value	Reason
Dec-15-2020 09:49:04 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Charlie Chao (b) (4)	<b>Data Entry:</b> Oct/7/2010	Initial Entry

***I.e Ongoing:***

Date	Location	User	Value	Reason
Dec-15-2020 09:49:04 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Charlie Chao (b) (4)	<b>Data Entry:</b> YES	Initial Entry

***I.f***

Date	Location	User	Value	Reason
Dec-15-2020 09:49:21 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Line/MH Num</b> 6 <b>ber:</b> <b>Medical Histor</b> Allergy to Bee <b>y Term:</b> Venom <b>Start Date:</b> Oct/7/2010	Initial Entry

**Header Text:** c4591001**Visit:** V1\_DAY1\_VAX1\_L**Form Version:** 22-Apr-2020 21:03**Site No:** 1126**Subject No:** 11261268**Generated By:** (b) (4)**Form:** GENERAL MEDICAL HISTORY - eCRF Audit Trail History**Form Status:** Data Complete, Frozen, Verified**Site Name:** (1126) Kaiser Permanente Santa Clara**Subject Initials:** ---**Generated Time (GMT):** 06-Apr-2021 15:36**Ongoing:** YES**I.f Line/MH Number:**

Date	Location	User	Value	Reason
Dec-15-2020 09:49:21 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 6	Initial Entry

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

Date	Location	User	Value	Reason
Dec-15-2020 09:49:21 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Charlie Chao (b) (4)	<b>Data Entry:</b> Allergy to Bee Venom	Initial Entry

**I.f Start Date:**

Date	Location	User	Value	Reason
Dec-15-2020 09:49:21 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Charlie Chao (b) (4)	<b>Data Entry:</b> Oct/7/2010	Initial Entry

**I.f Ongoing:**

Date	Location	User	Value	Reason
Dec-15-2020 09:49:21 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Charlie Chao (b) (4)	<b>Data Entry:</b> YES	Initial Entry

**I.g**

Date	Location	User	Value	Reason
Dec-16-2020 09:34:31 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Line/MH Number 7</b> : <b>Medical History T Premenarc</b> <b>erm:</b> hal	Initial Entry



**Header Text:** c4591001**Visit:** V1\_DAY1\_VAX1\_L**Form Version:** 22-Apr-2020 21:03**Site No:** 1126**Subject No:** 11261268**Generated By:** (b) (4)**Form:** GENERAL MEDICAL HISTORY - eCRF Audit Trail History**Form Status:** Data Complete, Frozen, Verified**Site Name:** (1126) Kaiser Permanente Santa Clara**Subject Initials:** ---**Generated Time (GMT):** 06-Apr-2021 15:36

			<b>Start Date:</b>	May/27/2007	
			<b>Ongoing:</b>	YES	

***1.g Line/MH Number:***

Date	Location	User	Value	Reason
Dec-16-2020 09:34:31 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 7	Initial Entry

***1.g Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:***

Date	Location	User	Value	Reason
Dec-16-2020 09:34:31 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Premenarchal	Initial Entry

***1.g Start Date:***

Date	Location	User	Value	Reason
Dec-16-2020 09:34:31 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> (b) (6) 2007	Initial Entry

***1.g Ongoing:***

Date	Location	User	Value	Reason
Dec-16-2020 09:34:31 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

**Header Text:** c4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form Version:** 15-Sep-2020 21:57

**Site No:** 1126

**Subject No:** 11261268

**Generated By:** (b) (4)

**Form:** HIV STATUS - eCRF Audit Trail History

**Form Status:** Data Complete, Frozen, Verified

**Site Name:** (1126) Kaiser Permanente Santa Clara

**Subject Initials:** ---

**Generated Time (GMT):** 06-Apr-2021 15:36

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

Date	Location	User	Value	Reason
Dec-15-2020 09:49:40 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Charlie Chao (b) (4)	<b>Data Entry:</b> The subject is NOT known to b e HIV POSITIVE	Initial Entry

**Header Text:** c4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form Version:** 10-Dec-2020 02:29

**Site No:** 1126

**Subject No:** 11261268

**Generated By:** (b) (4)

**Form:** VITAL SIGNS - BASELINE - eCRF Audit Trail History

**Form Status:** Data Complete, Frozen, Verified

**Site Name:** (1126) Kaiser Permanente Santa Clara

**Subject Initials:** ---

**Generated Time (GMT):** 06-Apr-2021 15:36

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**1. Date:**

Date	Location	User	Value	Reason
Dec-15-2020 09:50:04 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Charlie Chao (b) (4)	<b>Data Entry:</b> Dec/14/2020	Initial Entry

**2. Weight:**

Date	Location	User	Value	Reason
Dec-15-2020 09:50:04 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Charlie Chao (b) (4)	<b>Data Entry:</b> 33.0	Initial Entry

**3. Unit:**

Date	Location	User	Value	Reason
Dec-15-2020 09:50:04 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Charlie Chao (b) (4)	<b>Data Entry:</b> kg	Initial Entry

**4. Height:**

Date	Location	User	Value	Reason
Dec-15-2020 09:50:04 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Charlie Chao (b) (4)	<b>Data Entry:</b> 140.6	Initial Entry

**5. Unit:**

Date	Location	User	Value	Reason
Dec-15-2020 09:50:04 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Charlie Chao (b) (4)	<b>Data Entry:</b> cm	Initial Entry

**6. Body Mass Index:**

Date	Location	User	Value	Reason
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090177e196b72785\Final\Final On: 06-Apr-2021 19:12 (GMT)

**Header Text:** c4591001**Visit:** V1\_DAY1\_VAX1\_L**Form Version:** 10-Dec-2020 02:29**Site No:** 1126**Subject No:** 11261268**Generated By:** (b) (4)**Form:** VITAL SIGNS - BASELINE - eCRF Audit Trail History**Form Status:** Data Complete, Frozen, Verified**Site Name:** (1126) Kaiser Permanente Santa Clara**Subject Initials:** ---**Generated Time (GMT):** 06-Apr-2021 15:36

Dec-15-2020 09:50:04 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 16.7	Initial Entry
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**7.a**

Date	Location	User	Value	Reason
Dec-15-2020 09:50:04 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Charlie Chao (b) (4)	<b>Data Entry:</b> <b>Record Identifier:</b> 1 <b>Temperature:</b> 96.6 <b>Temperature Unit:</b> <b>Temperature Location:</b> ORAL CAVITY	Initial Entry

**7.a Record Identifier:**

Date	Location	User	Value	Reason
Dec-15-2020 09:50:04 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Charlie Chao (b) (4)	<b>Data Entry:</b> 1	Initial Entry

**7.a Temperature:**

Date	Location	User	Value	Reason
Dec-16-2020 22:46:51 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Closed as per site response.
Dec-16-2020 09:35:18 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	TEMPERATURE CORRECT AS RECORDED - NOT SIGNIFICANT
Dec-15-2020 09:50:04 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	Temperature 96.6 F is outside of Normal Range 97 - 99.5 F.

**Header Text:** c4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form Version:** 10-Dec-2020 02:29

**Site No:** 1126

**Subject No:** 11261268

**Generated By:** (b) (4)

**Form:** VITAL SIGNS - BASELINE - eCRF Audit Trail History

**Form Status:** Data Complete, Frozen, Verified

**Site Name:** (1126) Kaiser Permanente Santa Clara

**Subject Initials:** ---

**Generated Time (GMT):** 06-Apr-2021 15:36

Dec-15-2020 09:50:04 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Charlie Chao (b) (4)	<b>Data Entry:</b> 96.6	Initial Entry
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**7.a Unit:**

Date	Location	User	Value	Reason
Dec-15-2020 09:50:04 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Charlie Chao (b) (4)	<b>Data Entry:</b> F	Initial Entry

**7.a Temperature Location:**

Date	Location	User	Value	Reason
Dec-15-2020 09:50:04 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Charlie Chao (b) (4)	<b>Data Entry:</b> ORAL CAVITY	Initial Entry

090177e196b72785\Final\Final On: 06-Apr-2021 19:12 (GMT)

**Header Text:** c4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form Version:** 10-Dec-2020 02:23

**Site No:** 1126

**Subject No:** 11261268

**Generated By:** (b) (4)

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

**Form Status:** Data Complete, Frozen, Verified

**Site Name:** (1126) Kaiser Permanente Santa Clara

**Subject Initials:** ---

**Generated Time (GMT):** 06-Apr-2021 15:36

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**1. Lab Panel:**

Date	Location	User	Value	Reason
Dec-15-2020 09:50:31 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Charlie Chao (b) (4)	<b>Data Entry:</b> Not Applicable	Initial Entry

**2. Lab Sub-Panel:**

Date	Location	User	Value	Reason
Dec-15-2020 09:50:31 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Charlie Chao (b) (4)	<b>Data Entry:</b> Not Applicable	Initial Entry

**3. Collection Date:**

Date	Location	User	Value	Reason
Dec-16-2020 12:22:35 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	MH updated
Dec-16-2020 09:34:49 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	DONE
Dec-16-2020 07:52:26 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	CLINQUERY - Preg test reported as NOT APPLICABLE. Test is required of all females. If subject is Premenarchal, please add condition to MH page; otherwise explain.

090177e196b72785\Final\Final On: 06-Apr-2021 19:12 (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:** 1126**Site Name:** (1126) Kaiser Permanente Santa Clara**Subject No:** 11261268**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 06-Apr-2021 15:36

Dec-15-2020 09:50:31 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Charlie Chao (b) (4)	<b>Data Entry:</b> Not Applicable	Initial Entry
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**4. Laboratory Name and Address (Derived)**

Date	Location	User	Value	Reason
Dec-15-2020 09:50:31 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Charlie Chao (b) (4)	<b>Data Entry:</b> Not Applicable	Initial Entry

**5. Specimen Type:**

Date	Location	User	Value	Reason
Dec-15-2020 09:50:31 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Charlie Chao (b) (4)	<b>Data Entry:</b> Not Applicable	Initial Entry

**6.a**

Date	Location	User	Value	Reason
Dec-15-2020 09:50:31 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Charlie Chao (b) (4)	<b>Data Entry:</b> <b>Sponsor-Defined I</b> Not Appli <b>dentifier:</b> cable <b>Test::</b> Not Appli cable <b>Result::</b> Not Appli cable <b>Not Done::</b> Not Appli cable	Initial Entry

**6.a Sponsor ID:**

Date	Location	User	Value	Reason
Dec-15-2020 09:50:31 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Charlie Chao (b) (4)	<b>Data Entry:</b> Not Applicable	Initial Entry

**6.a Test:**

**Header Text:** c4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form Version:** 10-Dec-2020 02:23

**Site No:** 1126

**Subject No:** 11261268

**Generated By:** (b) (4)

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

**Form Status:** Data Complete, Frozen, Verified

**Site Name:** (1126) Kaiser Permanente Santa Clara

**Subject Initials:** ---

**Generated Time (GMT):** 06-Apr-2021 15:36

Date	Location	User	Value	Reason
Dec-15-2020 09:50:31 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Charlie Chao (b) (4)	<b>Data Entry:</b> Not Applicable	Initial Entry

**6.a Result:**

Date	Location	User	Value	Reason
Dec-15-2020 09:50:31 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Charlie Chao (b) (4)	<b>Data Entry:</b> Not Applicable	Initial Entry

**6.a Not Done:**

Date	Location	User	Value	Reason
Dec-15-2020 09:50:31 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Charlie Chao (b) (4)	<b>Data Entry:</b> Not Applicable	Initial Entry

090177e196b72785\Final\Final On: 06-Apr-2021 19:12 (GMT)



**Header Text:** c4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1126

**Subject No:** 11261268

**Generated By:** (b) (4)

**Form:** RANDOMIZATION - eCRF Audit Trail History

**Form Status:** Data Complete, Frozen, Verified

**Site Name:** (1126) Kaiser Permanente Santa Clara

**Subject Initials:** ---

**Generated Time (GMT):** 06-Apr-2021 15:36

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**1. Randomization Date :**

Date	Location	User	Value	Reason
Dec-15-2020 09:50:55 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Charlie Chao (b) (4)	<b>Data Entry:</b> Dec/14/2020	Initial Entry

**2. Randomization Number:**

Date	Location	User	Value	Reason
Dec-15-2020 09:50:55 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Charlie Chao (b) (4)	<b>Data Entry:</b> 22343	Initial Entry

090177e196b72785\Final\Final On: 06-Apr-2021 19:12 (GMT)

**Header Text:** c4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1126

**Subject No:** 11261268

**Generated By:** (b) (4)

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

**Form Status:** Data Complete, Frozen, Verified

**Site Name:** (1126) Kaiser Permanente Santa Clara

**Subject Initials:** ---

**Generated Time (GMT):** 06-Apr-2021 15:36

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**1. Data Origin**

Date	Location	User	Value	Reason
Dec-15-2020 09:51:06 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SITE	Initial Entry

**2. Sample Type**

Date	Location	User	Value	Reason
Dec-15-2020 09:51:06 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SERUM	Initial Entry

**3. Sample Collected?**

Date	Location	User	Value	Reason
Dec-15-2020 09:51:15 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Dec-15-2020 09:51:06 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Dec-15-2020 09:51:06 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Charlie Chao (b) (4)	<b>Data Entry:</b> YES Date of Collection:  Dec/14/2020	Initial Entry

**5.a**

Date	Location	User	Value	Reason
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090177e196b72785\Final\Final On: 06-Apr-2021 19:12 (GMT)

**Header Text:** c4591001**Visit:** V1\_DAY1\_VAX1\_L**Form:** ELECTRONIC SAMPLE TRACKING -  
IMMUNOGENICITY - eCRF Audit Trail History**Form Version:** 22-Apr-2020 21:03**Form Status:** Data Complete, Frozen, Verified**Site No:** 1126**Site Name:** (1126) Kaiser Permanente Santa Clara**Subject No:** 11261268**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 06-Apr-2021 15:36

Dec-15-2020 09:51:15 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Charlie Chao (b) (4)	<b>Data Entry:</b> <b>Sample ID:</b> BPZZ2L	Initial Entry
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**5.a Sample ID**

Date	Location	User	Value	Reason
Dec-15-2020 09:51:15 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Charlie Chao (b) (4)	<b>Data Entry:</b> BPZZ2L	Initial Entry

**5.b**

Date	Location	User	Value	Reason
Dec-15-2020 09:51:24 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Charlie Chao (b) (4)	<b>Data Entry:</b> <b>Sample ID:</b> BPZZ2M	Initial Entry

**5.b Sample ID**

Date	Location	User	Value	Reason
Dec-15-2020 09:51:24 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Charlie Chao (b) (4)	<b>Data Entry:</b> BPZZ2M	Initial Entry

**5.c**

Date	Location	User	Value	Reason
Dec-15-2020 09:51:32 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Charlie Chao (b) (4)	<b>Data Entry:</b> <b>Sample ID:</b> BS7VG6	Initial Entry

**5.c Sample ID**

Date	Location	User	Value	Reason
Dec-15-2020 09:51:32 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Charlie Chao (b) (4)	<b>Data Entry:</b> BS7VG6	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:** 1126**Site Name:** (1126) Kaiser Permanente Santa Clara**Subject No:** 11261268**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 06-Apr-2021 15:36[Back to Form](#)**1. Data Origin**

Date	Location	User	Value	Reason
Dec-15-2020 09:51:46 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SITE	Initial Entry

**2. Sample Type**

Date	Location	User	Value	Reason
Dec-15-2020 09:51:46 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> NASAL_SWAB	Initial Entry

**3. Sample Collected?**

Date	Location	User	Value	Reason
Dec-15-2020 09:52:50 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Dec-15-2020 09:51:46 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Dec-15-2020 09:51:46 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Charlie Chao (b) (4)	<b>Data Entry:</b> YES Date of Collection:  Dec/14/2020	Initial Entry

**5.a**

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:** 1126

**Subject No:** 11261268

**Generated By:** (b) (4)

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

**Form Status:** Data Complete, Frozen, Verified

**Site Name:** (1126) Kaiser Permanente Santa Clara

**Subject Initials:** ---

**Generated Time (GMT):** 06-Apr-2021 15:36

Dec-15-2020 09:52:50 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Charlie Chao (b) (4)	<b>Data Entry:</b> <b>Sample ID:</b> BP28ZG	Initial Entry
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**5.a Sample ID**

Date	Location	User	Value	Reason
Dec-15-2020 09:52:50 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Charlie Chao (b) (4)	<b>Data Entry:</b> BP28ZG	Initial Entry

090177e196b72785\Final\Final On: 06-Apr-2021 19:12 (GMT)

**Header Text:** c4591001**Visit:** V1\_DAY1\_VAX1\_L**Form Version:** 10-Dec-2020 02:26**Site No:** 1126**Subject No:** 11261268**Generated By:** (b) (4)**Form:** VACCINATION - eCRF Audit Trail History**Form Status:** Data Complete, Frozen, Verified**Site Name:** (1126) Kaiser Permanente Santa Clara**Subject Initials:** ---**Generated Time (GMT):** 06-Apr-2021 15:36[Back to Form](#)**1. Was there a temporary delay of vaccination?**

Date	Location	User	Value	Reason
Dec-15-2020 09:53:18 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Charlie Chao (b) (4)	<b>Data Entry:</b> NO	Initial Entry

**2. Treatment Name**

Date	Location	User	Value	Reason
Dec-15-2020 09:53:18 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> BLINDED THERAPY	Initial Entry

**3. Formulation:**

Date	Location	User	Value	Reason
Dec-15-2020 09:53:18 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> INJECTION	Initial Entry

**4. Dose Date Time:**

Date	Location	User	Value	Reason
Dec-15-2020 09:53:18 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Charlie Chao (b) (4)	<b>Data Entry:</b> Dec/14/2020 11:08	Initial Entry

**5. Anatomical Location:**

Date	Location	User	Value	Reason
Dec-15-2020 09:53:18 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> DELTOID MUSCLE	Initial Entry

**6. Body Side:**

Date	Location	User	Value	Reason
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**Header Text:** c4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form Version:** 10-Dec-2020 02:26

**Site No:** 1126

**Subject No:** 11261268

**Generated By:** (b) (4)

**Form:** VACCINATION - eCRF Audit Trail History

**Form Status:** Data Complete, Frozen, Verified

**Site Name:** (1126) Kaiser Permanente Santa Clara

**Subject Initials:** ---

**Generated Time (GMT):** 06-Apr-2021 15:36

Dec-15-2020 09:53:18  
(UTC-08:00) Pacific  
Time (US & Canada)

ACV0PFEINFP6000

Charlie  
Chao  
(b) (4)

**Data Entry:**  
LEFT

Initial Entry

**7. Route:**

Date	Location	User	Value	Reason
Dec-15-2020 09:53:18 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> INTRAMUSCULAR	Initial Entry

**10. Timeframe Subject Was Observed**

Date	Location	User	Value	Reason
Dec-15-2020 09:53:18 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 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-15-2020 09:53:18 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Charlie Chao (b) (4)	<b>Data Entry:</b> YES	Initial Entry

090177e196b72785\Final\Final On: 06-Apr-2021 19:12 (GMT)

**Header Text:** c4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form Version:** 06-Jul-2020 21:53

**Site No:** 1126

**Subject No:** 11261268

**Generated By:** (b) (4)

**Form:** REACTOGENICITY DIARY - eCRF Audit Trail History

**Form Status:** Data Complete, Frozen, Verified

**Site Name:** (1126) Kaiser Permanente Santa Clara

**Subject Initials:** ---

**Generated Time (GMT):** 06-Apr-2021 15:36

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***1. Select appropriate response - Reactogenicity diary collection***

Date	Location	User	Value	Reason
Dec-15-2020 09:53:26 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Charlie Chao (b) (4)	<b>Data Entry:</b> YES - REACTOGENICITY E- DIARY COLLECTED FOR T HIS SUBJECT	Initial Entry



**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

**Form Version:** 22-Apr-2020 21:02

**Site No:** 1126

**Subject No:** 11261268

**Generated By:** (b) (4)

**Form:** DATE OF VISIT - eCRF Audit Trail History

**Form Status:** Data Complete, Frozen, Verified

**Site Name:** (1126) Kaiser Permanente Santa Clara

**Subject Initials:** ---

**Generated Time (GMT):** 06-Apr-2021 15:36

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*I. Date of Visit*

Date	Location	User	Value	Reason
Jan-07-2021 08:38:09 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Charlie Chao (b) (4)	<b>Data Entry:</b> Jan/5/2021	Initial Entry

090177e196b72785\Final\Final On: 06-Apr-2021 19:12 (GMT)

**Header Text:** c4591001**Visit:** V2\_VAX2\_L**Form Version:** 10-Dec-2020 02:30**Site No:** 1126**Subject No:** 11261268**Generated By:** (b) (4)**Form:** VACCINATION SYMPTOMS DIARY - SYMPTOM  
RESOLVED DATES - eCRF Audit Trail History**Form Status:** Data Complete, Frozen, Verified**Site Name:** (1126) Kaiser Permanente Santa Clara**Subject Initials:** ---**Generated Time (GMT):** 06-Apr-2021 15:36[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
Jan-07-2021 08:38:31 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Charlie Chao (b) (4)	<b>Data Entry:</b> NO	Initial Entry

**2.a**

Date	Location	User	Value	Reason
Jan-07-2021 08:38:31 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Charlie Chao (b) (4)	<b>Data Entry:</b> <b>Symptom::</b> FE VE R  Were fever or systemic s N ymptoms present on the l O ast day the Subject Diary was completed?:	Initial Entry

**2.a Symptom:**

Date	Location	User	Value	Reason
Jan-07-2021 08:38:31 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Charlie Chao (b) (4)	<b>Data Entry:</b> 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-07-2021 08:38:31 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Charlie Chao (b) (4)	<b>Data Entry:</b> NO	Initial Entry

**2.b**

Date	Location	User	Value	Reason
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**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

**Form Version:** 10-Dec-2020 02:30

**Site No:** 1126

**Subject No:** 11261268

**Generated By:** (b) (4)

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

**Form Status:** Data Complete, Frozen, Verified

**Site Name:** (1126) Kaiser Permanente Santa Clara

**Subject Initials:** ---

**Generated Time (GMT):** 06-Apr-2021 15:36

Jan-07-2021 08:38:31 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Charlie Chao (b) (4)	<b>Data Entry:</b> <b>Symptom::</b> FA TI GU E  <b>Were fever or systemic s NO ymptoms present on the last day the Subject Diar y was completed?:</b>	Initial Entry
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**2.b Symptom:**

Date	Location	User	Value	Reason
Jan-07-2021 08:38:31 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Charlie Chao (b) (4)	<b>Data Entry:</b> 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-07-2021 08:38:31 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Charlie Chao (b) (4)	<b>Data Entry:</b> NO	Initial Entry

**2.c**

Date	Location	User	Value	Reason
Jan-07-2021 08:38:31 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Charlie Chao (b) (4)	<b>Data Entry:</b> <b>Symptom::</b> HE AD AC HE  <b>Were fever or systemic NO symptoms present on th e last day the Subject D iary was completed?:</b>	Initial Entry

090177e196b72785\Final\Final On: 06-Apr-2021 19:12 (GMT)

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

**Form Version:** 10-Dec-2020 02:30

**Site No:** 1126

**Subject No:** 11261268

**Generated By:** (b) (4)

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

**Form Status:** Data Complete, Frozen, Verified

**Site Name:** (1126) Kaiser Permanente Santa Clara

**Subject Initials:** ---

**Generated Time (GMT):** 06-Apr-2021 15:36

**2.c Symptom:**

Date	Location	User	Value	Reason
Jan-07-2021 08:38:31 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Charlie Chao (b) (4)	<b>Data Entry:</b> 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-07-2021 08:38:31 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Charlie Chao (b) (4)	<b>Data Entry:</b> NO	Initial Entry

**2.d**

Date	Location	User	Value	Reason
Jan-07-2021 08:38:31 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Charlie Chao (b) (4)	<b>Data Entry:</b> <b>Symptom::</b> CH IL LS  Were fever or systemic s N ymptoms present on the O last day the Subject Diar y was completed?:	Initial Entry

**2.d Symptom:**

Date	Location	User	Value	Reason
Jan-07-2021 08:38:31 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Charlie Chao (b) (4)	<b>Data Entry:</b> 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-07-2021 08:38:31 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Charlie Chao (b) (4)	<b>Data Entry:</b> NO	Initial Entry

090177e196b72785\Final\Final On: 06-Apr-2021 19:12 (GMT)

**Header Text:** c4591001**Visit:** V2\_VAX2\_L**Form Version:** 10-Dec-2020 02:30**Site No:** 1126**Subject No:** 11261268**Generated By:** (b) (4)**Form:** VACCINATION SYMPTOMS DIARY - SYMPTOM  
RESOLVED DATES - eCRF Audit Trail History**Form Status:** Data Complete, Frozen, Verified**Site Name:** (1126) Kaiser Permanente Santa Clara**Subject Initials:** ---**Generated Time (GMT):** 06-Apr-2021 15:36**2.e**

Date	Location	User	Value	Reason
Jan-07-2021 08:38:31 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Charlie Chao (b) (4)	<b>Data Entry:</b> <b>Symptom::</b> VO MIT ING  <b>Were fever or systemic symptoms present on th e last day the Subject D iary was completed?:</b> NO	Initial Entry

**2.e Symptom:**

Date	Location	User	Value	Reason
Jan-07-2021 08:38:31 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Charlie Chao (b) (4)	<b>Data Entry:</b> 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-07-2021 08:38:31 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Charlie Chao (b) (4)	<b>Data Entry:</b> NO	Initial Entry

**2.f**

Date	Location	User	Value	Reason
Jan-07-2021 08:38:31 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Charlie Chao (b) (4)	<b>Data Entry:</b> <b>Symptom::</b> DIA RR HE A  <b>Were fever or systemic s NO ymptoms present on the last day the Subject Dia ry was completed?:</b>	Initial Entry

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

**Form Version:** 10-Dec-2020 02:30

**Site No:** 1126

**Subject No:** 11261268

**Generated By:** (b) (4)

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

**Form Status:** Data Complete, Frozen, Verified

**Site Name:** (1126) Kaiser Permanente Santa Clara

**Subject Initials:** ---

**Generated Time (GMT):** 06-Apr-2021 15:36

**2.f Symptom:**

Date	Location	User	Value	Reason
Jan-07-2021 08:38:31 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Charlie Chao (b) (4)	<b>Data Entry:</b> 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-07-2021 08:38:31 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Charlie Chao (b) (4)	<b>Data Entry:</b> NO	Initial Entry

**2.g**

Date	Location	User	Value	Reason
Jan-07-2021 08:38:31 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Charlie Chao (b) (4)	<b>Data Entry:</b> <b>Symptom::</b> NEW OR WORSE NED MU SCLE PA IN  <b>Were fever or syste NO mic symptoms pres ent on the last day the Subject Diary was completed?:</b>	Initial Entry

090177e196b72785\Final\Final On: 06-Apr-2021 19:12 (GMT)

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

**Form Version:** 10-Dec-2020 02:30

**Site No:** 1126

**Subject No:** 11261268

**Generated By:** (b) (4)

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

**Form Status:** Data Complete, Frozen, Verified

**Site Name:** (1126) Kaiser Permanente Santa Clara

**Subject Initials:** ---

**Generated Time (GMT):** 06-Apr-2021 15:36

**2.g Symptom:**

Date	Location	User	Value	Reason
Jan-07-2021 08:38:31 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Charlie Chao (b) (4)	<b>Data Entry:</b> NEW OR WORSENER MUSC LE 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-07-2021 08:38:31 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Charlie Chao (b) (4)	<b>Data Entry:</b> NO	Initial Entry

**2.h**

Date	Location	User	Value	Reason
Jan-07-2021 08:38:31 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Charlie Chao (b) (4)	<b>Data Entry:</b> <b>Symptom::</b> NEW O R WOR SENER JOINT P AIN  <b>Were fever or syste NO mic symptoms pres ent on the last day t he Subject Diary w as completed?:</b>	Initial Entry

090177e196b72785\Final\On: 06-Apr-2021 19:12 (GMT)

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

**Form Version:** 10-Dec-2020 02:30

**Site No:** 1126

**Subject No:** 11261268

**Generated By:** (b) (4)

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

**Form Status:** Data Complete, Frozen, Verified

**Site Name:** (1126) Kaiser Permanente Santa Clara

**Subject Initials:** ---

**Generated Time (GMT):** 06-Apr-2021 15:36

**2.h Symptom:**

Date	Location	User	Value	Reason
Jan-07-2021 08:38:31 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Charlie Chao (b) (4)	<b>Data Entry:</b> NEW OR WORSENERD 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
Jan-07-2021 08:38:31 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Charlie Chao (b) (4)	<b>Data Entry:</b> NO	Initial Entry

**3. Injection Site Location:**

Date	Location	User	Value	Reason
Jan-07-2021 08:38:31 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> DELTOID MUSCLE	Initial Entry

**4. Injection Site Body Side:**

Date	Location	User	Value	Reason
Jan-07-2021 08:38:31 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Charlie Chao (b) (4)	<b>Data Entry:</b> LEFT	Initial Entry

**5.a**

Date	Location	User	Value	Reason
Jan-07-2021 08:38:31 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Charlie Chao (b) (4)	<b>Data Entry:</b> <b>Injection Site Reaction::</b> RE DN ES S	Initial Entry



**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

**Form Version:** 10-Dec-2020 02:30

**Site No:** 1126

**Subject No:** 11261268

**Generated By:** (b) (4)

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

**Form Status:** Data Complete, Frozen, Verified

**Site Name:** (1126) Kaiser Permanente Santa Clara

**Subject Initials:** ---

**Generated Time (GMT):** 06-Apr-2021 15:36

			Were injection site react NO ions present on the last day the Subject Diary w as completed?:	
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**5.a Injection Site Reaction:**

Date	Location	User	Value	Reason
Jan-07-2021 08:38:31 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Charlie Chao (b) (4)	<b>Data Entry:</b> 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-07-2021 08:38:31 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Charlie Chao (b) (4)	<b>Data Entry:</b> NO	Initial Entry

**5.b**

Date	Location	User	Value	Reason
Jan-07-2021 08:38:31 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Charlie Chao (b) (4)	<b>Data Entry:</b> <b>Injection Site Reaction:</b> SW : ELL ING  <b>Were injection site reac NO tions present on the last day the Subject Diary was completed?:</b>	Initial Entry

090177e196b72785\Final\Final On: 06-Apr-2021 19:12 (GMT)

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

**Form Version:** 10-Dec-2020 02:30

**Site No:** 1126

**Subject No:** 11261268

**Generated By:** (b) (4)

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

**Form Status:** Data Complete, Frozen, Verified

**Site Name:** (1126) Kaiser Permanente Santa Clara

**Subject Initials:** ---

**Generated Time (GMT):** 06-Apr-2021 15:36

**5.b Injection Site Reaction:**

Date	Location	User	Value	Reason
Jan-07-2021 08:38:31 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Charlie Chao (b) (4)	<b>Data Entry:</b> 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-07-2021 08:38:31 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Charlie Chao (b) (4)	<b>Data Entry:</b> NO	Initial Entry

**5.c**

Date	Location	User	Value	Reason
Jan-07-2021 08:38:31 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Charlie Chao (b) (4)	<b>Data Entry:</b> <b>Injection Site Reaction:</b> PAIN AT INJECTION SITE  <b>Were injection site reactions present on the last day the Subject Diary was completed?:</b> NO	Initial Entry

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

**Form Version:** 10-Dec-2020 02:30

**Site No:** 1126

**Subject No:** 11261268

**Generated By:** (b) (4)

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

**Form Status:** Data Complete, Frozen, Verified

**Site Name:** (1126) Kaiser Permanente Santa Clara

**Subject Initials:** ---

**Generated Time (GMT):** 06-Apr-2021 15:36

**5.c Injection Site Reaction:**

Date	Location	User	Value	Reason
Jan-07-2021 08:38:31 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Charlie Chao (b) (4)	<b>Data Entry:</b> 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
Jan-07-2021 08:38:31 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Charlie Chao (b) (4)	<b>Data Entry:</b> NO	Initial Entry

090177e196b72785\Final\Final On: 06-Apr-2021 19:12 (GMT)

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

**Form Version:** 10-Dec-2020 02:27

**Site No:** 1126

**Subject No:** 11261268

**Generated By:** (b) (4)

**Form:** VITAL SIGNS - TEMP - eCRF Audit Trail History

**Form Status:** Data Complete, Frozen, Verified

**Site Name:** (1126) Kaiser Permanente Santa Clara

**Subject Initials:** ---

**Generated Time (GMT):** 06-Apr-2021 15:36

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**1. Date:**

Date	Location	User	Value	Reason
Jan-07-2021 08:38:56 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Charlie Chao (b) (4)	<b>Data Entry:</b> Jan/5/2021	Initial Entry

**2.a**

Date	Location	User	Value	Reason
Jan-07-2021 08:38:56 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Charlie Chao (b) (4)	<b>Data Entry:</b> <b>Record Identifier:</b> 1 <b>Temperature:</b> 98.9 <b>Temperature Unit:</b> <b>Temperature Location:</b> ORAL CAVITY	Initial Entry

**2.a Record Identifier:**

Date	Location	User	Value	Reason
Jan-07-2021 08:38:56 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Charlie Chao (b) (4)	<b>Data Entry:</b> 1	Initial Entry

**2.a Temperature:**

Date	Location	User	Value	Reason
Jan-07-2021 08:38:56 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Charlie Chao (b) (4)	<b>Data Entry:</b> 98.9	Initial Entry

**2.a Unit:**

Date	Location	User	Value	Reason
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090177e196b72785\Final\Final On: 06-Apr-2021 19:12 (GMT)

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

**Form Version:** 10-Dec-2020 02:27

**Site No:** 1126

**Subject No:** 11261268

**Generated By:** (b) (4)

**Form:** VITAL SIGNS - TEMP - eCRF Audit Trail History

**Form Status:** Data Complete, Frozen, Verified

**Site Name:** (1126) Kaiser Permanente Santa Clara

**Subject Initials:** ---

**Generated Time (GMT):** 06-Apr-2021 15:36

Jan-07-2021 08:38:56  
(UTC-08:00) Pacific  
Time (US & Canada)

ACV0PFEINFP6000

Charlie  
Chao  
(b) (4)

**Data Entry:**  
F

Initial Entry

**2.a Temperature Location:**

**Date**

**Location**

**User**

**Value**

**Reason**

Jan-07-2021 08:38:56  
(UTC-08:00) Pacific  
Time (US & Canada)

ACV0PFEINFP6000

Charlie  
Chao  
(b) (4)

**Data Entry:**  
ORAL CAVITY

Initial Entry

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

**Form Version:** 10-Dec-2020 02:23

**Site No:** 1126

**Subject No:** 11261268

**Generated By:** (b) (4)

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

**Form Status:** Data Complete, Frozen, Verified

**Site Name:** (1126) Kaiser Permanente Santa Clara

**Subject Initials:** ---

**Generated Time (GMT):** 06-Apr-2021 15:36

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**1. Lab Panel:**

Date	Location	User	Value	Reason
Jan-07-2021 08:39:34 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Charlie Chao (b) (4)	<b>Data Entry:</b> Not Applicable	Initial Entry

**2. Lab Sub-Panel:**

Date	Location	User	Value	Reason
Jan-07-2021 08:39:34 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Charlie Chao (b) (4)	<b>Data Entry:</b> Not Applicable	Initial Entry

**3. Collection Date:**

Date	Location	User	Value	Reason
Jan-07-2021 08:39:34 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Charlie Chao (b) (4)	<b>Data Entry:</b> Not Applicable	Initial Entry

**4. Laboratory Name and Address (Derived)**

Date	Location	User	Value	Reason
Jan-07-2021 08:39:34 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Charlie Chao (b) (4)	<b>Data Entry:</b> Not Applicable	Initial Entry

**5. Specimen Type:**

Date	Location	User	Value	Reason
Jan-07-2021 08:39:34 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Charlie Chao (b) (4)	<b>Data Entry:</b> Not Applicable	Initial Entry

**6.a**

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**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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**Site No:** 1126

**Subject No:** 11261268

**Generated By:** (b) (4)

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

**Form Status:** Data Complete, Frozen, Verified

**Site Name:** (1126) Kaiser Permanente Santa Clara

**Subject Initials:** ---

**Generated Time (GMT):** 06-Apr-2021 15:36

Date	Location	User	Value	Reason
Jan-07-2021 08:39:34 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Charlie Chao (b) (4)	<b>Data Entry:</b> <b>Sponsor-Defined I</b> Not Appli <b>dentifier:</b> cable <b>Test::</b> Not Appli cable <b>Result::</b> Not Appli cable <b>Not Done::</b> Not Appli cable	Initial Entry

**6.a Sponsor ID:**

Date	Location	User	Value	Reason
Jan-07-2021 08:39:34 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Charlie Chao (b) (4)	<b>Data Entry:</b> Not Applicable	Initial Entry

**6.a Test:**

Date	Location	User	Value	Reason
Jan-07-2021 08:39:34 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Charlie Chao (b) (4)	<b>Data Entry:</b> Not Applicable	Initial Entry

**6.a Result:**

Date	Location	User	Value	Reason
Jan-07-2021 08:39:34 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Charlie Chao (b) (4)	<b>Data Entry:</b> Not Applicable	Initial Entry

**6.a Not Done:**

Date	Location	User	Value	Reason
Jan-07-2021 08:39:34 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Charlie Chao (b) (4)	<b>Data Entry:</b> Not Applicable	Initial Entry

090177e196b72785\Final\Final On: 06-Apr-2021 19:12 (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:** 1126**Site Name:** (1126) Kaiser Permanente Santa Clara**Subject No:** 11261268**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 06-Apr-2021 15:36[Back to Form](#)**1. Data Origin**

Date	Location	User	Value	Reason
Jan-07-2021 08:39:54 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SITE	Initial Entry

**2. Sample Type**

Date	Location	User	Value	Reason
Jan-07-2021 08:39:54 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> NASAL_SWAB	Initial Entry

**3. Sample Collected?**

Date	Location	User	Value	Reason
Jan-07-2021 08:40:03 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Jan-07-2021 08:39:54 (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.
Jan-07-2021 08:39:54 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Charlie Chao (b) (4)	<b>Data Entry:</b> YES Date of Collection:  Jan/5/2021	Initial Entry

**5.a**

Date	Location	User	Value	Reason
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**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1126

**Subject No:** 11261268

**Generated By:** (b) (4)

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

**Form Status:** Data Complete, Frozen, Verified

**Site Name:** (1126) Kaiser Permanente Santa Clara

**Subject Initials:** ---

**Generated Time (GMT):** 06-Apr-2021 15:36

Jan-07-2021 08:40:03 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Charlie Chao (b) (4)	<b>Data Entry:</b> <b>Sample ID:</b> BP293X	Initial Entry
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**5.a Sample ID**

Date	Location	User	Value	Reason
Jan-07-2021 08:40:03 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Charlie Chao (b) (4)	<b>Data Entry:</b> BP293X	Initial Entry

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**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

**Form Version:** 10-Dec-2020 02:26

**Site No:** 1126

**Subject No:** 11261268

**Generated By:** (b) (4)

**Form:** VACCINATION - eCRF Audit Trail History

**Form Status:** Data Complete, Frozen, Verified

**Site Name:** (1126) Kaiser Permanente Santa Clara

**Subject Initials:** ---

**Generated Time (GMT):** 06-Apr-2021 15:36

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**1. Was there a temporary delay of vaccination?**

Date	Location	User	Value	Reason
Jan-07-2021 08:40:27 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Charlie Chao (b) (4)	<b>Data Entry:</b> NO	Initial Entry

**2. Treatment Name**

Date	Location	User	Value	Reason
Jan-07-2021 08:40:27 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> BLINDED THERAPY	Initial Entry

**3. Formulation:**

Date	Location	User	Value	Reason
Jan-07-2021 08:40:27 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> INJECTION	Initial Entry

**4. Dose Date Time:**

Date	Location	User	Value	Reason
Jan-07-2021 08:40:27 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Charlie Chao (b) (4)	<b>Data Entry:</b> Jan/5/2021 16:05	Initial Entry

**5. Anatomical Location:**

Date	Location	User	Value	Reason
Jan-07-2021 08:40:27 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> DELTOID MUSCLE	Initial Entry

**6. Body Side:**

Date	Location	User	Value	Reason
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090177e196b72785\Final\Final On: 06-Apr-2021 19:12 (GMT)

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

**Form Version:** 10-Dec-2020 02:26

**Site No:** 1126

**Subject No:** 11261268

**Generated By:** (b) (4)

**Form:** VACCINATION - eCRF Audit Trail History

**Form Status:** Data Complete, Frozen, Verified

**Site Name:** (1126) Kaiser Permanente Santa Clara

**Subject Initials:** ---

**Generated Time (GMT):** 06-Apr-2021 15:36

Jan-07-2021 08:40:27  
(UTC-08:00) Pacific  
Time (US & Canada)

ACV0PFEINFP6000

Charlie  
Chao  
(b) (4)

**Data Entry:**  
LEFT

Initial Entry

**7. Route:**

Date	Location	User	Value	Reason
Jan-07-2021 08:40:27 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> INTRAMUSCULAR	Initial Entry

**10. Timeframe Subject Was Observed**

Date	Location	User	Value	Reason
Jan-07-2021 08:40:27 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 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
Jan-07-2021 08:40:27 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Charlie Chao (b) (4)	<b>Data Entry:</b> YES	Initial Entry

090177e196b72785\Final\Final On: 06-Apr-2021 19:12 (GMT)

**Header Text:** c4591001

**Visit:** V3\_MONTH1\_POSTVAX2\_L

**Form Version:** 22-Apr-2020 21:02

**Site No:** 1126

**Subject No:** 11261268

**Generated By:** (b) (4)

**Form:** DATE OF VISIT - eCRF Audit Trail History

**Form Status:** Data Complete, Frozen, Verified

**Site Name:** (1126) Kaiser Permanente Santa Clara

**Subject Initials:** ---

**Generated Time (GMT):** 06-Apr-2021 15:36

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*I. Date of Visit*

Date	Location	User	Value	Reason
Feb-08-2021 15:22:47 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 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:** 1126**Site Name:** (1126) Kaiser Permanente Santa Clara**Subject No:** 11261268**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 06-Apr-2021 15:36[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-08-2021 15:23:24 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**2.a**

Date	Location	User	Value	Reason
Feb-08-2021 15:23:24 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptom::</b> FE V ER  <b>Were fever or systemic N symptoms present on t O he last day the Subject Diary was completed?:</b>	Initial Entry

**2.a Symptom:**

Date	Location	User	Value	Reason
Feb-08-2021 15:23:24 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 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-08-2021 15:23:24 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**2.b**

Date	Location	User	Value	Reason
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**Header Text:** c4591001

**Visit:** V3\_MONTH1\_POSTVAX2\_L

**Form Version:** 10-Dec-2020 02:30

**Site No:** 1126

**Subject No:** 11261268

**Generated By:** (b) (4)

**Form:** VACCINATION SYMPTOMS DIARY - SYMPTOM  
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**Form Status:** Data Complete, Frozen, Verified

**Site Name:** (1126) Kaiser Permanente Santa Clara

**Subject Initials:** ---

**Generated Time (GMT):** 06-Apr-2021 15:36

Feb-08-2021 15:23:24 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptom::</b> FA TI GU E  <b>Were fever or systemic NO symptoms present on t he last day the Subject Diary was completed?:</b>	Initial Entry
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**2.b Symptom:**

Date	Location	User	Value	Reason
Feb-08-2021 15:23:24 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 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-08-2021 15:23:24 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**2.c**

Date	Location	User	Value	Reason
Feb-08-2021 15:23:24 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptom::</b> HE AD AC HE  <b>Were fever or systemi NO c symptoms present o n the last day the Sub ject Diary was comple ted?:</b>	Initial Entry

090177e196b72785\Final\Final On: 06-Apr-2021 19:12 (GMT)

**Header Text:** c4591001

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**Site No:** 1126

**Subject No:** 11261268

**Generated By:** (b) (4)

**Form:** VACCINATION SYMPTOMS DIARY - SYMPTOM  
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**Form Status:** Data Complete, Frozen, Verified

**Site Name:** (1126) Kaiser Permanente Santa Clara

**Subject Initials:** ---

**Generated Time (GMT):** 06-Apr-2021 15:36

**2.c Symptom:**

Date	Location	User	Value	Reason
Feb-08-2021 15:23:24 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 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-08-2021 15:23:24 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**2.d**

Date	Location	User	Value	Reason
Feb-08-2021 15:23:24 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptom::</b> C HI LL S  <b>Were fever or systemic N symptoms present on t O he last day the Subject Diary was completed?:</b>	Initial Entry

090177e196b72785\Final\Final On: 06-Apr-2021 19:12 (GMT)

**Header Text:** c4591001

**Visit:** V3\_MONTH1\_POSTVAX2\_L

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**Site No:** 1126

**Subject No:** 11261268

**Generated By:** (b) (4)

**Form:** VACCINATION SYMPTOMS DIARY - SYMPTOM  
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**Form Status:** Data Complete, Frozen, Verified

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**Subject Initials:** ---

**Generated Time (GMT):** 06-Apr-2021 15:36

**2.d Symptom:**

Date	Location	User	Value	Reason
Feb-08-2021 15:23:24 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 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-08-2021 15:23:24 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**2.e**

Date	Location	User	Value	Reason
Feb-08-2021 15:23:24 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptom::</b> VO MI TIN G  <b>Were fever or systemi NO c symptoms present o n the last day the Sub ject Diary was comple ted?:</b>	Initial Entry



**Header Text:** c4591001

**Visit:** V3\_MONTH1\_POSTVAX2\_L

**Form Version:** 10-Dec-2020 02:30

**Site No:** 1126

**Subject No:** 11261268

**Generated By:** (b) (4)

**Form:** VACCINATION SYMPTOMS DIARY - SYMPTOM  
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**Form Status:** Data Complete, Frozen, Verified

**Site Name:** (1126) Kaiser Permanente Santa Clara

**Subject Initials:** ---

**Generated Time (GMT):** 06-Apr-2021 15:36

**2.e Symptom:**

Date	Location	User	Value	Reason
Feb-08-2021 15:23:24 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 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-08-2021 15:23:24 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**2.f**

Date	Location	User	Value	Reason
Feb-08-2021 15:23:24 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>  <b>Symptom::</b> DI AR RH EA  <b>Were fever or systemi NO c symptoms present o n the last day the Subj ect Diary was complet ed?:</b>	Initial Entry

090177e196b72785\Final\Final On: 06-Apr-2021 19:12 (GMT)

**Header Text:** c4591001

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**Site No:** 1126

**Subject No:** 11261268

**Generated By:** (b) (4)

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

**Form Status:** Data Complete, Frozen, Verified

**Site Name:** (1126) Kaiser Permanente Santa Clara

**Subject Initials:** ---

**Generated Time (GMT):** 06-Apr-2021 15:36

**2.f Symptom:**

Date	Location	User	Value	Reason
Feb-08-2021 15:23:24 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 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-08-2021 15:23:24 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**2.g**

Date	Location	User	Value	Reason
Feb-08-2021 15:23:24 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptom::</b> NEW O R WOR SENE MUSCL E PAIN  <b>Were fever or sys NO</b> <b>temic symptoms</b> <b>present on the las</b> <b>t day the Subject</b> <b>Diary was comple</b> <b>ted?:</b>	Initial Entry

**Header Text:** c4591001

**Visit:** V3\_MONTH1\_POSTVAX2\_L

**Form Version:** 10-Dec-2020 02:30

**Site No:** 1126

**Subject No:** 11261268

**Generated By:** (b) (4)

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

**Form Status:** Data Complete, Frozen, Verified

**Site Name:** (1126) Kaiser Permanente Santa Clara

**Subject Initials:** ---

**Generated Time (GMT):** 06-Apr-2021 15:36

**2.g Symptom:**

Date	Location	User	Value	Reason
Feb-08-2021 15:23:24 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NEW OR WORSENERED MU 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-08-2021 15:23:24 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**2.h**

Date	Location	User	Value	Reason
Feb-08-2021 15:23:24 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptom::</b> NEW O R WOR SENERED JOINT P AIN  <b>Were fever or syst NO emic symptoms p resent on the last day the Subject D iary was complete d?:</b>	Initial Entry

090177e196b72785\Final\Final On: 06-Apr-2021 19:12 (GMT)

**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:** 1126**Site Name:** (1126) Kaiser Permanente Santa Clara**Subject No:** 11261268**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 06-Apr-2021 15:36**2.h Symptom:**

Date	Location	User	Value	Reason
Feb-08-2021 15:23:24 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NEW OR WORSENER JOI NT 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-08-2021 15:23:24 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**3. Injection Site Location:**

Date	Location	User	Value	Reason
Feb-08-2021 15:23:24 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> DELTOID MUSCLE	Initial Entry

**4. Injection Site Body Side:**

Date	Location	User	Value	Reason
Feb-08-2021 15:23:24 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> LEFT	Initial Entry

**5.a**

Date	Location	User	Value	Reason
Feb-08-2021 15:23:24 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Injection Site Reactio RE n:: DN ES S	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:** 1126**Site Name:** (1126) Kaiser Permanente Santa Clara**Subject No:** 11261268**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 06-Apr-2021 15:36

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

**5.a Injection Site Reaction:**

Date	Location	User	Value	Reason
Feb-08-2021 15:23:24 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 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-08-2021 15:23:24 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**5.b**

Date	Location	User	Value	Reason
Feb-08-2021 15:23:24 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Injection Site Reaction: SWELLING  Were injection site reactions present on the 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:** 1126

**Subject No:** 11261268

**Generated By:** (b) (4)

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

**Form Status:** Data Complete, Frozen, Verified

**Site Name:** (1126) Kaiser Permanente Santa Clara

**Subject Initials:** ---

**Generated Time (GMT):** 06-Apr-2021 15:36

**5.b Injection Site Reaction:**

Date	Location	User	Value	Reason
Feb-08-2021 15:23:24 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 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-08-2021 15:23:24 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**5.c**

Date	Location	User	Value	Reason
Feb-08-2021 15:23:24 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Injection Site Reaction::</b> PAIN AT INJ ECTI ON SI TE  <b>Were injection site reactions present on the last day the Subject Diary was completed?:</b> NO	Initial Entry

090177e196b72785\Final\Final On: 06-Apr-2021 19:12 (GMT)

**Header Text:** c4591001

**Visit:** V3\_MONTH1\_POSTVAX2\_L

**Form Version:** 10-Dec-2020 02:30

**Site No:** 1126

**Subject No:** 11261268

**Generated By:** (b) (4)

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

**Form Status:** Data Complete, Frozen, Verified

**Site Name:** (1126) Kaiser Permanente Santa Clara

**Subject Initials:** ---

**Generated Time (GMT):** 06-Apr-2021 15:36

**5.c Injection Site Reaction:**

Date	Location	User	Value	Reason
Feb-08-2021 15:23:24 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 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-08-2021 15:23:24 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**Header Text:** c4591001

**Visit:** V3\_MONTH1\_POSTVAX2\_L

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1126

**Subject No:** 11261268

**Generated By:** (b) (4)

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

**Form Status:** Data Complete, Frozen, Verified

**Site Name:** (1126) Kaiser Permanente Santa Clara

**Subject Initials:** ---

**Generated Time (GMT):** 06-Apr-2021 15:36

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**1. Data Origin**

Date	Location	User	Value	Reason
Feb-08-2021 15:24:38 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SITE	Initial Entry

**2. Sample Type**

Date	Location	User	Value	Reason
Feb-08-2021 15:24:38 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SERUM	Initial Entry

**3. Sample Collected?**

Date	Location	User	Value	Reason
Feb-08-2021 15:24:38 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES Date of Collection:  Feb/5/2021	Initial Entry

**5.a**

Date	Location	User	Value	Reason
Feb-08-2021 15:23:53 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sample ID: BR7Z7H	Initial Entry

**5.a Sample ID**

Date	Location	User	Value	Reason
Feb-08-2021 15:23:53 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BR7Z7H	Initial Entry

090177e196b72785\Final\Final On: 06-Apr-2021 19:12 (GMT)



**Header Text:** c4591001

**Visit:** V3\_MONTH1\_POSTVAX2\_L

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1126

**Subject No:** 11261268

**Generated By:** (b) (4)

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

**Form Status:** Data Complete, Frozen, Verified

**Site Name:** (1126) Kaiser Permanente Santa Clara

**Subject Initials:** ---

**Generated Time (GMT):** 06-Apr-2021 15:36

**5.b**

Date	Location	User	Value	Reason
Feb-08-2021 15:24:04 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample ID:</b> BR7Z7J	Initial Entry

**5.b Sample ID**

Date	Location	User	Value	Reason
Feb-08-2021 15:24:04 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BR7Z7J	Initial Entry

**5.c**

Date	Location	User	Value	Reason
Feb-08-2021 15:24:16 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample ID:</b> BS7VRM	Initial Entry

**5.c Sample ID**

Date	Location	User	Value	Reason
Feb-08-2021 15:24:16 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BS7VRM	Initial Entry

090177e196b72785\Final\Final On: 06-Apr-2021 19:12 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

**Form Version:** 22-Apr-2020 21:02

**Site No:** 1126

**Subject No:** 11261268

**Generated By:** (b) (4)

**Form:** ADVERSE EVENT REPORT - Audit Trail

**Form Status:**

**Site Name:** (1126) Kaiser Permanente Santa Clara

**Subject Initials:** ---

**Generated Time (GMT):** 06-Apr-2021 15:36

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Date	Location	User	Value	Reason
Jan-08-2021 16:03:38 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Charlie Chao (b) (4)	Form Created	

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

**Form Version:** 22-Apr-2020 21:02

**Site No:** 1126

**Subject No:** 11261268

**Generated By:** (b) (4)

**Form:** ADVERSE EVENT REPORT - Audit Trail

**Form Status:**

**Site Name:** (1126) Kaiser Permanente Santa Clara

**Subject Initials:** ---

**Generated Time (GMT):** 06-Apr-2021 15:36

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Date	Location	User	Value	Reason
Feb-09-2021 13:48:27 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Charlie Chao (b) (4)	Form Created	

090177e196b72785\Final\Final On: 06-Apr-2021 19:12 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

**Form Version:** 22-Apr-2020 21:02

**Site No:** 1126

**Subject No:** 11261268

**Generated By:** (b) (4)

**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History

**Form Status:** Data Complete, Frozen

**Site Name:** (1126) Kaiser Permanente Santa Clara

**Subject Initials:** ---

**Generated Time (GMT):** 06-Apr-2021 15:36

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**1. Category:**

Date	Location	User	Value	Reason
Jan-08-2021 16:03:38 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> ADVERSE EVENT	Initial Entry

**2. AE ID:**

Date	Location	User	Value	Reason
Jan-08-2021 16:03:38 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 1	Initial Entry

**3. Adverse Event:**

*(If possible specify diagnosis, not individual symptoms)*

Date	Location	User	Value	Reason
Jan-13-2021 00:21:16 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Clo sed	Response satisfies query
Jan-12-2021 11:32:49 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: An swere d	Transcription Error
Jan-12-2021 11:32:49 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry</b> : Facial Urtica ria, w orseni ng	Transcription Error

**Header Text:** c4591001**Visit:** Logs - Unscheduled**Form Version:** 22-Apr-2020 21:02**Site No:** 1126**Subject No:** 11261268**Generated By:** (b) (4)**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History**Form Status:** Data Complete, Frozen**Site Name:** (1126) Kaiser Permanente Santa Clara**Subject Initials:** ---**Generated Time (GMT):** 06-Apr-2021 15:36

Jan-10-2021 22:54:13 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	PFE SDQ PROD (b) (4)	Query 1: Op ened	The AE Facial Urticaria was reported but is also listed in Medical History. Please clarify if this is a worsening of the baseline condition, and if so, please consider adding "worsening" to the AE term. AE as baseline conditions should only be reported as AEs if they worsen. (b) (4)
Jan-08-2021 16:03:38 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Charlie Chao (b) (4)	<b>Data Entry</b> : Facial Urtica ria	Initial Entry

**4. Start Date Time:**

Date	Location	User	Value	Reason
Jan-12-2021 22:17:06 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Jan-12-2021 11:33:19 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Initial Entry

**Header Text:** c4591001**Visit:** Logs - Unscheduled**Form Version:** 22-Apr-2020 21:02**Site No:** 1126**Subject No:** 11261268**Generated By:** (b) (4)**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History**Form Status:** Data Complete, Frozen**Site Name:** (1126) Kaiser Permanente Santa Clara**Subject Initials:** ---**Generated Time (GMT):** 06-Apr-2021 15:36

Jan-12-2021 11:33:19 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Dec/18/2020 UNK:UNK	Initial Entry
Jan-10-2021 22:28:52 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	DM: The response for Data item#4,5 and 13 are missing. Kindly review and update.

**5. Is the adverse event still ongoing?**

Date	Location	User	Value	Reason
Jan-12-2021 11:33:19 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO End Date Time:  Dec/31/2020 UNK:UNK	Initial Entry

**6. Toxicity Grade:**

Date	Location	User	Value	Reason
Jan-08-2021 16:03:38 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Charlie Chao (b) (4)	<b>Data Entry:</b> 1	Initial Entry

**7. Is the adverse event serious?****If Yes, NOTIFY PFIZER IMMEDIATELY.**

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

Date	Location	User	Value	Reason
Jan-08-2021 16:03:38 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Charlie Chao (b) (4)	<b>Data Entry:</b> NO	Initial Entry

**8. Is this adverse event the result of a study Medication Error?****If Yes, record the type of medication error on the Medication Error Log.**

**Header Text:** c4591001**Visit:** Logs - Unscheduled**Form Version:** 22-Apr-2020 21:02**Site No:** 1126**Subject No:** 11261268**Generated By:** (b) (4)**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History**Form Status:** Data Complete, Frozen**Site Name:** (1126) Kaiser Permanente Santa Clara**Subject Initials:** ---**Generated Time (GMT):** 06-Apr-2021 15:36

Date	Location	User	Value	Reason
Jan-08-2021 16:03:38 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Charlie Chao (b) (4)	<b>Data Entry:</b> NO	Initial Entry

**9. Is this event related to study treatment:**

Date	Location	User	Value	Reason
Jan-08-2021 16:03:38 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Charlie Chao (b) (4)	<b>Data Entry:</b> NOT RELATED If Not Related to study treatment(s), this event is due to:  OTHER  <i>If Other, specify:</i>  Trigger unknown	Initial Entry

**10. Latest Action Taken with Study Treatment:**

Date	Location	User	Value	Reason
Jan-08-2021 16:03:38 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Charlie Chao (b) (4)	<b>Data Entry:</b> NOT APPLICABLE	Initial Entry

**11. Was a Concomitant Medication given?**

Date	Location	User	Value	Reason
Jan-08-2021 16:03:38 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Charlie Chao (b) (4)	<b>Data Entry:</b> NO	Initial Entry

**12. Was a Non-Drug Treatment given?**

Date	Location	User	Value	Reason
Jan-08-2021 16:03:38 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Charlie Chao (b) (4)	<b>Data Entry:</b> NO	Initial Entry

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

**Form Version:** 22-Apr-2020 21:02

**Site No:** 1126

**Subject No:** 11261268

**Generated By:** (b) (4)

**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History

**Form Status:** Data Complete, Frozen

**Site Name:** (1126) Kaiser Permanente Santa Clara

**Subject Initials:** ---

**Generated Time (GMT):** 06-Apr-2021 15:36

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

Date	Location	User	Value	Reason
Jan-12-2021 11:33:19 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> RECOVERED/RESOLVED	Initial Entry

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

Date	Location	User	Value	Reason
Jan-08-2021 16:03:38 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Charlie Chao (b) (4)	<b>Data Entry:</b> NO	Initial Entry



**Header Text:** c4591001**Visit:** Logs - Unscheduled**Form Version:** 22-Apr-2020 21:02**Site No:** 1126**Subject No:** 11261268**Generated By:** (b) (4)**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History**Form Status:** Data Complete**Site Name:** (1126) Kaiser Permanente Santa Clara**Subject Initials:** ---**Generated Time (GMT):** 06-Apr-2021 15:36[Back to Form](#)**1. Category:**

Date	Location	User	Value	Reason
Feb-09-2021 13:48:27 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> ADVERSE EVENT	Initial Entry

**2. AE ID:**

Date	Location	User	Value	Reason
Feb-09-2021 13:48:27 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 2	Initial Entry

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

Date	Location	User	Value	Reason
Feb-09-2021 13:48:27 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Charlie Chao (b) (4)	<b>Data Entry:</b> Juvenile Osteochondrosis of bil ateral fifth metatarsals	Initial Entry

**4. Start Date Time:**

Date	Location	User	Value	Reason
Feb-09-2021 13:48:27 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Charlie Chao (b) (4)	<b>Data Entry:</b> Dec/28/2020 UNK:UNK	Initial Entry

**5. Is the adverse event still ongoing?**

Date	Location	User	Value	Reason
Mar-01-2021 09:21:27 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Feb-26-2021	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	ONGOING

**Header Text:** c4591001**Visit:** Logs - Unscheduled**Form Version:** 22-Apr-2020 21:02**Site No:** 1126**Subject No:** 11261268**Generated By:** (b) (4)**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History**Form Status:** Data Complete**Site Name:** (1126) Kaiser Permanente Santa Clara**Subject Initials:** ---**Generated Time (GMT):** 06-Apr-2021 15:36

13:38:30 (UTC-08:00) Pacific Time (US & Canada)		(b) (4), (b) (6)		
Feb-22-2021 06:43:26 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	CLINQUERY - OSTEOCHRONDOSIS BILATERAL FIFTH METATARSALS (28 DEC 20) is still reported as ONGOING. Please confirm or enter END DATE if known.
Feb-09-2021 13:48:27 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Charlie Chao (b) (4)	<b>Data Entry:</b> YES	Initial Entry

**6. Toxicity Grade:**

Date	Location	User	Value	Reason
Feb-09-2021 13:48:27 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Charlie Chao (b) (4)	<b>Data Entry:</b> 2	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-09-2021 13:48:27 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Charlie Chao (b) (4)	<b>Data Entry:</b> NO	Initial Entry

**8. Is this adverse event the result of a study Medication Error?****If Yes, record the type of medication error on the Medication Error Log.**

Date	Location	User	Value	Reason
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**Header Text:** c4591001**Visit:** Logs - Unscheduled**Form Version:** 22-Apr-2020 21:02**Site No:** 1126**Subject No:** 11261268**Generated By:** (b) (4)**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History**Form Status:** Data Complete**Site Name:** (1126) Kaiser Permanente Santa Clara**Subject Initials:** ---**Generated Time (GMT):** 06-Apr-2021 15:36Feb-09-2021 13:48:27  
(UTC-08:00) Pacific  
Time (US & Canada)

ACV0PFEINFP6000

Charlie  
Chao  
(b) (4)**Data Entry:**  
NO

Initial Entry

**9. Is this event related to study treatment:**

Date	Location	User	Value	Reason
Feb-09-2021 13:48:27 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Charlie Chao (b) (4)	<b>Data Entry:</b> NOT RELATED If Not Related to study treatment(s), this event is due to:  OTHER  <i>If Other, specify:</i>  Gymnastic injury	Initial Entry

**10. Latest Action Taken with Study Treatment:**

Date	Location	User	Value	Reason
Feb-09-2021 13:48:27 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Charlie Chao (b) (4)	<b>Data Entry:</b> NOT APPLICABLE	Initial Entry

**11. Was a Concomitant Medication given?**

Date	Location	User	Value	Reason
Feb-09-2021 13:48:27 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Charlie Chao (b) (4)	<b>Data Entry:</b> YES	Initial Entry

**12. Was a Non-Drug Treatment given?**

Date	Location	User	Value	Reason
Feb-09-2021 13:48:27 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Charlie Chao (b) (4)	<b>Data Entry:</b> YES	Initial Entry

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

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

**Form Version:** 22-Apr-2020 21:02

**Site No:** 1126

**Subject No:** 11261268

**Generated By:** (b) (4)

**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History

**Form Status:** Data Complete

**Site Name:** (1126) Kaiser Permanente Santa Clara

**Subject Initials:** ---

**Generated Time (GMT):** 06-Apr-2021 15:36

Date	Location	User	Value	Reason
Feb-09-2021 13:48:27 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Charlie Chao (b) (4)	<b>Data Entry:</b> RECOVERING/RESOLVING	Initial Entry

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

Date	Location	User	Value	Reason
Feb-09-2021 13:48:27 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Charlie Chao (b) (4)	<b>Data Entry:</b> NO	Initial Entry

**Header Text:** c4591001**Visit:** End of Treatment - Unscheduled**Form Version:** 10-Dec-2020 02:29**Site No:** 1126**Subject No:** 11261268**Generated By:** (b) (4)**Form:** DISPOSITION - TREATMENT - eCRF Audit Trail History**Form Status:** Data Complete, Frozen, Verified**Site Name:** (1126) Kaiser Permanente Santa Clara**Subject Initials:** ---**Generated Time (GMT):** 06-Apr-2021 15:36[Back to Form](#)**1. Date of Completion/Discontinuation/Death :**

Date	Location	User	Value	Reason
Feb-08-2021 15:25:15 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Feb/5/2021	Initial Entry

**2. Phase of Disposition:**

Date	Location	User	Value	Reason
Feb-08-2021 15:25:15 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> VACCINATION	Initial Entry

**3. Status:**

Date	Location	User	Value	Reason
Feb-08-2021 15:25:15 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> COMPLETED	Initial Entry

**Header Text:** c4591001

**Visit:** Subject Status - Unscheduled

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1126

**Subject No:** 11261268

**Generated By:** (b) (4)

**Form:** SUBJECT STATUS - eCRF Audit Trail History

**Form Status:** Data Complete, Verified

**Site Name:** (1126) Kaiser Permanente Santa Clara

**Subject Initials:** ---

**Generated Time (GMT):** 06-Apr-2021 15:36

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**1. Subject Status**

Date	Location	User	Value	Reason
Feb-08-2021 15:25:15 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> FOLLOW-UP	Initial Entry
Dec-15-2020 09:50:55 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> ENROLLED/RANDOMIZED	Initial Entry
Dec-15-2020 09:46:42 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SCREENED	Initial Entry

**2. Subject Status Date**

Date	Location	User	Value	Reason
Feb-08-2021 15:25:15 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> Feb/5/2021	Initial Entry
Dec-15-2020 09:50:55 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> Dec/14/2020	Initial Entry
Dec-15-2020 09:46:42 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> Dec/14/2020	Initial Entry

090177e196b72785\Final\Final On: 06-Apr-2021 19:12 (GMT)

**Header Text:** c4591001

**Visit:** Investigator Signature - Unscheduled

**Form:** CASEBOOK SIGNATURE FORM - eCRF Audit Trail History

**Form Version:** 22-Apr-2020 21:04

**Form Status:** Data Complete, Signed, Verified

**Site No:** 1126

**Site Name:** (1126) Kaiser Permanente Santa Clara

**Subject No:** 11261268

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 06-Apr-2021 15:36

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***1. Casebook Signature***

Date	Location	User	Value	Reason
Mar-11-2021 09:55:46 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	<b>Data Entry:</b> Click Here to Enable	Initial Entry