

**Header Text:** c4591001

**Visit:** COHORT\_SELECTION

**Form:** COHORT SELECTION

**Form Version:** 10-Oct-2020 16:01

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

**Site No:** 1126

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

**Subject No:** 11261244

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 11:09

[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:** MAIN INFORMED CONSENT

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

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

**Site No:** 1126

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

**Subject No:** 11261244

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 11:09

[eCRF Audit Trail History](#)

**Informed Consent**

1.	Consent Was:	OBTAINED Date Written Consent Obtained Dec/2/2020
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**Header Text:** c4591001

**Visit:** COHORT\_SELECTION

**Form:** DEMOGRAPHY

**Form Version:** 15-Sep-2020 21:54

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

**Site No:** 1126

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

**Subject No:** 11261244

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 11:09

[eCRF Audit Trail History](#)

**Demography**

1.	Subject ID	[11261244]
2.	Birth Date:	(b) (6) /2004
3.	Sex:	MALE
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:** 11261244

**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):** 29-Mar-2021 11:09

[eCRF Audit Trail History](#)

**Date of Visit**

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

**Header Text:** c4591001

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

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

**Site No:** 1126

**Subject No:** 11261244

**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):** 29-Mar-2021 11:09

**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:** 11261244

**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):** 29-Mar-2021 11:09

[eCRF Audit Trail History](#)

**Disposition - Screening**

1.	Date of Completion/Discontinuation /Death	Dec/2/2020
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:** 11261244

**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):** 29-Mar-2021 11:09

[eCRF Audit Trail History](#)

**Medical History Details**

1.a	Line/MH Number:	[1]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Acne]
	Start Date:	Jan/22/2018
	Ongoing:	YES
1.b	Line/MH Number:	[2]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Intermittent Asthma]
	Start Date:	Apr/20/2010
	Ongoing:	YES

090177e196ae3d4d\Final\Final On: 01-Apr-2021 04:30 (GMT)

**Header Text:** c4591001

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

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

**Site No:** 1126

**Subject No:** 11261244

**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):** 29-Mar-2021 11:09

[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
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**Header Text:** c4591001

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

**Form Version:** 10-Oct-2020 16:04

**Site No:** 1126

**Subject No:** 11261244

**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):** 29-Mar-2021 11:09

[eCRF Audit Trail History](#)

**Vital Signs**

1.	Date:	Dec/2/2020
2.	Weight:	[58.51]
3.	Unit:	kg
4.	Height:	[172.72]
5.	Unit:	cm
6.	Body Mass Index:	[19.6]

**Vital Signs Details**

7.a	Record Identifier:	1
	Temperature:	[98.3]
	Unit:	F
	Temperature Location:	ORAL CAVITY

090177e196ae3d4d\Final\Final On: 01-Apr-2021 04:30 (GMT)

**Header Text:** c4591001

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

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

**Site No:** 1126

**Subject No:** 11261244

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

**Form:** RANDOMIZATION

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

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

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:09

[eCRF Audit Trail History](#)

**Disposition**

1.	Randomization Date :	Dec/2/2020
2.	Randomization Number:	[117216]
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:** 11261244

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 11:09

[eCRF Audit Trail History](#)

**Electronic Sample Tracking**

1.	Data Origin	SITE
2.	Sample Type	SERUM
3.	Sample Collected?	YES Date of Collection: Dec/2/2020
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	[BPZZ18]
5.b	Sample ID	[BS7VF9]
5.c	Sample ID	[BLC3JG]

090177e196ae3d4d\Final\Final On: 01-Apr-2021 04:30 (GMT)

**Header Text:** c4591001

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

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

**Site No:** 1126

**Subject No:** 11261244

**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):** 29-Mar-2021 11:09

[eCRF Audit Trail History](#)

**Electronic Sample Tracking**

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Dec/2/2020
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	[BP28YC]
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090177e196ae3d4d\Final\Final On: 01-Apr-2021 04:30 (GMT)

**Header Text:** c4591001

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

**Form Version:** 22-Apr-2020 21:04

**Site No:** 1126

**Subject No:** 11261244

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

**Form:** VACCINATION

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

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

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:09

[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/2/2020 14:30
5.	Anatomical Location:	DELTOID MUSCLE
6.	Body Side:	LEFT
7.	Route:	INTRAMUSCULAR
8.	Actual Dose:	[ ]
9.	Unit:	
10.	Timeframe Subject Was Observed	THE PROTOCOL SPECIFIED OBSERVATION PERIOD
11.	Was the subject observed for at least the protocol specified observation period after investigational product administration?	YES

090177e196ae3d4d\Final\Final On: 01-Apr-2021 04:30 (GMT)

**Header Text:** c4591001

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

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

**Site No:** 1126

**Subject No:** 11261244

**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):** 29-Mar-2021 11:09

[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:** 11261244

**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):** 29-Mar-2021 11:09

[eCRF Audit Trail History](#)

**Date of Visit**

1.	Date of Visit	Dec/23/2020
2.	Erroneous Visit	

Header Text: c4591001

Visit: V2\_VAX2\_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES

Form Version: 10-Oct-2020 16:03

Form Status: Data Complete, Frozen, Verified

Site No: 1126

Site Name: (1126) Kaiser Permanente Santa Clara

Subject No: 11261244

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:09

[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

090177e196ae3d4d\Final\Final On: 01-Apr-2021 04:30 (GMT)



**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

**Form Version:** 10-Oct-2020 16:03

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

**Site No:** 1126

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

**Subject No:** 11261244

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 11:09

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

090177e196ae3d4d\Final\Final On: 01-Apr-2021 04:30 (GMT)

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1126

**Subject No:** 11261244

**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):** 29-Mar-2021 11:09

[eCRF Audit Trail History](#)

**Vital Signs**

1.	Date:	Dec/23/2020
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**Vital Signs Details**

2.a	Record Identifier:	1
	Temperature:	[98.4]
	Unit:	F
	Temperature Location:	ORAL CAVITY

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1126

**Subject No:** 11261244

**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):** 29-Mar-2021 11:09

[eCRF Audit Trail History](#)

**Electronic Sample Tracking**

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Dec/23/2020
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	[BP2921]
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090177e196ae3d4d\Final\Final On: 01-Apr-2021 04:30 (GMT)

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1126

**Subject No:** 11261244

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

**Form:** VACCINATION

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

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

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:09

[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/23/2020 11:20
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

090177e196ae3d4d\Final\Final On: 01-Apr-2021 04:30 (GMT)

**Header Text:** c4591001

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

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

**Site No:** 1126

**Subject No:** 11261244

**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):** 29-Mar-2021 11:09

[eCRF Audit Trail History](#)

**Date of Visit**

1.	Date of Visit	Jan/26/2021
2.	Erroneous Visit	

**Header Text:** c4591001

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

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

**Form Version:** 10-Oct-2020 16:03

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

**Site No:** 1126

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

**Subject No:** 11261244

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 11:09

[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

090177e196ae3d4d\Final\Final On: 01-Apr-2021 04:30 (GMT)

**Header Text:** c4591001

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

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

**Form Version:** 10-Oct-2020 16:03

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

**Site No:** 1126

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

**Subject No:** 11261244

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 11:09

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 WORSENERD MUSCLE PAIN
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO
2 h	Symptom:	NEW OR WORSENERD 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

090177e196ae3d4d\Final\Final On: 01-Apr-2021 04:30 (GMT)

**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:** 11261244

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 11:09

[eCRF Audit Trail History](#)

**Electronic Sample Tracking**

1.	Data Origin	SITE
2.	Sample Type	SERUM
3.	Sample Collected?	YES Date of Collection: Jan/26/2021
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	[BR7Z59]
5.b	Sample ID	[BS7VP3]
5.c	Sample ID	[BRYLHB]



**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:** 11261244

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 11:09

**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:** 11261244

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 11:09

**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:	[ ]
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**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL - New Unscheduled **Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB SELF Visit

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

**Form Status:** Not Started

**Site No:** 1126

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

**Subject No:** 11261244

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 11:09

**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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090177e196ae3d4d\Final\Final On: 01-Apr-2021 04:30 (GMT)

**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:** 11261244

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 11:09

**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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090177e196ae3d4d\Final\Final On: 01-Apr-2021 04:30 (GMT)

**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:** 11261244

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 11:09

**Health Care Utilization**

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

**Health Care Utilization Other**

2.	Other Type of Practitioner Specify:	[ ]
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**Health Care Utilization**

3.	Has the subject been hospitalized due to potential COVID-19 illness?	
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090177e196ae3d4d\Final\Final On: 01-Apr-2021 04:30 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL - New Unscheduled Visit    **Form:** ILLNESS DETAILS

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

**Form Status:** Not Started

**Site No:** 1126

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

**Subject No:** 11261244

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 11:09

**Illness Details**

1.	Category of Clinical Event:	
2.	Was a diagnosis obtained for Potential COVID-19 Illness?	
3.	Toxicity Grade:	

**Header Text:** c4591001

**Visit:** POT\_COVID\_CONVA - New  
Unscheduled Visit

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

**Form Version:** 22-Apr-2020 21:04

**Form Status:** Not Started

**Site No:** 1126

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

**Subject No:** 11261244

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 11:09

**Date of Visit**

1.	Date of Visit	//
2.	Erroneous Visit	

**COVID-19 Illness Visit**

3.	COVID-19 Illness Visit:	
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**Header Text:** c4591001

**Visit:** POT\_COVID\_CONVA - New  
Unscheduled Visit

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

**Site No:** 1126

**Subject No:** 11261244

**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):** 29-Mar-2021 11:09

**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	[ ]
----	-----------	-----

090177e196ae3d4d\Final\Final On: 01-Apr-2021 04:30 (GMT)



**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:** 11261244

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 11:09

**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:** 11261244

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 11:09

**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	[ ]
----	-----------	-----

090177e196ae3d4d\Final\Final On: 01-Apr-2021 04:30 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1126

**Subject No:** 11261244

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

**Form:** ADVERSE EVENT REPORT

**Form Status:** Not Started

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

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:09

**Adverse Event Report**

1.	Category:	
2.	AE ID:	[ ]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[ ]
4.	Start Date Time:	//
5.	Is the adverse event still ongoing?	
6.	Toxicity Grade:	
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).	
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.	
9.	Is this event related to study treatment:	
10.	Latest Action Taken with Study Treatment:	
11.	Was a Concomitant Medication given?	

090177e196ae3d4d\Final\Final On: 01-Apr-2021 04:30 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1126

**Subject No:** 11261244

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

**Form:** ADVERSE EVENT REPORT

**Form Status:** Not Started

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

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:09

12.	Was a Non-Drug Treatment given?	
13.	What was the outcome of this adverse event?:	
14.	Did the adverse event cause the subject to be discontinued from the study?	
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:** 11261244

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 11:09

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

090177e196ae3d4d\Final\Final On: 01-Apr-2021 04:30 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1126

**Subject No:** 11261244

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

**Form:** MEDICATION ERROR

**Form Status:** Not Started

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

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:09

[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	[ ]

090177e196ae3d4d\Final\Final On: 01-Apr-2021 04:30 (GMT)

**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:** 11261244

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 11:09

#	Sponsor-Defined Identifier	Category for Medication	Concomitant Medications Pre-specified	Name of Medication	Start Date	Form Instance
1.	1	VACCINATIONS	NO	MEN-ACYW (MENVEO) (meningococcal oligosaccharide ACYW-135)	Jan/26/2021	<a href="#">Repeating Pages</a>

090177e196ae3d4d\Final\Final On: 01-Apr-2021 04:30 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**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:** 11261244

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 11:09

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

**Concomitant Medications**

1.	What is the medication identifier?	[1]
2.	Category:	VACCINATIONS
3.	Concomitant Medications Pre-specified:	NO
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).	[MEN-ACYW (MENVEO) (meningococcal oligosaccharide ACYW-135)]
5.	Date:	Jan/26/2021

090177e196ae3d4d\Final\Final On: 01-Apr-2021 04:30 (GMT)



**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:** 11261244

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 11:09

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

090177e196ae3d4d\Final\Final On: 01-Apr-2021 04:30 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1126

**Subject No:** 11261244

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

**Form:** CONCOMITANT MEDICATIONS - PROHIBITED

**Form Status:** Not Started

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

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:09

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**Concomitant Medications**

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

090177e196ae3d4d\Final\Final On: 01-Apr-2021 04:30 (GMT)

**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:** 11261244

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 11:09

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

090177e196ae3d4d\Final\Final On: 01-Apr-2021 04:30 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1126

**Subject No:** 11261244

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

**Form:** RADIATION TREATMENT

**Form Status:** Not Started

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

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:09

[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:** 11261244

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 11:09

#	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:** 11261244

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

**Form:** TRANSFUSIONS

**Form Status:** Not Started

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

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:09

[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:** 11261244

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 11:09

**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:** 11261244

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 11:09

**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:** 11261244

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 11:09

**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:** 11261244

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 11:09

**Vital Signs**

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

**Vital Signs Details**

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

**Header Text:** c4591001

**Visit:** Unplanned Vaccination - Unscheduled

**Form:** VACCINATION

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

**Form Status:** Not Started

**Site No:** 1126

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

**Subject No:** 11261244

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 11:09

**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?	

090177e196ae3d4d\Final\Final On: 01-Apr-2021 04:30 (GMT)

**Header Text:** c4591001

**Visit:** Unplanned Vaccination - Unscheduled

**Form:** CONTACT OUTCOME - MONTH 1

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

**Form Status:** Not Started

**Site No:** 1126

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

**Subject No:** 11261244

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 11:09

**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:** 11261244

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 11:09

**Contact Outcome**

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

**Header Text:** c4591001

**Visit:** End of Treatment - Unscheduled

**Form:** DISPOSITION - TREATMENT

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

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

**Site No:** 1126

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

**Subject No:** 11261244

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 11:09

[eCRF Audit Trail History](#)

**Disposition - Treatment**

1.	Date of Completion/Discontinuation /Death :	Jan/26/2021
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:** Data Complete, Frozen, Verified

**Site No:** 1126

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

**Subject No:** 11261244

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 11:09

[eCRF Audit Trail History](#)

**Date of Visit**

1.	Date of Visit	Feb/4/2021
2.	Erroneous Visit	

**Header Text:** c4591001

**Visit:** Potential ReVax Initial Contact -  
Unscheduled

**Form:** FURTHER VACCINATION CONFIRMATION

**Form Version:** 10-Dec-2020 02:25

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

**Site No:** 1126

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

**Subject No:** 11261244

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 11:09

[eCRF Audit Trail History](#)

**Further Vaccination Confirmation**

1.	Select appropriate response - Is participant willing to return for Vaccination 3?	Participant is willing to return for Vaccination 3 Participant is: eligible per other protocol allowance(s) and confirmed to have received only placebo at Vaccination 1/2
----	---	--



**Header Text:** c4591001

**Visit:** Follow-Up - Unscheduled

**Form Version:** 15-Sep-2020 21:53

**Site No:** 1126

**Subject No:** 11261244

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

**Form:** DISPOSITION - FOLLOW-UP

**Form Status:** Not Started

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

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:09

**Disposition - Follow-Up**

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

**Header Text:** c4591001

**Visit:** Disposition - Unscheduled

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

**Site No:** 1126

**Subject No:** 11261244

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

**Form:** TREATMENT UNBLINDED

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

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

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:09

[eCRF Audit Trail History](#)

**Treatment Unblinded**

1.	Date Treatment Unblinded :	Feb/4/2021
2.	Primary Reason for Unblinding:	ASSESS ELIGIBILITY FOR ADDITIONAL VACCINATION

**Header Text:** c4591001

**Visit:** Disposition - Unscheduled

**Form:** WITHDRAWAL OF CONSENT

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

**Form Status:** Not Started

**Site No:** 1126

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

**Subject No:** 11261244

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 11:09

**Withdrawal Of Consent**

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

090177e196ae3d4d\Final\Final On: 01-Apr-2021 04:30 (GMT)

**Header Text:** c4591001

**Visit:** Disposition - Unscheduled

**Form:** DEATH DETAILS CODED

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

**Form Status:** Not Started

**Site No:** 1126

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

**Subject No:** 11261244

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 11:09

**Death Details**

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

**Cause of Death**

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

**Header Text:** c4591001

**Visit:** V101\_VAX3

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

**Site No:** 1126

**Subject No:** 11261244

**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):** 29-Mar-2021 11:09

[eCRF Audit Trail History](#)

**Date of Visit**

1.	Date of Visit	Feb/24/2021
2.	Erroneous Visit	

**Header Text:** c4591001

**Visit:** V101\_VAX3

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

**Site No:** 1126

**Subject No:** 11261244

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

**Form:** INFORMED CONSENT - FURTHER VACCINATION

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

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

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:09

[eCRF Audit Trail History](#)

**Informed Consent - Further Vaccination**

1.	Consent Was:	OBTAINED Date Written Consent Obtained Feb/24/2021
----	--------------	--

**Header Text:** c4591001

**Visit:** V101\_VAX3

**Form:** INCLUSION/EXCLUSION CRITERIA - FURTHER VACCINATION

**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:** 11261244

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 11:09

**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
----	--	----------------

**Header Text:** c4591001

**Visit:** V101\_VAX3

**Form:** DISPOSITION - SCREENING FOR FURTHER VACCINATION

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

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

**Site No:** 1126

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

**Subject No:** 11261244

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 11:09

[eCRF Audit Trail History](#)

**Disposition - Screening for Further Vaccination**

1.	Date of Completion/Discontinuation/Death :	Feb/24/2021
2.	Phase of Disposition:	REPEAT SCREENING 1
3.	Status:	COMPLETED
4.	Specify Status:	[ ]



**Header Text:** c4591001

**Visit:** V101\_VAX3

**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:** 11261244

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 11:09

[eCRF Audit Trail History](#)

**Electronic Sample Tracking**

1.	Data Origin	SITE
2.	Sample Type	SERUM
3.	Sample Collected?	YES Date of Collection: Feb/24/2021
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	[BR7ZBC]
5.b	Sample ID	[BRYLVH]
5.c	Sample ID	[BRYLKD]

090177e196ae3d4d\Final\Final On: 01-Apr-2021 04:30 (GMT)

**Header Text:** c4591001

**Visit:** V101\_VAX3

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

**Site No:** 1126

**Subject No:** 11261244

**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):** 29-Mar-2021 11:09

[eCRF Audit Trail History](#)

**Electronic Sample Tracking**

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Feb/24/2021
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	[BR7Z0C]
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090177e196ae3d4d\Final\Final On: 01-Apr-2021 04:30 (GMT)

**Header Text:** c4591001

**Visit:** V101\_VAX3

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

**Site No:** 1126

**Subject No:** 11261244

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

**Form:** VACCINATION

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

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

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:09

[eCRF Audit Trail History](#)

**Vaccination**

1.	Was there a temporary delay of vaccination?	NO
2.	Treatment Name	[BNT162b2]
3.	Formulation:	INJECTION
4.	Dose Date Time:	Feb/24/2021 14:15
5.	Anatomical Location:	DELTOID MUSCLE
6.	Body Side:	LEFT
7.	Route:	INTRAMUSCULAR
8.	Actual Dose:	[30.0]
9.	Unit:	ug
10.	Timeframe Subject Was Observed	30 MINUTES
11.	Was the subject observed for at least the protocol specified observation period after investigational product administration?	YES

090177e196ae3d4d\Final\Final On: 01-Apr-2021 04:30 (GMT)

**Header Text:** c4591001

**Visit:** V102\_VAX4

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

**Site No:** 1126

**Subject No:** 11261244

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

**Form:** DATE OF VISIT

**Form Status:** Not Started

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

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:09

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

**Header Text:** c4591001

**Visit:** V102\_VAX4

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

**Site No:** 1126

**Subject No:** 11261244

**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):** 29-Mar-2021 11:09

**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	[ ]
----	-----------	-----

090177e196ae3d4d\Final\Final On: 01-Apr-2021 04:30 (GMT)

**Header Text:** c4591001

**Visit:** V102\_VAX4

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

**Site No:** 1126

**Subject No:** 11261244

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

**Form:** VACCINATION

**Form Status:** Not Started

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

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:09

**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?	

090177e196ae3d4d\Final\Final On: 01-Apr-2021 04:30 (GMT)

**Header Text:** c4591001

**Visit:** V103\_MONTH1

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

**Site No:** 1126

**Subject No:** 11261244

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

**Form:** DATE OF VISIT

**Form Status:** Not Started

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

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:09

**Date of Visit**

1.	Date of Visit	//
2.	Erroneous Visit	

**Header Text:** c4591001

**Visit:** V103\_MONTH1

**Form Version:** 22-Apr-2020 21:04

**Site No:** 1126

**Subject No:** 11261244

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

**Form:** CONTACT OUTCOME

**Form Status:** Not Started

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

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:09

**Contact Outcome**

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



**Header Text:** c4591001

**Visit:** V104\_MONTH6

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

**Site No:** 1126

**Subject No:** 11261244

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

**Form:** DATE OF VISIT

**Form Status:** Not Started

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

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:09

**Date of Visit**

1.	Date of Visit	//
2.	Erroneous Visit	

**Header Text:** c4591001

**Visit:** V104\_MONTH6

**Form Version:** 22-Apr-2020 21:04

**Site No:** 1126

**Subject No:** 11261244

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

**Form:** CONTACT OUTCOME

**Form Status:** Not Started

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

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:09

**Contact Outcome**

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

**Header Text:** c4591001

**Visit:** V105\_MONTH18

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

**Site No:** 1126

**Subject No:** 11261244

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

**Form:** DATE OF VISIT

**Form Status:** Not Started

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

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:09

**Date of Visit**

1.	Date of Visit	//
2.	Erroneous Visit	

**Header Text:** c4591001

**Visit:** V105\_MONTH18

**Form Version:** 22-Apr-2020 21:04

**Site No:** 1126

**Subject No:** 11261244

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

**Form:** CONTACT OUTCOME

**Form Status:** Not Started

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

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:09

**Contact Outcome**

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

**Header Text:** c4591001

**Visit:** FURTHER\_VACCINATION\_EOT -  
Unscheduled

**Form:** DISPOSITION - TREATMENT

**Form Version:** 20-Feb-2021 02:26

**Form Status:** Not Started

**Site No:** 1126

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

**Subject No:** 11261244

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 11:09

**Disposition - Treatment**

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:** 11261244

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

**Form:** SUBJECT STATUS

**Form Status:** Data Complete, Verified

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

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:09

[eCRF Audit Trail History](#)

**Subject Status**

1.	Subject Status	FOLLOW-UP
2.	Subject Status Date	Jan/26/2021

**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:** 11261244

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 11:09

[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:** 11261244

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 11:09

[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 14:45:05 (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:** 11261244

**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):** 29-Mar-2021 11:09

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Item	Date	User	Comment
Form	Dec-03-2020 14:34:16 (UTC-08:00) Pacific Time (US & Canada)	Charlie Chao (b) (4)	N/A _____ Not Applicable

**Header Text:** c4591001

**Visit:** V101\_VAX3

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

**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:** 11261244

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 11:09

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Item	Date	User	Comment
Form	Feb-25-2021 15:56:05 (UTC-08:00) Pacific Time (US & Canada)	Charlie Chao (b) (4)	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:** 11261244

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 11:09

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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 14:45:05 (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.

090177e196ae3d4d\Final\Final On: 01-Apr-2021 04:30 (GMT)

**Header Text:** c4591001

**Visit:** COHORT\_SELECTION

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

**Form Version:** 10-Oct-2020 16:01

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

**Site No:** 1126

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

**Subject No:** 11261244

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 11:09

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

Date	Location	User	Value	Reason
Dec-03-2020 14:33:16 (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-03-2020 14:33:16 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Charlie Chao (b) (4)	<b>Data Entry:</b> STAGE 3 COHORTS	Initial Entry

090177e196ae3d4d\Final\Final On: 01-Apr-2021 04:30 (GMT)

**Header Text:** c4591001

**Visit:** COHORT\_SELECTION

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

**Site No:** 1126

**Subject No:** 11261244

**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):** 29-Mar-2021 11:09

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*1. Consent Was:*

Date	Location	User	Value	Reason
Dec-03-2020 14:33:28 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Charlie Chao (b) (4)	<b>Data Entry:</b> OBTAINED Date Written Consent Obtained  Dec/2/2020	Initial Entry

090177e196ae3d4d\Final\Final On: 01-Apr-2021 04:30 (GMT)

Header Text: c4591001

Visit: COHORT\_SELECTION

Form: DEMOGRAPHY - eCRF Audit Trail History

Form Version: 15-Sep-2020 21:54

Form Status: Data Complete, Frozen, Verified

Site No: 1126

Site Name: (1126) Kaiser Permanente Santa Clara

Subject No: 11261244

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:09

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**1. Subject ID**

Date	Location	User	Value	Reason
Dec-03-2020 14:33:02 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 11261244	Item copied from previous form

**2. Birth Date:**

Date	Location	User	Value	Reason
Dec-03-2020 14:32:59 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> (b) (6)/2004	Enrollment Entry

**3. Sex:**

Date	Location	User	Value	Reason
Dec-03-2020 14:33:49 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Charlie Chao (b) (4)	<b>Data Entry:</b> MALE	Initial Entry

**4. Ethnicity:**

Date	Location	User	Value	Reason
Dec-03-2020 14:33:49 (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-03-2020 14:33:49 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Charlie Chao (b) (4)	<b>Data Entry:</b> WHITE	Initial Entry

090177e196ae3d4d\Final\Final On: 01-Apr-2021 04:30 (GMT)

**Header Text:** c4591001

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

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

**Site No:** 1126

**Subject No:** 11261244

**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):** 29-Mar-2021 11:09

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*1. Date of Visit*

Date	Location	User	Value	Reason
Dec-03-2020 14:34:00 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Charlie Chao (b) (4)	<b>Data Entry:</b> Dec/2/2020	Initial Entry

090177e196ae3d4d\Final\Final On: 01-Apr-2021 04:30 (GMT)

**Header Text:** c4591001

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

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

**Site No:** 1126

**Subject No:** 11261244

**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):** 29-Mar-2021 11:09

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

Date	Location	User	Value	Reason
Dec-03-2020 14:34:31 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Charlie Chao (b) (4)	<b>Data Entry:</b> Dec/2/2020	Initial Entry

**2. Phase of Disposition:**

Date	Location	User	Value	Reason
Dec-03-2020 14:34:31 (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-03-2020 14:34:31 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Charlie Chao (b) (4)	<b>Data Entry:</b> COMPLETED	Initial Entry

090177e196ae3d4d\Final\Final On: 01-Apr-2021 04:30 (GMT)



Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 22-Apr-2020 21:03

Site No: 1126

Subject No: 11261244

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): 29-Mar-2021 11:09

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*1.a*

Date	Location	User	Value	Reason
Dec-03-2020 14:35:06 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Line/MH Number:</b> 1 <b>Medical History Te</b> Acne <b>rm:</b> <b>Start Date:</b> Jan/22/20 18 <b>Ongoing:</b> YES	Initial Entry

*1.a Line/MH Number:*

Date	Location	User	Value	Reason
Dec-03-2020 14:35:06 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 1	Initial Entry

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

Date	Location	User	Value	Reason
Dec-03-2020 14:35:06 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Charlie Chao (b) (4)	<b>Data Entry:</b> Acne	Initial Entry

*1.a Start Date:*

Date	Location	User	Value	Reason
Dec-03-2020 14:35:06 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Charlie Chao (b) (4)	<b>Data Entry:</b> Jan/22/2018	Initial Entry

*1.a Ongoing:*

Date	Location	User	Value	Reason
Dec-03-2020 14:35:06 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Charlie Chao (b) (4)	<b>Data Entry:</b> YES	Initial Entry

090177e196ae3d4d\Final\Final On: 01-Apr-2021 04:30 (GMT)

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 22-Apr-2020 21:03

Site No: 1126

Subject No: 11261244

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): 29-Mar-2021 11:09

**1.b**

Date	Location	User	Value	Reason
Dec-03-2020 14:35:30 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> Line/MH Numb 2 <b>er:</b> <b>Medical History</b> Intermittent A <b>sthma</b> <b>Term:</b> sthma <b>Start Date:</b> Apr/20/2010 <b>Ongoing:</b> YES	Initial Entry

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

Date	Location	User	Value	Reason
Dec-03-2020 14:35:30 (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-03-2020 14:35:30 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Charlie Chao (b) (4)	<b>Data Entry:</b> Intermittent Asthma	Initial Entry

**1.b Start Date:**

Date	Location	User	Value	Reason
Dec-03-2020 14:35:30 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Charlie Chao (b) (4)	<b>Data Entry:</b> Apr/20/2010	Initial Entry

**1.b Ongoing:**

Date	Location	User	Value	Reason
Dec-03-2020 14:35:30 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Charlie Chao (b) (4)	<b>Data Entry:</b> YES	Initial Entry

090177e196ae3d4d\Final\Final On: 01-Apr-2021 04:30 (GMT)

**Header Text:** c4591001

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

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

**Site No:** 1126

**Subject No:** 11261244

**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):** 29-Mar-2021 11:09

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

Date	Location	User	Value	Reason
Dec-03-2020 14:35:47 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Charlie Chao (b) (4)	<b>Data Entry:</b> The subject is NOT known to be HIV POSITIVE	Initial Entry

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 10-Oct-2020 16:04

Site No: 1126

Subject No: 11261244

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): 29-Mar-2021 11:09

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**1. Date:**

Date	Location	User	Value	Reason
Dec-03-2020 14:36:23 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Charlie Chao (b) (4)	<u>Data Entry:</u> Dec/2/2020	Initial Entry

**2. Weight:**

Date	Location	User	Value	Reason
Dec-03-2020 14:36:23 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Charlie Chao (b) (4)	<u>Data Entry:</u> 58.51	Initial Entry

**3. Unit:**

Date	Location	User	Value	Reason
Dec-03-2020 14:36:23 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Charlie Chao (b) (4)	<u>Data Entry:</u> kg	Initial Entry

**4. Height:**

Date	Location	User	Value	Reason
Dec-03-2020 14:36:23 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Charlie Chao (b) (4)	<u>Data Entry:</u> 172.72	Initial Entry

**5. Unit:**

Date	Location	User	Value	Reason
Dec-03-2020 14:36:23 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Charlie Chao (b) (4)	<u>Data Entry:</u> cm	Initial Entry

**6. Body Mass Index:**

Date	Location	User	Value	Reason
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090177e196ae3d4d\Final\Final On: 01-Apr-2021 04:30 (GMT)

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 10-Oct-2020 16:04

Site No: 1126

Subject No: 11261244

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): 29-Mar-2021 11:09

Dec-03-2020 14:36:23 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 19.6	Initial Entry
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7.a

Date	Location	User	Value	Reason
Dec-03-2020 14:36:23 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Charlie Chao (b) (4)	<b>Data Entry:</b> <b>Record Identifier</b> 1 :: <b>Temperature:</b> 98.3 <b>Temperature Uni</b> F <b>t:</b> <b>Temperature Loc</b> ORAL CAV <b>ation::</b> ITY	Initial Entry

7.a Record Identifier:

Date	Location	User	Value	Reason
Dec-03-2020 14:36:23 (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-03-2020 14:36:23 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Charlie Chao (b) (4)	<b>Data Entry:</b> 98.3	Initial Entry

7.a Unit:

Date	Location	User	Value	Reason
Dec-03-2020 14:36:23 (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
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090177e196ae3d4d\Final\Final On: 01-Apr-2021 04:30 (GMT)

**Header Text:** c4591001

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

**Form Version:** 10-Oct-2020 16:04

**Site No:** 1126

**Subject No:** 11261244

**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):** 29-Mar-2021 11:09

Dec-03-2020 14:36:23 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Charlie Chao (b) (4)	<b>Data Entry:</b> ORAL CAVITY	Initial Entry
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**Header Text:** c4591001

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

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

**Site No:** 1126

**Subject No:** 11261244

**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):** 29-Mar-2021 11:09

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**1. Randomization Date :**

Date	Location	User	Value	Reason
Dec-03-2020 14:36:44 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Charlie Chao (b) (4)	<b>Data Entry:</b> Dec/2/2020	Initial Entry

**2. Randomization Number:**

Date	Location	User	Value	Reason
Dec-03-2020 14:36:44 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Charlie Chao (b) (4)	<b>Data Entry:</b> 117216	Initial Entry

090177e196ae3d4d\Final\Final On: 01-Apr-2021 04:30 (GMT)

**Header Text:** c4591001**Visit:** V1\_DAY1\_VAX1\_L**Form Version:** 22-Apr-2020 21:03**Site No:** 1126**Subject No:** 11261244**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):** 29-Mar-2021 11:09[Back to Form](#)**1. Data Origin**

Date	Location	User	Value	Reason
Dec-03-2020 14:36:58 (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-03-2020 14:36:58 (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-03-2020 14:37:06 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Dec-03-2020 14:36:58 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Dec-03-2020 14:36:58 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Charlie Chao (b) (4)	<b>Data Entry:</b> YES Date of Collection:  Dec/2/2020	Initial Entry

**5.a**

Date	Location	User	Value	Reason
Dec-03-2020 14:37:06 (UTC-08:00) Pacific	ACV0PFEINFP6000	Charlie Chao	<b>Data Entry:</b>	Initial Entry



Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1126

Site Name: (1126) Kaiser Permanente Santa Clara

Subject No: 11261244

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:09

Time (US & Canada)		(b) (4)	Sample ID: BPZZ18	
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5.a Sample ID

Date	Location	User	Value	Reason
Dec-03-2020 14:37:06 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Charlie Chao (b) (4)	<b>Data Entry:</b> BPZZ18	Initial Entry

5.b

Date	Location	User	Value	Reason
Dec-03-2020 14:37:18 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Charlie Chao (b) (4)	<b>Data Entry:</b> Sample ID: BS7VF9	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Dec-03-2020 14:37:18 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Charlie Chao (b) (4)	<b>Data Entry:</b> BS7VF9	Initial Entry

5.c

Date	Location	User	Value	Reason
Dec-03-2020 14:37:28 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Charlie Chao (b) (4)	<b>Data Entry:</b> Sample ID: BLC3JG	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Dec-03-2020 14:37:28 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Charlie Chao (b) (4)	<b>Data Entry:</b> BLC3JG	Initial Entry

090177e196ae3d4d\Final\Final On: 01-Apr-2021 04:30 (GMT)

**Header Text:** c4591001**Visit:** V1\_DAY1\_VAX1\_L**Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB - eCRF Audit Trail History**Form Version:** 22-Apr-2020 21:03**Form Status:** Data Complete, Frozen, Verified**Site No:** 1126**Site Name:** (1126) Kaiser Permanente Santa Clara**Subject No:** 11261244**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 11:09[Back to Form](#)**1. Data Origin**

Date	Location	User	Value	Reason
Dec-03-2020 14:37:41 (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-03-2020 14:37:41 (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-03-2020 14:37:50 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Dec-03-2020 14:37:41 (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-03-2020 14:37:41 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Charlie Chao (b) (4)	<b>Data Entry:</b> YES Date of Collection:  Dec/2/2020	Initial Entry

**5.a**

Date	Location	User	Value	Reason
Dec-03-2020 14:37:50 (UTC-08:00) Pacific	ACV0PFEINFP6000	Charlie Chao	<b>Data Entry:</b>	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:** 11261244

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 11:09

Time (US & Canada)

(b) (4)

**Sample ID:** BP28YC

**5.a Sample ID**

Date	Location	User	Value	Reason
Dec-03-2020 14:37:50 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Charlie Chao (b) (4)	<b>Data Entry:</b> BP28YC	Initial Entry

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 22-Apr-2020 21:04

Site No: 1126

Subject No: 11261244

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): 29-Mar-2021 11:09

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

Date	Location	User	Value	Reason
Dec-03-2020 14:39:28 (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-07-2020 19:01:35 (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-07-2020 19:01:35 (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-07-2020 22:45:10 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Closed as data entered.
Dec-07-2020 19:01:35 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Initial Entry
Dec-07-2020 19:01:35 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Dec/2/2020 14:30	Initial Entry
Dec-06-2020 23:12:52 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	DM: Please complete this item. Thank you.

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Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 22-Apr-2020 21:04

Site No: 1126

Subject No: 11261244

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): 29-Mar-2021 11:09

5. Anatomical Location:

Date	Location	User	Value	Reason
Dec-07-2020 19:01:35 (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
Dec-03-2020 14:39:28 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Charlie Chao (b) (4)	<b>Data Entry:</b> LEFT	Initial Entry

7. Route:

Date	Location	User	Value	Reason
Dec-07-2020 19:01:35 (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-07-2020 19:01:35 (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-03-2020 14:39:28 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Charlie Chao (b) (4)	<b>Data Entry:</b> YES	Initial Entry

090177e196ae3d4d\Final\Final On: 01-Apr-2021 04:30 (GMT)

**Header Text:** c4591001

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

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

**Site No:** 1126

**Subject No:** 11261244

**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):** 29-Mar-2021 11:09

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*1. Select appropriate response - Reactogenicity diary collection*

<b>Date</b>	<b>Location</b>	<b>User</b>	<b>Value</b>	<b>Reason</b>
Dec-03-2020 14:39:39 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Charlie Chao (b) (4)	<b>Data Entry:</b> YES - REACTOGENICITY E- DIARY COLLECTED FOR TH IS SUBJECT	Initial Entry

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1126

**Subject No:** 11261244

**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):** 29-Mar-2021 11:09

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*1. Date of Visit*

Date	Location	User	Value	Reason
Dec-27-2020 19:23:48 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [Redacted]	<b>Data Entry:</b> Dec/23/2020	Transcription Error
Dec-22-2020 11:08:44 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [Redacted]	<b>Data Entry:</b> Dec/21/2020	Initial Entry

090177e196ae3d4d\Final\Final On: 01-Apr-2021 04:30 (GMT)

**Header Text:** c4591001**Visit:** V2\_VAX2\_L**Form Version:** 10-Oct-2020 16:03**Site No:** 1126**Subject No:** 11261244**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):** 29-Mar-2021 11:09[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
Dec-22-2020 11:09:25 (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
Dec-22-2020 11:09:25 (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 s N ymptoms present on the O last day the Subject Dia ry was completed?:</b>	Initial Entry

**2.a Symptom:**

Date	Location	User	Value	Reason
Dec-22-2020 11:09:25 (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
Dec-22-2020 11:09:25 (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: V2\_VAX2\_L

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

Form Version: 10-Oct-2020 16:03

Form Status: Data Complete, Frozen, Verified

Site No: 1126

Site Name: (1126) Kaiser Permanente Santa Clara

Subject No: 11261244

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:09

Dec-22-2020 11:09:25 (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 symptoms present on t he last day the Subject Diary was completed?:</b> NO	Initial Entry
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2.b Symptom:

Date	Location	User	Value	Reason
Dec-22-2020 11:09:25 (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
Dec-22-2020 11:09:25 (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
Dec-27-2020 19:24:09 (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 systemic symptoms present on t he last day the Subject Diary was completed?:</b> NO	Transcription Error
Dec-22-2020 11:09:25 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptom::</b> HEADA CHE	Initial Entry

090177e196ae3d4d\Final\Final On: 01-Apr-2021 04:30 (GMT)

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

**Form Version:** 10-Oct-2020 16:03

**Site No:** 1126

**Subject No:** 11261244

**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):** 29-Mar-2021 11:09

			<p><b>Were fever or systemic symptoms present on the last day the Subject Diary was completed?:</b></p> <p>YES Ongoing?</p> <p>NO</p> <p>Stop Date : De c/8 /20 20</p>	
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Header Text: c4591001

Visit: V2\_VAX2\_L

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

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Site No: 1126

Site Name: (1126) Kaiser Permanente Santa Clara

Subject No: 11261244

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:09

2.c Symptom:

Date	Location	User	Value	Reason
Dec-22-2020 11:09:25 (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
Dec-28-2020 22:10:05 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1 : Closed	Data updated by site.
Dec-27-2020 19:24:09 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1 : Answered	Transcription Error
Dec-27-2020 19:24:09 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Transcription Error
Dec-24-2020 00:21:54 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1 : Reissued: Opened	eDiary RQ1: Per diary records, Day 7 is the last day reported on 08-Dec-2020 & HEADACHE is not present on Last day however

090177e196ae3d4d\Final\Final On: 01-Apr-2021 04:30 (GMT)

Header Text: c4591001

Visit: V2\_VAX2\_L

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

Form Version: 10-Oct-2020 16:03

Form Status: Data Complete, Frozen, Verified

Site No: 1126

Site Name: (1126) Kaiser Permanente Santa Clara

Subject No: 11261244

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:09

				inform is entered with 'Yes' for the same. Please verify and update. Else, clarify in query response. Thanks
Dec-23-2020 10:57:20 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1 : Answered	V1 Data needs to be updated - Please unfreeze the screen.
Dec-23-2020 04:04:50 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	PFE SDQ PROD (b) (4)	Query 1 : Opened	eDiary: Per eDiary records, "Headache occurrence" is not reported on Last day (Day 7) however the last day in Inform CRF data is entered as Yes for the same. Please verify and update. Else, clarify. Thanks (b) (4)
Dec-22-2020 11:09:25 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES Ongoing?	Initial Entry

090177e196ae3d4d\Final\Final On: 01-Apr-2021 04:30 (GMT)

Header Text: c4591001

Visit: V2\_VAX2\_L

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

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Form Status: Data Complete, Frozen, Verified

Site No: 1126

Site Name: (1126) Kaiser Permanente Santa Clara

Subject No: 11261244

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:09

Canada)				NO
				Sto p D ate:
				D ec /8 /2 0 2 0

2.d

Date	Location	User	Value	Reason
Dec-22-2020 11:09:25 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptom::</b> CH IL LS  <b>Were fever or systemic N symptoms present on th O e last day the Subject D iary was completed?:</b>	Initial Entry

2.d Symptom:

Date	Location	User	Value	Reason
Dec-22-2020 11:09:25 (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
Dec-22-2020 11:09:25 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

090177e196ae3d4d\Final\Final On: 01-Apr-2021 04:30 (GMT)

Header Text: c4591001

Visit: V2\_VAX2\_L

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

Form Version: 10-Oct-2020 16:03

Form Status: Data Complete, Frozen, Verified

Site No: 1126

Site Name: (1126) Kaiser Permanente Santa Clara

Subject No: 11261244

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:09

2.e

Date	Location	User	Value	Reason
Dec-22-2020 11:09:25 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptom::</b> VO MIT ING  <b>Were fever or systemic NO symptoms present on t he last day the Subject Diary was completed?:</b>	Initial Entry

2.e Symptom:

Date	Location	User	Value	Reason
Dec-22-2020 11:09:25 (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
Dec-22-2020 11:09:25 (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
Dec-22-2020 11:09:25 (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 systemic NO symptoms present on t he last day the Subject Diary was completed?:</b>	Initial Entry

090177e196ae3d4d\Final\Final On: 01-Apr-2021 04:30 (GMT)

Header Text: c4591001

Visit: V2\_VAX2\_L

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

Form Version: 10-Oct-2020 16:03

Form Status: Data Complete, Frozen, Verified

Site No: 1126

Site Name: (1126) Kaiser Permanente Santa Clara

Subject No: 11261244

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:09

2.f Symptom:

Date	Location	User	Value	Reason
Dec-22-2020 11:09:25 (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
Dec-22-2020 11:09:25 (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
Dec-22-2020 11:09:25 (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 syst NO emic symptoms pr esent on the last d ay the Subject Dia ry was completed ?:</b>	Initial Entry

090177e196ae3d4d\Final\Final On: 01-Apr-2021 04:30 (GMT)

Header Text: c4591001

Visit: V2\_VAX2\_L

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

Form Version: 10-Oct-2020 16:03

Form Status: Data Complete, Frozen, Verified

Site No: 1126

Site Name: (1126) Kaiser Permanente Santa Clara

Subject No: 11261244

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:09

2.g Symptom:

Date	Location	User	Value	Reason
Dec-22-2020 11:09:25 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NEW OR WORSENER MUS CLE 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
Dec-22-2020 11:09:25 (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
Dec-22-2020 11:09:25 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptom::</b> NEW O R WOR SENER JOINT P AIN  <b>Were fever or syst</b> NO <b>emic symptoms pr</b> <b>esent on the last d</b> <b>ay the Subject Dia</b> <b>ry was completed?</b> :	Initial Entry

090177e196ae3d4d\Final\Final On: 01-Apr-2021 04:30 (GMT)



Header Text: c4591001

Visit: V2\_VAX2\_L

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

Form Version: 10-Oct-2020 16:03

Form Status: Data Complete, Frozen, Verified

Site No: 1126

Site Name: (1126) Kaiser Permanente Santa Clara

Subject No: 11261244

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:09

2.h Symptom:

Date	Location	User	Value	Reason
Dec-22-2020 11:09:25 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NEW OR WORSENER JOIN T 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
Dec-22-2020 11:09:25 (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
Dec-22-2020 11:09:25 (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
Dec-22-2020 11:09:25 (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
Dec-22-2020 11:09:25 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Injection Site Reaction RE :: DN ES S Were injection site reac NO tions present on the las t day the Subject Diary was completed?:	Initial Entry

090177e196ae3d4d\Final\Final On: 01-Apr-2021 04:30 (GMT)

Header Text: c4591001

Visit: V2\_VAX2\_L

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

Form Version: 10-Oct-2020 16:03

Form Status: Data Complete, Frozen, Verified

Site No: 1126

Site Name: (1126) Kaiser Permanente Santa Clara

Subject No: 11261244

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:09

5.a Injection Site Reaction:

Date	Location	User	Value	Reason
Dec-22-2020 11:09:25 (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
Dec-22-2020 11:09:25 (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
Dec-22-2020 11:09:25 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Injection Site Reaction SW :: ELL ING  Were injection site rea NO ctions present on the l ast day the Subject Di ary was completed?:	Initial Entry

5.b Injection Site Reaction:

Date	Location	User	Value	Reason
Dec-22-2020 11:09:25 (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
Dec-22-2020 11:09:25 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

090177e196ae3d4d\Final\Final On: 01-Apr-2021 04:30 (GMT)

Header Text: c4591001

Visit: V2\_VAX2\_L

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

Form Version: 10-Oct-2020 16:03

Form Status: Data Complete, Frozen, Verified

Site No: 1126

Site Name: (1126) Kaiser Permanente Santa Clara

Subject No: 11261244

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:09

5.c

Date	Location	User	Value	Reason
Dec-22-2020 11:09:25 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<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

5.c Injection Site Reaction:

Date	Location	User	Value	Reason
Dec-22-2020 11:09:25 (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
Dec-22-2020 11:09:25 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

090177e196ae3d4d\Final\Final On: 01-Apr-2021 04:30 (GMT)

**Header Text:** c4591001**Visit:** V2\_VAX2\_L**Form Version:** 10-Dec-2020 02:27**Site No:** 1126**Subject No:** 11261244**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):** 29-Mar-2021 11:09[Back to Form](#)**1. Date:**

Date	Location	User	Value	Reason
Dec-27-2020 19:25:41 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Dec-27-2020 19:24:41 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	Vital Signs Date is not same as Vaccination Date in the same visit. Please review and update as appropriate or clarify.
Dec-27-2020 19:24:41 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	<b>Data Entry:</b> Dec/23/2020	Transcription Error
Dec-22-2020 11:10:03 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	<b>Data Entry:</b> Dec/21/2020	Initial Entry

**2.a**

Date	Location	User	Value	Reason
Dec-22-2020 11:10:03 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	<b>Data Entry:</b> <b>Record Identifie</b> 1 <b>r::</b> <b>Temperature:</b> 98.4 <b>Temperature U F</b> <b>nit:</b> <b>Temperature Lo ORAL CA</b> <b>cation::</b> VITY	Initial Entry

**2.a Record Identifier:**

Date	Location	User	Value	Reason
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Header Text: c4591001

Visit: V2\_VAX2\_L

Form Version: 10-Dec-2020 02:27

Site No: 1126

Subject No: 11261244

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): 29-Mar-2021 11:09

Dec-22-2020 11:10:03 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 1	Initial Entry
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**2.a Temperature:**

Date	Location	User	Value	Reason
Dec-22-2020 11:10:03 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 98.4	Initial Entry

**2.a Unit:**

Date	Location	User	Value	Reason
Dec-22-2020 11:10:03 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> F	Initial Entry

**2.a Temperature Location:**

Date	Location	User	Value	Reason
Dec-22-2020 11:10:03 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> ORAL CAVITY	Initial Entry

090177e196ae3d4d\Final\Final On: 01-Apr-2021 04:30 (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: 11261244

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:09

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**1. Data Origin**

Date	Location	User	Value	Reason
Dec-22-2020 11:10:24 (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-22-2020 11:10:24 (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-27-2020 19:25:41 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Dec-27-2020 19:24:56 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	Nasal Swab sample is collected after Vaccination 2, however response to "If no sample was collected or sample was not collected according to protocol, please provide reason:" is missing. Please update.
Dec-27-2020 19:24:56 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES Date of Collection:	Transcription Error

090177e196ae3d4d\Final\Final On: 01-Apr-2021 04:30 (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: 11261244

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:09

			Dec/23/2020	
Dec-22-2020 11:10:24 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES Date of Collection:  Dec/21/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Dec-27-2020 19:25:14 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sample ID: BP2921	Transcription Error
Dec-22-2020 11:10:15 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sample ID: BP2915	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Dec-27-2020 19:25:14 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BP2921	Transcription Error
Dec-22-2020 11:10:15 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BP2915	Initial Entry

090177e196ae3d4d\Final\Final On: 01-Apr-2021 04:30 (GMT)

Header Text: c4591001

Visit: V2\_VAX2\_L

Form Version: 10-Dec-2020 02:26

Site No: 1126

Subject No: 11261244

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): 29-Mar-2021 11:09

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

Date	Location	User	Value	Reason
Dec-22-2020 11:10:47 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**2. Treatment Name**

Date	Location	User	Value	Reason
Dec-22-2020 11:10:47 (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-22-2020 11:10:47 (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-27-2020 19:25:41 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Dec-27-2020 19:25:41 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Dec/23/2020 11:20	Transcription Error
Dec-27-2020 19:23:48 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	Dose Date is not equal to Date of Visit 23/Dec/2020 of the corresponding Visit. Please review and update as appropriate.

090177e196ae3d4d\Final\Final On: 01-Apr-2021 04:30 (GMT)



Header Text: c4591001

Visit: V2\_VAX2\_L

Form Version: 10-Dec-2020 02:26

Site No: 1126

Subject No: 11261244

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): 29-Mar-2021 11:09

Dec-22-2020 11:10:47 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Dec/21/2020 12:16	Initial Entry
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**5. Anatomical Location:**

Date	Location	User	Value	Reason
Dec-22-2020 11:10:47 (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
Dec-22-2020 11:10:47 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> LEFT	Initial Entry

**7. Route:**

Date	Location	User	Value	Reason
Dec-22-2020 11:10:47 (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-22-2020 11:10:47 (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-22-2020 11:10:47 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

090177e196ae3d4d\Final\Final On: 01-Apr-2021 04:30 (GMT)

**Header Text:** c4591001

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

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

**Site No:** 1126

**Subject No:** 11261244

**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):** 29-Mar-2021 11:09

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*1. Date of Visit*

Date	Location	User	Value	Reason
Jan-27-2021 11:22:50 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Charlie Chao (b) (4)	<b>Data Entry:</b> Jan/26/2021	Initial Entry

**Header Text:** c4591001**Visit:** V3\_MONTH1\_POSTVAX2\_L**Form:** VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History**Form Version:** 10-Oct-2020 16:03**Form Status:** Data Complete, Frozen, Verified**Site No:** 1126**Site Name:** (1126) Kaiser Permanente Santa Clara**Subject No:** 11261244**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 11:09[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-27-2021 11:23:11 (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-27-2021 11:23:11 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Charlie Chao (b) (4)	<b>Data Entry:</b> <b>Symptom::</b> FE VE R <b>Were fever or systemic sy N</b> <b>mptoms present on the las O</b> <b>t day the Subject Diary w</b> <b>as completed?:</b>	Initial Entry

**2.a Symptom:**

Date	Location	User	Value	Reason
Jan-27-2021 11:23:11 (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-27-2021 11:23:11 (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: V3\_MONTH1\_POSTVAX2\_L

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

Form Version: 10-Oct-2020 16:03

Form Status: Data Complete, Frozen, Verified

Site No: 1126

Site Name: (1126) Kaiser Permanente Santa Clara

Subject No: 11261244

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:09

Jan-27-2021 11:23:11 (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 sy NO mptoms present on the la st day the Subject Diary was completed?:</b>	Initial Entry
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**2.b Symptom:**

Date	Location	User	Value	Reason
Jan-27-2021 11:23:11 (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-27-2021 11:23:11 (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-27-2021 11:23:11 (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 s NO ymptoms present on the last day the Subject Diar y was completed?:</b>	Initial Entry

090177e196ae3d4d\Final\Final On: 01-Apr-2021 04:30 (GMT)

**Header Text:** c4591001**Visit:** V3\_MONTH1\_POSTVAX2\_L**Form:** VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History**Form Version:** 10-Oct-2020 16:03**Form Status:** Data Complete, Frozen, Verified**Site No:** 1126**Site Name:** (1126) Kaiser Permanente Santa Clara**Subject No:** 11261244**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 11:09**2.c Symptom:**

Date	Location	User	Value	Reason
Jan-27-2021 11:23:11 (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-27-2021 11:23:11 (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-27-2021 11:23:11 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Charlie Chao (b) (4)	<b>Data Entry:</b> Symptom:: CH IL LS  Were fever or systemic sy NO mptoms present on the la st day the Subject Diary was completed?:	Initial Entry

**2.d Symptom:**

Date	Location	User	Value	Reason
Jan-27-2021 11:23:11 (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-27-2021 11:23:11 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Charlie Chao (b) (4)	<b>Data Entry:</b> NO	Initial Entry

Header Text: c4591001

Visit: V3\_MONTH1\_POSTVAX2\_L

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

Form Version: 10-Oct-2020 16:03

Form Status: Data Complete, Frozen, Verified

Site No: 1126

Site Name: (1126) Kaiser Permanente Santa Clara

Subject No: 11261244

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:09

2.e

Date	Location	User	Value	Reason
Jan-27-2021 11:23:11 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Charlie Chao (b) (4)	<u>Data Entry:</u> Symptom:: VO MIT ING  Were fever or systemic s NO ymptoms present on the last day the Subject Diar y was completed?:	Initial Entry

2.e Symptom:

Date	Location	User	Value	Reason
Jan-27-2021 11:23:11 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Charlie Chao (b) (4)	<u>Data Entry:</u> 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-27-2021 11:23:11 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Charlie Chao (b) (4)	<u>Data Entry:</u> NO	Initial Entry

2.f

Date	Location	User	Value	Reason
Jan-27-2021 11:23:11 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Charlie Chao (b) (4)	<u>Data Entry:</u> Symptom:: DIA RR HE A  Were fever or systemic s NO ymptoms present on the last day the Subject Diar y was completed?:	Initial Entry

090177e196ae3d4d\Final\Final On: 01-Apr-2021 04:30 (GMT)

Header Text: c4591001

Visit: V3\_MONTH1\_POSTVAX2\_L

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

Form Version: 10-Oct-2020 16:03

Form Status: Data Complete, Frozen, Verified

Site No: 1126

Site Name: (1126) Kaiser Permanente Santa Clara

Subject No: 11261244

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:09

2.f Symptom:

Date	Location	User	Value	Reason
Jan-27-2021 11:23:11 (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-27-2021 11:23:11 (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-27-2021 11:23:11 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Charlie Chao (b) (4)	<b>Data Entry:</b>  Symptom:: NEW OR WORSE NED MU SCLE PA IN  Were fever or syste NO mic symptoms pres ent on the last day t he Subject Diary w as completed?:	Initial Entry

090177e196ae3d4d\Final\Final On: 01-Apr-2021 04:30 (GMT)

Header Text: c4591001

Visit: V3\_MONTH1\_POSTVAX2\_L

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

Form Version: 10-Oct-2020 16:03

Form Status: Data Complete, Frozen, Verified

Site No: 1126

Site Name: (1126) Kaiser Permanente Santa Clara

Subject No: 11261244

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:09

2.g Symptom:

Date	Location	User	Value	Reason
Jan-27-2021 11:23:11 (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-27-2021 11:23:11 (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-27-2021 11:23:11 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Charlie Chao (b) (4)	<b>Data Entry:</b>  Symptom:: NEW O R WORS ENED J OINT PA IN  Were fever or syste NO mic symptoms prese nt on the last day th e Subject Diary was completed?:	Initial Entry

090177e196ae3d4d\Final\Final On: 01-Apr-2021 04:30 (GMT)



Header Text: c4591001

Visit: V3\_MONTH1\_POSTVAX2\_L

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

Form Version: 10-Oct-2020 16:03

Form Status: Data Complete, Frozen, Verified

Site No: 1126

Site Name: (1126) Kaiser Permanente Santa Clara

Subject No: 11261244

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:09

2.h Symptom:

Date	Location	User	Value	Reason
Jan-27-2021 11:23:11 (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-27-2021 11:23:11 (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-27-2021 11:23:11 (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-27-2021 11:23:11 (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-27-2021 11:23:11 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Charlie Chao (b) (4)	<b>Data Entry:</b> Injection Site Reaction:: RE DN ESS  Were injection site reacti NO ons present on the last da y the Subject Diary was c ompleted?:	Initial Entry

090177e196ae3d4d\Final\Final On: 01-Apr-2021 04:30 (GMT)

Header Text: c4591001

Visit: V3\_MONTH1\_POSTVAX2\_L

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

Form Version: 10-Oct-2020 16:03

Form Status: Data Complete, Frozen, Verified

Site No: 1126

Site Name: (1126) Kaiser Permanente Santa Clara

Subject No: 11261244

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:09

5.a Injection Site Reaction:

Date	Location	User	Value	Reason
Jan-27-2021 11:23:11 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Charlie Chao (b) (4)	<u>Data Entry:</u> 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-27-2021 11:23:11 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Charlie Chao (b) (4)	<u>Data Entry:</u> NO	Initial Entry

5.b

Date	Location	User	Value	Reason
Jan-27-2021 11:23:11 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Charlie Chao (b) (4)	<u>Data Entry:</u> Injection Site Reaction:: SW ELL ING  Were injection site react NO ions present on the last day the Subject Diary w as completed?:	Initial Entry

5.b Injection Site Reaction:

Date	Location	User	Value	Reason
Jan-27-2021 11:23:11 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Charlie Chao (b) (4)	<u>Data Entry:</u> 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-27-2021 11:23:11 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Charlie Chao (b) (4)	<u>Data Entry:</u> NO	Initial Entry

090177e196ae3d4d\Final\Final On: 01-Apr-2021 04:30 (GMT)

Header Text: c4591001

Visit: V3\_MONTH1\_POSTVAX2\_L

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

Form Version: 10-Oct-2020 16:03

Form Status: Data Complete, Frozen, Verified

Site No: 1126

Site Name: (1126) Kaiser Permanente Santa Clara

Subject No: 11261244

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:09

5.c

Date	Location	User	Value	Reason
Jan-27-2021 11:23:11 (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

5.c Injection Site Reaction:

Date	Location	User	Value	Reason
Jan-27-2021 11:23:11 (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-27-2021 11:23:11 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Charlie Chao (b) (4)	<b>Data Entry:</b> NO	Initial Entry

090177e196ae3d4d\Final\Final On: 01-Apr-2021 04:30 (GMT)

**Header Text:** c4591001**Visit:** V3\_MONTH1\_POSTVAX2\_L**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF Audit Trail History**Form Version:** 22-Apr-2020 21:03**Form Status:** Data Complete, Frozen, Verified**Site No:** 1126**Site Name:** (1126) Kaiser Permanente Santa Clara**Subject No:** 11261244**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 11:09[Back to Form](#)**1. Data Origin**

Date	Location	User	Value	Reason
Jan-27-2021 11:23:22 (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-27-2021 11:23:22 (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
Jan-27-2021 11:23:31 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Jan-27-2021 11:23:22 (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-27-2021 11:23:22 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Charlie Chao (b) (4)	<b>Data Entry:</b> YES Date of Collection:  Jan/26/2021	Initial Entry

**5.a**

Date	Location	User	Value	Reason
Jan-27-2021 11:23:31 (UTC-08:00) Pacific	ACV0PFEINFP6000	Charlie Chao	<b>Data Entry:</b>	Initial Entry

Header Text: c4591001

Visit: V3\_MONTH1\_POSTVAX2\_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1126

Site Name: (1126) Kaiser Permanente Santa Clara

Subject No: 11261244

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:09

Time (US & Canada)

(b) (4)

Sample ID: BR7Z59

5.a Sample ID

Date	Location	User	Value	Reason
Jan-27-2021 11:23:31 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Charlie Chao (b) (4)	<u>Data Entry:</u> BR7Z59	Initial Entry

5.b

Date	Location	User	Value	Reason
Jan-27-2021 11:23:41 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Charlie Chao (b) (4)	<u>Data Entry:</u> Sample ID: BS7VP3	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Jan-27-2021 11:23:41 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Charlie Chao (b) (4)	<u>Data Entry:</u> BS7VP3	Initial Entry

5.c

Date	Location	User	Value	Reason
Jan-27-2021 11:23:50 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Charlie Chao (b) (4)	<u>Data Entry:</u> Sample ID: BRYLHB	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Jan-27-2021 11:23:50 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Charlie Chao (b) (4)	<u>Data Entry:</u> BRYLHB	Initial Entry

090177e196ae3d4d\Final\Final On: 01-Apr-2021 04:30 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

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

**Form Status:**

**Site No:** 1126

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

**Subject No:** 11261244

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 11:09

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Date	Location	User	Value	Reason
Jan-27-2021 11:24:29 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Charlie Chao (b) (4)	Form Created	

Header Text: c4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - NON STUDY  
VACCINATIONS - 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: 11261244

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:09

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**1. What is the medication identifier?**

Date	Location	User	Value	Reason
Jan-27-2021 11:24:29 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 1	Initial Entry

**2. Category:**

Date	Location	User	Value	Reason
Jan-27-2021 11:24:29 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> VACCINATIONS	Initial Entry

**3. Concomitant Medications Pre-specified:**

Date	Location	User	Value	Reason
Jan-27-2021 11:24:29 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> NO	Initial Entry

**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).*

Date	Location	User	Value	Reason
Jan-27-2021 11:24:29 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Charlie Chao (b) (4)	<b>Data Entry:</b> MEN-ACYW (MENVEO) (men ingococcal oligosaccharide AC YW-135)	Initial Entry

**5. Date:**

Date	Location	User	Value	Reason
Jan-27-2021 11:24:29 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Charlie Chao (b) (4)	<b>Data Entry:</b> Jan/26/2021	Initial Entry

090177e196ae3d4d\Final\Final On: 01-Apr-2021 04:30 (GMT)

**Header Text:** c4591001

**Visit:** End of Treatment - Unscheduled

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

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

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

**Site No:** 1126

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

**Subject No:** 11261244

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 11:09

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

Date	Location	User	Value	Reason
Jan-27-2021 11:24:04 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Charlie Chao (b) (4)	<b>Data Entry:</b> Jan/26/2021	Initial Entry

**2. Phase of Disposition:**

Date	Location	User	Value	Reason
Jan-27-2021 11:24:04 (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
Jan-27-2021 11:24:04 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Charlie Chao (b) (4)	<b>Data Entry:</b> COMPLETED	Initial Entry

090177e196ae3d4d\Final\Final On: 01-Apr-2021 04:30 (GMT)



**Header Text:** c4591001

**Visit:** Potential ReVax Initial Contact -  
Unscheduled

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

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

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

**Site No:** 1126

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

**Subject No:** 11261244

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 11:09

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*1. Date of Visit*

Date	Location	User	Value	Reason
Feb-04-2021 20:00:49 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Feb/4/2021	Initial Entry

**Header Text:** c4591001

**Visit:** Potential ReVax Initial Contact -  
Unscheduled

**Form Version:** 10-Dec-2020 02:25

**Site No:** 1126

**Subject No:** 11261244

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

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

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

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

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:09

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

Date	Location	User	Value	Reason
Feb-04-2021 20:00:56 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Participant is willing to return f or Vaccination 3 Participant is:  eligible per other protocol al lowance(s) and confirmed to have received only placebo at Vaccination 1/2	Initial Entry

**Header Text:** c4591001

**Visit:** Disposition - Unscheduled

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

**Site No:** 1126

**Subject No:** 11261244

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

**Form:** TREATMENT UNBLINDED - eCRF Audit Trail History

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

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

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:09

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**1. Date Treatment Unblinded :**

Date	Location	User	Value	Reason
Feb-04-2021 20:00:40 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Feb/4/2021	Initial Entry

**2. Primary Reason for Unblinding:**

Date	Location	User	Value	Reason
Feb-04-2021 20:00:40 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> ASSESS ELIGIBILITY FOR ADDITIONAL VACCINATIO N	Initial Entry

090177e196ae3d4d\Final\Final On: 01-Apr-2021 04:30 (GMT)

**Header Text:** c4591001

**Visit:** V101\_VAX3

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

**Site No:** 1126

**Subject No:** 11261244

**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):** 29-Mar-2021 11:09

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*1. Date of Visit*

Date	Location	User	Value	Reason
Feb-25-2021 15:55:46 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Charlie Chao (b) (4)	<u>Data Entry:</u> Feb/24/2021	Initial Entry

**Header Text:** c4591001

**Visit:** V101\_VAX3

**Form:** INFORMED CONSENT - FURTHER VACCINATION - eCRF  
Audit Trail History

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

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

**Site No:** 1126

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

**Subject No:** 11261244

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 11:09

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*1. Consent Was:*

Date	Location	User	Value	Reason
Feb-25-2021 15:55:55 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Charlie Chao (b) (4)	<b>Data Entry:</b> OBTAINED Date Written Consent Obtained  Feb/24/2021	Initial Entry

090177e196ae3d4d\Final\Final On: 01-Apr-2021 04:30 (GMT)

Header Text: c4591001

Visit: V101\_VAX3

Form: DISPOSITION - SCREENING FOR FURTHER VACCINATION - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:31

Form Status: Data Complete, Frozen, Verified

Site No: 1126

Site Name: (1126) Kaiser Permanente Santa Clara

Subject No: 11261244

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:09

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

Date	Location	User	Value	Reason
Feb-25-2021 15:56:22 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Charlie Chao (b) (4)	<u>Data Entry:</u> Feb/24/2021	Initial Entry

**2. Phase of Disposition:**

Date	Location	User	Value	Reason
Feb-25-2021 15:56:22 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> REPEAT SCREENING 1	Initial Entry

**3. Status:**

Date	Location	User	Value	Reason
Feb-25-2021 15:56:22 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Charlie Chao (b) (4)	<u>Data Entry:</u> COMPLETED	Initial Entry

090177e196ae3d4d\Final\Final On: 01-Apr-2021 04:30 (GMT)

Header Text: c4591001

Visit: V101\_VAX3

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: 11261244

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:09

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**1. Data Origin**

Date	Location	User	Value	Reason
Feb-25-2021 15:56:35 (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-25-2021 15:56:35 (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-25-2021 15:56:44 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Feb-25-2021 15:56:35 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Feb-25-2021 15:56:35 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Charlie Chao (b) (4)	<b>Data Entry:</b> YES Date of Collection:  Feb/24/2021	Initial Entry

**5.a**

Date	Location	User	Value	Reason
Feb-25-2021 15:56:44 (UTC-08:00) Pacific	ACV0PFEINFP6000	Charlie Chao	<b>Data Entry:</b>	Initial Entry

090177e196ae3d4d\Final\Final On: 01-Apr-2021 04:30 (GMT)

Header Text: c4591001

Visit: V101\_VAX3

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: 11261244

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:09

Time (US & Canada)

(b) (4)

Sample ID: BR7ZBC

5.a Sample ID

Date	Location	User	Value	Reason
Feb-25-2021 15:56:44 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Charlie Chao (b) (4)	<u>Data Entry:</u> BR7ZBC	Initial Entry

5.b

Date	Location	User	Value	Reason
Feb-25-2021 15:56:52 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Charlie Chao (b) (4)	<u>Data Entry:</u> Sample ID: BRYLVH	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Feb-25-2021 15:56:52 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Charlie Chao (b) (4)	<u>Data Entry:</u> BRYLVH	Initial Entry

5.c

Date	Location	User	Value	Reason
Feb-25-2021 15:56:59 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Charlie Chao (b) (4)	<u>Data Entry:</u> Sample ID: BRYLKD	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Feb-25-2021 15:56:59 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Charlie Chao (b) (4)	<u>Data Entry:</u> BRYLKD	Initial Entry

090177e196ae3d4d\Final\Final On: 01-Apr-2021 04:30 (GMT)



Header Text: c4591001

Visit: V101\_VAX3

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: 11261244

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:09

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**1. Data Origin**

Date	Location	User	Value	Reason
Feb-25-2021 15:57:08 (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-25-2021 15:57:08 (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
Feb-25-2021 15:57:19 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Feb-25-2021 15:57:08 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Feb-25-2021 15:57:08 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Charlie Chao (b) (4)	<b>Data Entry:</b> YES Date of Collection:  Feb/24/2021	Initial Entry

**5.a**

Date	Location	User	Value	Reason
Feb-25-2021 15:57:19 (UTC-08:00) Pacific	ACV0PFEINFP6000	Charlie Chao	<b>Data Entry:</b>	Initial Entry

090177e196ae3d4d\Final\Final On: 01-Apr-2021 04:30 (GMT)

**Header Text:** c4591001

**Visit:** V101\_VAX3

**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:** 11261244

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 11:09

Time (US & Canada)

(b) (4)

**Sample ID:** BR7Z0C

**5.a Sample ID**

Date	Location	User	Value	Reason
Feb-25-2021 15:57:19 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Charlie Chao (b) (4)	<u>Data Entry:</u> BR7Z0C	Initial Entry

Header Text: c4591001

Visit: V101\_VAX3

Form Version: 10-Dec-2020 02:26

Site No: 1126

Subject No: 11261244

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): 29-Mar-2021 11:09

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

Date	Location	User	Value	Reason
Feb-25-2021 15:57:37 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Charlie Chao (b) (4)	<u>Data Entry:</u> NO	Initial Entry

**2. Treatment Name**

Date	Location	User	Value	Reason
Feb-25-2021 15:57:37 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> BNT162b2	Initial Entry

**3. Formulation:**

Date	Location	User	Value	Reason
Feb-25-2021 15:57:37 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> INJECTION	Initial Entry

**4. Dose Date Time:**

Date	Location	User	Value	Reason
Feb-25-2021 15:57:37 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Charlie Chao (b) (4)	<u>Data Entry:</u> Feb/24/2021 14:15	Initial Entry

**5. Anatomical Location:**

Date	Location	User	Value	Reason
Feb-25-2021 15:57:37 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> DELTOID MUSCLE	Initial Entry

**6. Body Side:**

Date	Location	User	Value	Reason
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090177e196ae3d4d\Final\Final On: 01-Apr-2021 04:30 (GMT)

Header Text: c4591001

Visit: V101\_VAX3

Form Version: 10-Dec-2020 02:26

Site No: 1126

Subject No: 11261244

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): 29-Mar-2021 11:09

Feb-25-2021 15:57:37 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Charlie Chao (b) (4)	<b>Data Entry:</b> LEFT	Initial Entry
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**7. Route:**

Date	Location	User	Value	Reason
Feb-25-2021 15:57:37 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> INTRAMUSCULAR	Initial Entry

**8. Actual Dose:**

Date	Location	User	Value	Reason
Feb-25-2021 15:57:37 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 30.0	Initial Entry

**9. Unit:**

Date	Location	User	Value	Reason
Feb-25-2021 15:57:37 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> ug	Initial Entry

**10. Timeframe Subject Was Observed**

Date	Location	User	Value	Reason
Feb-25-2021 15:57:37 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 30 MINUTES	Initial Entry

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

Date	Location	User	Value	Reason
Feb-25-2021 15:57:37 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Charlie Chao (b) (4)	<b>Data Entry:</b> YES	Initial Entry

090177e196ae3d4d\Final\Final On: 01-Apr-2021 04:30 (GMT)

**Header Text:** c4591001

**Visit:** Subject Status - Unscheduled

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

**Site No:** 1126

**Subject No:** 11261244

**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):** 29-Mar-2021 11:09

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**1. Subject Status**

Date	Location	User	Value	Reason
Jan-27-2021 11:24:04 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> FOLLOW-UP	Initial Entry
Dec-03-2020 14:36:44 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> ENROLLED/RANDOMIZED	Initial Entry
Dec-03-2020 14:34:31 (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
Jan-27-2021 11:24:04 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> Jan/26/2021	Initial Entry
Dec-03-2020 14:36:44 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> Dec/2/2020	Initial Entry
Dec-03-2020 14:34:31 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> Dec/2/2020	Initial Entry

090177e196ae3d4d\Final\Final On: 01-Apr-2021 04:30 (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:** 11261244

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 11:09

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*1. Casebook Signature*

Date	Location	User	Value	Reason
Mar-11-2021 09:11:26 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [Redacted]	<b>Data Entry:</b> Click Here to Enable	Initial Entry