

Header Text: c4591001

Visit: COHORT_SELECTION

Form Version: 10-Oct-2020 16:01

Site No: 1126

Subject No: 11261263

Generated By: (b) (4)

Form: COHORT_SELECTION

Form Status: Data Complete, Frozen, Verified

Site Name: (1126) Kaiser Permanente Santa Clara

Subject Initials: ---

Generated Time (GMT): 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 Version: 22-Apr-2020 21:02

Site No: 1126

Subject No: 11261263

Generated By: (b) (4)

Form: MAIN INFORMED CONSENT

Form Status: Data Complete, Frozen, Verified

Site Name: (1126) Kaiser Permanente Santa Clara

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Informed Consent

1.	Consent Was:	OBTAINED Date Written Consent Obtained Dec/4/2020
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Header Text: c4591001

Visit: COHORT_SELECTION

Form Version: 15-Sep-2020 21:54

Site No: 1126

Subject No: 11261263

Generated By: (b) (4)

Form: DEMOGRAPHY

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](#)

Demography

1.	Subject ID	[11261263]
2.	Birth Date:	(b) (6) 2005
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: 11261263

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/4/2020
2.	Erroneous Visit	

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 10-Oct-2020 16:00

Site No: 1126

Subject No: 11261263

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

Exclusion Criteria Met

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

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 15-Sep-2020 21:52

Site No: 1126

Subject No: 11261263

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/4/2020
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: 11261263

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:	[Appendicitis]
	Start Date:	Oct/26/2016
	Ongoing:	NO End Date: Oct/26/2016

1.b	Line/MH Number:	[2]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Laparoscopic Appendectomy]
	Start Date:	Oct/26/2016
	Ongoing:	NO End Date: Oct/26/2016

090177e196ae4003\Final\Final On: 01-Apr-2021 05:28 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 15-Sep-2020 21:57

Site No: 1126

Subject No: 11261263

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:** 11261263**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/4/2020
2.	Weight:	[55.0]
3.	Unit:	kg
4.	Height:	[169.0]
5.	Unit:	cm
6.	Body Mass Index:	[19.3]

Vital Signs Details

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

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1126

Subject No: 11261263

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/4/2020
2.	Randomization Number:	[21033]
3.	Randomization Group:	[]

Header Text: c4591001**Visit:** V1_DAY1_VAX1_L**Form Version:** 22-Apr-2020 21:03**Site No:** 1126**Subject No:** 11261263**Generated By:** (b) (4)**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY**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	SERUM
3.	Sample Collected?	YES Date of Collection: Dec/4/2020
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[]

Aliquot

Please enter barcode for each aliquot.

5.a	Sample ID	[BPZZ25]
5.b	Sample ID	[BPZZ26]
5.c	Sample ID	[BS7VIFY]

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1126

Subject No: 11261263

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

Aliquot

Please enter barcode for each aliquot.

5.a	Sample ID	[BP28Z1]
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090177e196ae4003\Final\Final On: 01-Apr-2021 05:28 (GMT)

Header Text: c4591001**Visit:** V1_DAY1_VAX1_L**Form Version:** 22-Apr-2020 21:04**Site No:** 1126**Subject No:** 11261263**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/4/2020 16:51
5.	Anatomical Location:	DELTOID MUSCLE
6.	Body Side:	LEFT
7.	Route:	INTRAMUSCULAR
8.	Actual Dose:	[]
9.	Unit:	
10.	Timeframe Subject Was Observed	THE PROTOCOL SPECIFIED OBSERVATION PERIOD
11.	Was the subject observed for at least the protocol specified observation period after investigational product administration?	YES

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 06-Jul-2020 21:53

Site No: 1126

Subject No: 11261263

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: 11261263

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	

090177e196ae4003\Final\Final On: 01-Apr-2021 05:28 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 10-Oct-2020 16:03

Site No: 1126

Subject No: 11261263

Generated By: (b) (4)

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM
RESOLVED DATES

Form Status: Data Complete, Frozen, Verified

Site Name: (1126) Kaiser Permanente Santa Clara

Subject Initials: ---

Generated Time (GMT): 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

090177e196ae4003\Final\Final On: 01-Apr-2021 05:28 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 10-Oct-2020 16:03

Site No: 1126

Subject No: 11261263

Generated By: (b) (4)

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM
RESOLVED DATES

Form Status: Data Complete, Frozen, Verified

Site Name: (1126) Kaiser Permanente Santa Clara

Subject Initials: ---

Generated Time (GMT): 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

090177e196ae4003\Final\Final On: 01-Apr-2021 05:28 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 10-Dec-2020 02:27

Site No: 1126

Subject No: 11261263

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:	[98.3]
	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: 11261263

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	[BP2928]
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090177e196ae4003\Final\Final On: 01-Apr-2021 05:28 (GMT)

Header Text: c4591001**Visit:** V2_VAX2_L**Form Version:** 10-Dec-2020 02:26**Site No:** 1126**Subject No:** 11261263**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 15:39
5.	Anatomical Location:	DELTOID MUSCLE
6.	Body Side:	LEFT
7.	Route:	INTRAMUSCULAR
8.	Actual Dose:	[]
9.	Unit:	
10.	Timeframe Subject Was Observed	THE PROTOCOL SPECIFIED OBSERVATION PERIOD
11.	Was the subject observed for at least the protocol specified observation period after investigational product administration?	YES

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 1126

Subject No: 11261263

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/20/2021
2.	Erroneous Visit	

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form Version: 10-Oct-2020 16:03

Site No: 1126

Subject No: 11261263

Generated By: (b) (4)

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM
RESOLVED DATES

Form Status: Data Complete, Frozen, Verified

Site Name: (1126) Kaiser Permanente Santa Clara

Subject Initials: ---

Generated Time (GMT): 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

090177e196ae4003\Final\Final On: 01-Apr-2021 05:28 (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: 11261263

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

090177e196ae4003\Final\Final On: 01-Apr-2021 05:28 (GMT)

Header Text: c4591001**Visit:** V3_MONTH1_POSTVAX2_L**Form Version:** 22-Apr-2020 21:03**Site No:** 1126**Subject No:** 11261263**Generated By:** (b) (4)**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY**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	SERUM
3.	Sample Collected?	YES Date of Collection: Jan/20/2021
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	[BPZZBN]
5.b	Sample ID	[BPZZBP]
5.c	Sample ID	[BS7VN4]

Header Text: c4591001

Visit: V4_MONTH6_L

Form Version: 22-Apr-2020 21:02

Site No: 1126

Subject No: 11261263

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:** V4_MONTH6_L**Form Version:** 22-Apr-2020 21:03**Site No:** 1126**Subject No:** 11261263**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	[]
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Header Text: c4591001

Visit: V5_MONTH12_L

Form Version: 22-Apr-2020 21:02

Site No: 1126

Subject No: 11261263

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:** V5_MONTH12_L**Form Version:** 22-Apr-2020 21:03**Site No:** 1126**Subject No:** 11261263**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	[]
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Header Text: c4591001

Visit: V6_MONTH24_L

Form Version: 22-Apr-2020 21:02

Site No: 1126

Subject No: 11261263

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:** V6_MONTH24_L**Form Version:** 22-Apr-2020 21:03**Site No:** 1126**Subject No:** 11261263**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	[]
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Header Text: c4591001

Visit: POT_COVID_ILL - New Unscheduled Visit

Form: DATE OF VISIT - ILLNESS ONSET

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1126

Site Name: (1126) Kaiser Permanente Santa Clara

Subject No: 11261263

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 Visit**Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19**Form Version:** 20-Feb-2021 02:17**Form Status:** Not Started**Site No:** 1126**Site Name:** (1126) Kaiser Permanente Santa Clara**Subject No:** 11261263**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 Visit**Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB SELF**Form Version:** 22-Apr-2020 21:03**Form Status:** Not Started**Site No:** 1126**Site Name:** (1126) Kaiser Permanente Santa Clara**Subject No:** 11261263**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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Header Text: c4591001**Visit:** POT_COVID_ILL - New Unscheduled Visit**Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB**Form Version:** 22-Apr-2020 21:03**Form Status:** Not Started**Site No:** 1126**Site Name:** (1126) Kaiser Permanente Santa Clara**Subject No:** 11261263**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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Header Text: c4591001

Visit: POT_COVID_ILL - New Unscheduled Visit

Form: HEALTH CARE UTILIZATION

Form Version: 20-Feb-2021 02:19

Form Status: Not Started

Site No: 1126

Site Name: (1126) Kaiser Permanente Santa Clara

Subject No: 11261263

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

Health Care Utilization

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

090177e196ae4003\Final\Final On: 01-Apr-2021 05:28 (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: 11261263

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 Version: 22-Apr-2020 21:04

Site No: 1126

Subject No: 11261263

Generated By: (b) (4)

Form: DATE OF VISIT - ILLNESS CONVALESCENT

Form Status: Not Started

Site Name: (1126) Kaiser Permanente Santa Clara

Subject Initials: ---

Generated Time (GMT): 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_CONVA - New
Unscheduled Visit**Form Version:** 22-Apr-2020 21:03**Site No:** 1126**Subject No:** 11261263**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	[]
----	-----------	-----

Header Text: c4591001

Visit: POT_COVID_REPEAT_SWAB - New
Unscheduled Visit

Form: DATE OF VISIT - REPEAT SWAB

Form Version: 10-Oct-2020 15:57

Form Status: Not Started

Site No: 1126

Site Name: (1126) Kaiser Permanente Santa Clara

Subject No: 11261263

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
Unscheduled Visit**Form:** ELECTRONIC SAMPLE TRACKING - REPEAT SWAB**Form Version:** 10-Oct-2020 15:57**Form Status:** Not Started**Site No:** 1126**Site Name:** (1126) Kaiser Permanente Santa Clara**Subject No:** 11261263**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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Header Text: c4591001

Visit: Logs

Form: ADVERSE EVENT REPORT

Form Version: 22-Apr-2020 21:02

Site No: 1126

Site Name: (1126) Kaiser Permanente Santa Clara

Subject No: 11261263

Subject Initials: ---

Generated By: (b) (4)

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

#	Category	AE Identifier	Adverse Event	Start Date	Is the Adverse Event Still Ongoing	Form Instance
1.	ADVERSE EVENT	1	LEFT AXILLA LYMPH NODE SWELLING	Dec/10/2020 UNK:UNK	NO End Date Time: Dec/13/2020 UNK:UNK	Repeating Pages
2.	ADVERSE EVENT	2	RIGHT DISTAL RADIUS TO RUS FRACTURE	Dec/20/2020 UNK:UNK	NO End Date Time: Jan/20/2021 UNK:UNK	Repeating Pages
3.	ADVERSE EVENT	3	Mechanical Fall	Dec/20/2020 UNK:UNK	NO End Date Time: Dec/20/2020 UNK:UNK	Repeating Pages

090177e196ae4003\Final\Final On: 01-Apr-2021 05:28 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1126

Subject No: 11261263

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Frozen

Site Name: (1126) Kaiser Permanente Santa Clara

Subject Initials: ---

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

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[Form Audit Trail](#)

Adverse Event Report

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

090177e196ae4003\Final\Final On: 01-Apr-2021 05:28 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1126

Subject No: 11261263

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Frozen

Site Name: (1126) Kaiser Permanente Santa Clara

Subject Initials: ---

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

11.	Was a Concomitant Medication given?	NO
12.	Was a Non-Drug Treatment given?	NO
13.	What was the outcome of this adverse event?:	RECOVERED/RESOLVED
14.	Did the adverse event cause the subject to be discontinued from the study?	NO
15.	Serious Adverse Event Number: For Pfizer Use Only	[]

Header Text: c4591001**Visit:** Logs - Unscheduled**Form Version:** 22-Apr-2020 21:02**Site No:** 1126**Subject No:** 11261263**Generated By:** (b) (4)**Form:** ADVERSE EVENT REPORT**Form Status:** Data Complete, Frozen**Site Name:** (1126) Kaiser Permanente Santa Clara**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 11:09

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Adverse Event Report

1.	Category:	ADVERSE EVENT
2.	AE ID:	[2]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[RIGHT DISTAL RADIUS TORUS FRACTURE]
4.	Start Date Time:	Dec/20/2020 UNK:UNK
5.	Is the adverse event still ongoing?	NO End Date Time: Jan/20/2021 UNK:UNK
6.	Toxicity Grade:	2
7.	Is the adverse event serious? If Yes, NOTIFY PFIZER IMMEDIATELY. Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).	NO
8.	Is this adverse event the result of a study Medication Error? If Yes, record the type of medication error on the Medication Error Log.	NO
9.	Is this event related to study treatment:	NOT RELATED If Not Related to study treatment(s), this event is due to: OTHER If Other, specify: [MECHANICAL FALL]

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1126

Subject No: 11261263

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Frozen

Site Name: (1126) Kaiser Permanente Santa Clara

Subject Initials: ---

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

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

090177e196ae4003\Final\Final On: 01-Apr-2021 05:28 (GMT)

Header Text: c4591001**Visit:** Logs - Unscheduled**Form Version:** 22-Apr-2020 21:02**Site No:** 1126**Subject No:** 11261263**Generated By:** (b) (4)**Form:** ADVERSE EVENT REPORT**Form Status:** Data Complete, Frozen**Site Name:** (1126) Kaiser Permanente Santa Clara**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 11:09[Back to Form](#)[eCRF Audit Trail History](#)[Form Audit Trail](#)**Adverse Event Report**

1.	Category:	ADVERSE EVENT
2.	AE ID:	[3]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[Mechanical Fall]
4.	Start Date Time:	Dec/20/2020 UNK:UNK
5.	Is the adverse event still ongoing?	NO End Date Time: Dec/20/2020 UNK:UNK
6.	Toxicity Grade:	2
7.	Is the adverse event serious? If Yes, NOTIFY PFIZER IMMEDIATELY. Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).	NO
8.	Is this adverse event the result of a study Medication Error? If Yes, record the type of medication error on the Medication Error Log.	NO
9.	Is this event related to study treatment:	NOT RELATED If Not Related to study treatment(s), this event is due to: OTHER If Other, specify: [Snow boarding]

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1126

Subject No: 11261263

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Frozen

Site Name: (1126) Kaiser Permanente Santa Clara

Subject Initials: ---

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

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

Header Text: c4591001

Visit: Logs

Form: MEDICATION ERROR

Form Version: 17-Jul-2020 21:54

Site No: 1126

Site Name: (1126) Kaiser Permanente Santa Clara

Subject No: 11261263

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.						Repeating Pages

Header Text: c4591001**Visit:** Logs - Unscheduled**Form Version:** 17-Jul-2020 21:54**Site No:** 1126**Subject No:** 11261263**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	[]

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: 11261263

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.						Repeating Pages

Header Text: c4591001**Visit:** Logs - Unscheduled**Form:** CONCOMITANT MEDICATIONS - NON STUDY VACCINATIONS**Form Version:** 22-Apr-2020 21:03**Form Status:** Not Started**Site No:** 1126**Site Name:** (1126) Kaiser Permanente Santa Clara**Subject No:** 11261263**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 11:09[Back to Form](#)**Concomitant Medications**

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

Header Text: c4591001

Visit: Logs

Form: CONCOMITANT MEDICATIONS - PROHIBITED

Form Version: 22-Apr-2020 21:03

Site No: 1126

Site Name: (1126) Kaiser Permanente Santa Clara

Subject No: 11261263

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.						Repeating Pages

Header Text: c4591001**Visit:** Logs - Unscheduled**Form Version:** 22-Apr-2020 21:03**Site No:** 1126**Subject No:** 11261263**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[Back to Form](#)**Concomitant Medications**

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

Header Text: c4591001

Visit: Logs

Form: RADIATION TREATMENT

Form Version: 22-Apr-2020 21:02

Site No: 1126

Site Name: (1126) Kaiser Permanente Santa Clara

Subject No: 11261263

Subject Initials: ---

Generated By: (b) (4)

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

#	Categor y	Treatment Identifi er	Con Non-Drug Treatments Pre-specifi ed	Treatmen t	Start Dat e	Form Instance
1.						Repeating Pages

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1126

Subject No: 11261263

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: 11261263

Subject Initials: ---

Generated By: (b) (4)

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

#	Transfusion Type	Date of Transfusion	Form Instance
1.			Repeating Pages

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1126

Subject No: 11261263

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

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

Header Text: c4591001

Visit: Unplanned 1 - Unscheduled Visit on
Dec/06/2020

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: 11261263

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	Dec/6/2020
2.	Erroneous Visit	

Header Text: c4591001

Visit: Unplanned 1 - Unscheduled Visit on
Dec/06/2020

Form: UNPLANNED VISIT

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Frozen, Verified

Site No: 1126

Site Name: (1126) Kaiser Permanente Santa Clara

Subject No: 11261263

Subject Initials: ---

Generated By: (b) (4)

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

[eCRF Audit Trail History](#)

Unplanned Assessments

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

Header Text: c4591001

Visit: Unplanned 1 - Unscheduled Visit on
Dec/06/2020

Form: CONTACT OUTCOME - UNPLANNED

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Frozen, Verified

Site No: 1126

Site Name: (1126) Kaiser Permanente Santa Clara

Subject No: 11261263

Subject Initials: ---

Generated By: (b) (4)

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

[eCRF Audit Trail History](#)

Contact Outcome

1.	Contact Type:	TELEPHONE VISIT
2.	Was contact made?	YES Date of Contact: Dec/6/2020 Contact Outcome: VISIT NOT ARRANGED, REACTION NO LONGER PRESENT
3.	Comments:	[]

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: 11261263

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: 11261263

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:** 11261263**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?	

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:** 11261263**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: 11261263

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: V201_SURVEIL_CONSENT -
Unscheduled

Form: DATE OF VISIT

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Verified

Site No: 1126

Site Name: (1126) Kaiser Permanente Santa Clara

Subject No: 11261263

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	Mar/11/2021
2.	Erroneous Visit	

Header Text: c4591001

Visit: V201_SURVEIL_CONSENT -
Unscheduled

Form Version: 14-Jan-2021 02:29

Site No: 1126

Subject No: 11261263

Generated By: (b) (4)

Form: INFORMED CONSENT - ASYMPTOMATIC
SURVEILLANCE

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](#)

Informed Consent - Asymptomatic Surveillance

1.	Consent Was:	OBTAINED Date Written Consent Obtained Mar/11/2021
----	--------------	--

Header Text: c4591001**Visit:** V201_SURVEIL_CONSENT -
Unscheduled**Form Version:** 22-Apr-2020 21:03**Site No:** 1126**Subject No:** 11261263**Generated By:** (b) (4)**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY**Form Status:** Data Complete, Queries, 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	SERUM
3.	Sample Collected?	YES Date of Collection: Mar/12/2021
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	[BR7ZDH]
5.b	Sample ID	[BR7ZDJ]
5.c	Sample ID	[BRYLX2]

Header Text: c4591001**Visit:** V201_SURVEIL_CONSENT -
Unscheduled**Form Version:** 22-Apr-2020 21:03**Site No:** 1126**Subject No:** 11261263**Generated By:** (b) (4)**Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB**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](#)**Electronic Sample Tracking**

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Mar/11/2021
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	[BR7Z18]
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Header Text: c4591001

Visit: End of Treatment - Unscheduled

Form Version: 10-Dec-2020 02:29

Site No: 1126

Subject No: 11261263

Generated By: (b) (4)

Form: DISPOSITION - TREATMENT

Form Status: Data Complete, Frozen, Verified

Site Name: (1126) Kaiser Permanente Santa Clara

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Disposition - Treatment

1.	Date of Completion/Discontinuation/Death :	Jan/20/2021
2.	Phase of Disposition:	VACCINATION
3.	Status:	COMPLETED
4.	Specify Status:	[]

Header Text: c4591001

Visit: V202_SURVEIL_SWAB - New
Unscheduled Visit

Form Version: 14-Jan-2021 02:22

Site No: 1126

Subject No: 11261263

Generated By: (b) (4)

Form: DATE OF VISIT - ASYMPTOMATIC SURVEILLANCE

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	

COVID-19 Surveillance Visit

3.	COVID-19 Surveillance Visit:	
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Header Text: c4591001**Visit:** V202_SURVEIL_SWAB - New
Unscheduled Visit**Form Version:** 10-Oct-2020 15:57**Site No:** 1126**Subject No:** 11261263**Generated By:** (b) (4)**Form:** ELECTRONIC SAMPLE TRACKING - REPEAT 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	[]
----	-----------	-----

Header Text: c4591001**Visit:** Potential ReVax Initial Contact -
Unscheduled**Form:** DATE OF VISIT**Form Version:** 22-Apr-2020 21:02**Form Status:** Not Started**Site No:** 1126**Site Name:** (1126) Kaiser Permanente Santa Clara**Subject No:** 11261263**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:** Potential ReVax Initial Contact -
Unscheduled**Form:** FURTHER VACCINATION CONFIRMATION**Form Version:** 10-Dec-2020 02:25**Form Status:** Not Started**Site No:** 1126**Site Name:** (1126) Kaiser Permanente Santa Clara**Subject No:** 11261263**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 11:09**Further Vaccination Confirmation**

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

Header Text: c4591001

Visit: Follow-Up - Unscheduled

Form Version: 15-Sep-2020 21:53

Site No: 1126

Subject No: 11261263

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: 11261263

Generated By: (b) (4)

Form: TREATMENT UNBLINDED

Form Status: Not Started

Site Name: (1126) Kaiser Permanente Santa Clara

Subject Initials: ---

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

Treatment Unblinded

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

Header Text: c4591001

Visit: Disposition - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1126

Subject No: 11261263

Generated By: (b) (4)

Form: WITHDRAWAL OF CONSENT

Form Status: Not Started

Site Name: (1126) Kaiser Permanente Santa Clara

Subject Initials: ---

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

Withdrawal Of Consent

1.	Withdrawal of Consent Date :	//
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090177e196ae4003\Final\Final On: 01-Apr-2021 05:28 (GMT)

Header Text: c4591001

Visit: Disposition - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1126

Subject No: 11261263

Generated By: (b) (4)

Form: DEATH DETAILS CODED

Form Status: Not Started

Site Name: (1126) Kaiser Permanente Santa Clara

Subject Initials: ---

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: Subject Status - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1126

Subject No: 11261263

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/20/2021

090177e196ae4003\Final\Final On: 01-Apr-2021 05:28 (GMT)

Header Text: c4591001

Visit: Investigator Signature - Unscheduled

Form Version: 22-Apr-2020 21:04

Site No: 1126

Subject No: 11261263

Generated By: (b) (4)

Form: CASEBOOK SIGNATURE FORM

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](#)

Casebook Signature Form

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

Header Text: c4591001

Visit: Investigator Signature - Unscheduled

Form: CASEBOOK SIGNATURE FORM

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Verified

Site No: 1126

Site Name: (1126) Kaiser Permanente Santa Clara

Subject No: 11261263

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
- CRF_Sign_1

Name	Signature Meaning	Date	Type	Action
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Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 10-Oct-2020 16:00

Site No: 1126

Subject No: 11261263

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-07-2020 12:40:39 (UTC-08:00) Pacific Time (US & Canada)	(b) (4), (b) (6) [REDACTED]	Not Applicable

Header Text: c4591001

Visit: Investigator Signature - Unscheduled

Form Version: 22-Apr-2020 21:04

Site No: 1126

Subject No: 11261263

Generated By: (b) (4)

Form: CASEBOOK SIGNATURE FORM - Signature History

Form Status: Data Complete, Verified

Site Name: (1126) Kaiser Permanente Santa Clara

Subject Initials: ---

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

[Back to Form](#)

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

- CRF_Sign
- CRF_Sign_1

Name	Signature Meaning	Date	Type	Action
(b) (6)	N/A	Mar-12-2021 16:43:30 (UTC-08:00) Pacific Time (US & Canada)		Edit - All signatures invalidated

Affidavit:

N/A

Nicola Klein	Approved	Mar-11-2021 14:57:16 (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.

090177e196ae4003\Final\Final On: 01-Apr-2021 05:28 (GMT)

Header Text: c4591001

Visit: COHORT_SELECTION

Form Version: 10-Oct-2020 16:01

Site No: 1126

Subject No: 11261263

Generated By: (b) (4)

Form: COHORT SELECTION - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1126) Kaiser Permanente Santa Clara

Subject Initials: ---

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

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1. Select appropriate response - Protocol version

Date	Location	User	Value	Reason
Dec-07-2020 12:39:34 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 06 OCT 2020	Initial Entry

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

Date	Location	User	Value	Reason
Dec-07-2020 12:39:34 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: STAGE 3 COHORTS	Initial Entry

Header Text: c4591001

Visit: COHORT_SELECTION

Form Version: 22-Apr-2020 21:02

Site No: 1126

Subject No: 11261263

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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I. Consent Was:

Date	Location	User	Value	Reason
Dec-07-2020 12:39:42 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: OBTAINED Date Written Consent Obtained Dec/4/2020	Initial Entry

090177e196ae4003\Final\Final On: 01-Apr-2021 05:28 (GMT)

Header Text: c4591001

Visit: COHORT_SELECTION

Form Version: 15-Sep-2020 21:54

Site No: 1126

Subject No: 11261263

Generated By: (b) (4)

Form: DEMOGRAPHY - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1126) Kaiser Permanente Santa Clara

Subject Initials: ---

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

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1. Subject ID

Date	Location	User	Value	Reason
Dec-07-2020 12:39:23 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 11261263	Item copied from previous form

2. Birth Date:

Date	Location	User	Value	Reason
Dec-07-2020 12:39:20 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: (b) (6) 2005	Enrollment Entry

3. Sex:

Date	Location	User	Value	Reason
Dec-07-2020 12:39:54 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: MALE	Initial Entry

4. Ethnicity:

Date	Location	User	Value	Reason
Dec-07-2020 12:39:54 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NOT HISPANIC OR LATINO(A) OR OF SPANISH ORIGIN	Initial Entry

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

Date	Location	User	Value	Reason
Dec-07-2020 12:39:54 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: WHITE	Initial Entry

090177e196ae4003\Final\Final On: 01-Apr-2021 05:28 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:02

Site No: 1126

Subject No: 11261263

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-07-2020 12:40:28 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry: Dec/4/2020	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 15-Sep-2020 21:52

Site No: 1126

Subject No: 11261263

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-07-2020 12:40:54 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Dec/4/2020	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Dec-07-2020 12:40:54 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SCREENING	Initial Entry

3. Status:

Date	Location	User	Value	Reason
Dec-07-2020 12:40:54 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: COMPLETED	Initial Entry

090177e196ae4003\Final\Final On: 01-Apr-2021 05:28 (GMT)

Header Text: c4591001**Visit:** V1_DAY1_VAX1_L**Form Version:** 22-Apr-2020 21:03**Site No:** 1126**Subject No:** 11261263**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[Back to Form](#)**I.a**

Date	Location	User	Value	Reason
Dec-07-2020 12:41:20 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number 1 : Medical History T Appendicitis erm: Start Date: Oct/26/2016 Ongoing: NO End Date: Oct/26/2016	Initial Entry

I.a Line/MH Number:

Date	Location	User	Value	Reason
Dec-07-2020 12:41:20 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 1	Initial Entry

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

Date	Location	User	Value	Reason
Dec-07-2020 12:41:20 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Appendicitis	Initial Entry

I.a Start Date:

Date	Location	User	Value	Reason
Dec-07-2020 12:41:20 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Oct/26/2016	Initial Entry

I.a Ongoing:

Date	Location	User	Value	Reason
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Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1126

Subject No: 11261263

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

Dec-07-2020 12:41:20 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO End Date: Oct/26/2016	Initial Entry
---	-----------------	---------------------	--	---------------

1.b

Date	Location	User	Value	Reason
Dec-07-2020 12:41:41 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 2 Medical History Term: Laparoscopic Appendectomy Start Date: Oct/26/2016 Ongoing: NO End Date: Oct/26/2016	Initial Entry

090177e196ae4003\Final\Final On: 01-Apr-2021 05:28 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1126

Subject No: 11261263

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 Line/MH Number:

Date	Location	User	Value	Reason
Dec-07-2020 12:41:41 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 2	Initial Entry

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

Date	Location	User	Value	Reason
Dec-07-2020 12:41:41 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Laparoscopic Appendectomy	Initial Entry

1.b Start Date:

Date	Location	User	Value	Reason
Dec-07-2020 12:41:41 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Oct/26/2016	Initial Entry

1.b Ongoing:

Date	Location	User	Value	Reason
Dec-07-2020 12:41:41 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO End Date: Oct/26/2016	Initial Entry

090177e196ae4003\Final\Final On: 01-Apr-2021 05:28 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 15-Sep-2020 21:57

Site No: 1126

Subject No: 11261263

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-07-2020 12:41:59 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry: 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: 11261263

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-07-2020 12:42:33 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Dec/4/2020	Initial Entry

2. Weight:

Date	Location	User	Value	Reason
Dec-07-2020 12:42:33 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 55.0	Initial Entry

3. Unit:

Date	Location	User	Value	Reason
Dec-07-2020 12:42:33 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: kg	Initial Entry

4. Height:

Date	Location	User	Value	Reason
Dec-07-2020 12:42:33 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 169.0	Initial Entry

5. Unit:

Date	Location	User	Value	Reason
Dec-07-2020 12:42:33 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: cm	Initial Entry

6. Body Mass Index:

Date	Location	User	Value	Reason
Dec-07-2020 12:42:33	ACV0PFEINFP6000	auto calc	Data Entry:	Initial Entry

090177e196ae4003\Final\Final On: 01-Apr-2021 05:28 (GMT)

Header Text: c4591001**Visit:** V1_DAY1_VAX1_L**Form Version:** 10-Oct-2020 16:04**Site No:** 1126**Subject No:** 11261263**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(UTC-08:00) Pacific
Time (US & Canada)

(autocalc) 19.3

7.a

Date	Location	User	Value	Reason
Dec-07-2020 12:44:09 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Record Identifier 1 :: Temperature: 98.3 Temperature Unit: F Temperature Location: ORAL CAVITY	Transcription Error
Dec-07-2020 12:42:33 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Record Identifier 1 :: Temperature: 98.3 Temperature Unit: C Temperature Location: ORAL CAVITY	Initial Entry

7.a Record Identifier:

Date	Location	User	Value	Reason
Dec-07-2020 12:42:33 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 1	Initial Entry

7.a Temperature:

Date	Location	User	Value	Reason
Dec-07-2020 12:44:09 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Closed	Close Auto Query
Dec-07-2020 12:44:09 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query

Header Text: c4591001**Visit:** V1_DAY1_VAX1_L**Form Version:** 10-Oct-2020 16:04**Site No:** 1126**Subject No:** 11261263**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-07-2020 12:42:33 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Opened	Temperature is greater than or equal to 38.0 C, however 'FEVER OR ACUTE ILLNESS' is not ticked for the reason for temporary Delay of vaccination on VACCINATION CRF. Please review and update as appropriate.
Dec-07-2020 12:42:33 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	Temperature 98.3 C is outside of Normal Range 36.1 - 37.5 C.
Dec-07-2020 12:42:33 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 98.3	Initial Entry

7.a Unit:

Date	Location	User	Value	Reason
Dec-07-2020 12:44:09 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: F	Transcription Error
Dec-07-2020 12:42:33 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: C	Initial Entry

7.a Temperature Location:

Date	Location	User	Value	Reason
Dec-07-2020 12:42:33 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: ORAL CAVITY	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1126

Subject No: 11261263

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-07-2020 12:42:51 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Dec/4/2020	Initial Entry

2. Randomization Number:

Date	Location	User	Value	Reason
Dec-07-2020 12:42:51 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 21033	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1126

Subject No: 11261263

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

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1. Data Origin

Date	Location	User	Value	Reason
Dec-07-2020 12:43:01 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Dec-07-2020 12:43:01 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SERUM	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Dec-07-2020 12:43:08 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Dec-07-2020 12:43:01 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Dec-07-2020 12:43:01 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Collection: Dec/4/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Dec-07-2020 12:43:08 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BPZZ25	Initial Entry

090177e196ae4003\Final\Final On: 01-Apr-2021 05:28 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1126

Subject No: 11261263

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

5.a Sample ID

Date	Location	User	Value	Reason
Dec-07-2020 12:43:08 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BPZZ25	Initial Entry

5.b

Date	Location	User	Value	Reason
Dec-07-2020 12:43:17 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BPZZ26	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Dec-07-2020 12:43:17 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BPZZ26	Initial Entry

5.c

Date	Location	User	Value	Reason
Dec-07-2020 12:43:24 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BS7VFY	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Dec-07-2020 12:43:24 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BS7VFY	Initial Entry

090177e196ae4003\Final\On: 01-Apr-2021 05:28 (GMT)

Header Text: c4591001**Visit:** V1_DAY1_VAX1_L**Form Version:** 22-Apr-2020 21:03**Site No:** 1126**Subject No:** 11261263**Generated By:** (b) (4)**Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB - eCRF
Audit Trail History**Form Status:** Data Complete, Frozen, Verified**Site Name:** (1126) Kaiser Permanente Santa Clara**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 11:09[Back to Form](#)**1. Data Origin**

Date	Location	User	Value	Reason
Dec-07-2020 12:44:22 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Dec-07-2020 12:44:22 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: NASAL_SWAB	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Dec-07-2020 12:44:30 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Dec-07-2020 12:44:22 (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.
Dec-07-2020 12:44:22 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry: YES Date of Collection: Dec/4/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Dec-07-2020 12:44:30 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry: Sample ID: BP28Z1	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1126

Subject No: 11261263

Generated By: (b) (4)

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

Form Status: Data Complete, Frozen, Verified

Site Name: (1126) Kaiser Permanente Santa Clara

Subject Initials: ---

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

5.a Sample ID

Date	Location	User	Value	Reason
Dec-07-2020 12:44:30 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry: BP28Z1	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:04

Site No: 1126

Subject No: 11261263

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-07-2020 12:44:49 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2. Treatment Name

Date	Location	User	Value	Reason
Dec-07-2020 12:44:49 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: BLINDED THERAPY	Initial Entry

3. Formulation:

Date	Location	User	Value	Reason
Dec-07-2020 12:44:49 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INJECTION	Initial Entry

4. Dose Date Time:

Date	Location	User	Value	Reason
Dec-11-2020 00:55:13 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	unplanned contact added with date 6/Dec/2020
Dec-09-2020 08:21:06 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Please clarify query - as previously stated IF there is no DOV then NO other pages will populate; therefore CONTACT OUTCOME

Header Text: c4591001**Visit:** V1_DAY1_VAX1_L**Form Version:** 22-Apr-2020 21:04**Site No:** 1126**Subject No:** 11261263**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

				does not populate and data CAN NOT be entered.
Dec-08-2020 23:46:15 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Query 1: Reissued :Opened	PDQ RQ1: Thanks for response. Per Protocol, CONTACT OUTCOME should be completed. Thus, per response please consider updating UNPLANNED VISIT form by selecting WAS CONTACT MADE? As NO present on UNPLANNED VISIT (UNPL) form. Else clarify
Dec-08-2020 08:22:44 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Query 1: Answered	Please clarify query - per DEG there should be the option to mark NO for Unplanned visit due to the fact that the symptoms were no longer present and there was no visit arranged, but that is NOT the case. Waiting for direction from

Header Text: c4591001**Visit:** V1_DAY1_VAX1_L**Form Version:** 22-Apr-2020 21:04**Site No:** 1126**Subject No:** 11261263**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

				CRA
Dec-07-2020 22:22:33 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	PFE SDQ PROD (b) (4)	Query 1: Opened	PDQ: Subject has reported with Severe symptoms reactions on 2020 12 05 . Per protocol, subjects experiencing Grade 3 local reactions should be contacted. Please confirm if an UNPLANNED CONTACT was made and update the corresponding form as appropriate. (b) (4)
Dec-07-2020 12:44:49 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Dec/4/2020 16:51	Initial Entry

5. Anatomical Location:

Date	Location	User	Value	Reason
Dec-07-2020 12:44:49 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: DELTOID MUSCLE	Initial Entry

6. Body Side:

Date	Location	User	Value	Reason
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Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:04

Site No: 1126

Subject No: 11261263

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-07-2020 12:44:49 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: LEFT	Initial Entry
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7. Route:

Date	Location	User	Value	Reason
Dec-07-2020 12:44:49 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INTRAMUSCULAR	Initial Entry

10. Timeframe Subject Was Observed

Date	Location	User	Value	Reason
Dec-07-2020 12:44:49 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: THE PROTOCOL SPECIFIED O BSERVATION 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-07-2020 12:44:49 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

090177e196ae4003\Final\Final On: 01-Apr-2021 05:28 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 06-Jul-2020 21:53

Site No: 1126

Subject No: 11261263

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

Date	Location	User	Value	Reason
Dec-07-2020 12:44:56 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry: YES - REACTOGENICITY E-D IARY COLLECTED FOR THIS SUBJECT	Initial Entry

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 1126

Subject No: 11261263

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 19:38:55 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry: Dec/23/2020	Initial Entry

Header Text: c4591001**Visit:** V2_VAX2_L**Form Version:** 10-Oct-2020 16:03**Site No:** 1126**Subject No:** 11261263**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-27-2020 19:39:26 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry: NO	Initial Entry

2.a

Date	Location	User	Value	Reason
Dec-27-2020 19:39:26 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry: Symptom:: FE VE R Were fever or systemic sy N mptoms present on the las O t day the Subject Diary wa s completed?:	Initial Entry

2.a Symptom:

Date	Location	User	Value	Reason
Dec-27-2020 19:39:26 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry: FEVER	Initial Entry

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

Date	Location	User	Value	Reason
Dec-27-2020 19:39:26 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry: NO	Initial Entry

2.b

Date	Location	User	Value	Reason
Dec-27-2020 19:39:26 (UTC-08:00) Pacific	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry: Symptom:: FA	Initial Entry

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 10-Oct-2020 16:03

Site No: 1126

Subject No: 11261263

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

Time (US & Canada)		(b) (4), (b) (6)	TI GU E Were fever or systemic sy NO mptoms present on the la st day the Subject Diary was completed?:	
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2.b Symptom:

Date	Location	User	Value	Reason
Dec-27-2020 19:39:26 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> 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-27-2020 19:39:26 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

2.c

Date	Location	User	Value	Reason
Dec-27-2020 19:39:26 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Symptom:: HE AD AC HE Were fever or systemic s NO ymptoms present on the l ast day the Subject Diary was completed?:	Initial Entry

090177e196ae4003\Final\Final On: 01-Apr-2021 05:28 (GMT)

Header Text: c4591001**Visit:** V2_VAX2_L**Form Version:** 10-Oct-2020 16:03**Site No:** 1126**Subject No:** 11261263**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**2.c Symptom:**

Date	Location	User	Value	Reason
Dec-27-2020 19:39:26 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: HEADACHE	Initial Entry

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

Date	Location	User	Value	Reason
Dec-27-2020 19:39:26 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2.d

Date	Location	User	Value	Reason
Dec-27-2020 19:39:26 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom:: CH IL LS Were fever or systemic sy NO mptoms present on the las t day the Subject Diary w as completed?:	Initial Entry

2.d Symptom:

Date	Location	User	Value	Reason
Dec-27-2020 19:39:26 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: CHILLS	Initial Entry

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

Date	Location	User	Value	Reason
Dec-27-2020 19:39:26 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2.e

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 10-Oct-2020 16:03

Site No: 1126

Subject No: 11261263

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

Date	Location	User	Value	Reason
Dec-27-2020 19:39:26 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom:: VO MIT ING Were fever or systemic s NO ymptoms present on the l ast day the Subject Diary was completed?:	Initial Entry

2.e Symptom:

Date	Location	User	Value	Reason
Dec-27-2020 19:39:26 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: VOMITING	Initial Entry

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

Date	Location	User	Value	Reason
Dec-27-2020 19:39:26 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2.f

Date	Location	User	Value	Reason
Dec-27-2020 19:39:26 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom:: DIA RR HE A Were fever or systemic sy NO mptoms present on the la st day the Subject Diary was completed?:	Initial Entry

090177e196ae4003\Final\Final On: 01-Apr-2021 05:28 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 10-Oct-2020 16:03

Site No: 1126

Subject No: 11261263

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

2.f Symptom:

Date	Location	User	Value	Reason
Dec-27-2020 19:39:26 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: DIARRHEA	Initial Entry

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

Date	Location	User	Value	Reason
Dec-27-2020 19:39:26 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2.g

Date	Location	User	Value	Reason
Dec-27-2020 19:39:26 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom:: NEW OR WORSE NED MU SCLE PA IN Were fever or syste NO mic symptoms prese nt on the last day th e Subject Diary was completed?:	Initial Entry

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 10-Oct-2020 16:03

Site No: 1126

Subject No: 11261263

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

2.g Symptom:

Date	Location	User	Value	Reason
Dec-27-2020 19:39:26 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 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
Dec-27-2020 19:39:26 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2.h

Date	Location	User	Value	Reason
Dec-27-2020 19:39:26 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 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

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 10-Oct-2020 16:03

Site No: 1126

Subject No: 11261263

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

2.h Symptom:

Date	Location	User	Value	Reason
Dec-27-2020 19:39:26 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry: 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
Dec-27-2020 19:39:26 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry: NO	Initial Entry

3. Injection Site Location:

Date	Location	User	Value	Reason
Dec-27-2020 19:39:26 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: DELTOID MUSCLE	Initial Entry

4. Injection Site Body Side:

Date	Location	User	Value	Reason
Dec-27-2020 19:39:26 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry: LEFT	Initial Entry

5.a

Date	Location	User	Value	Reason
Dec-27-2020 19:39:26 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry: 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

5.a Injection Site Reaction:

Header Text: c4591001**Visit:** V2_VAX2_L**Form Version:** 10-Oct-2020 16:03**Site No:** 1126**Subject No:** 11261263**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

Date	Location	User	Value	Reason
Dec-27-2020 19:39:26 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry: REDNESS	Initial Entry

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

Date	Location	User	Value	Reason
Dec-27-2020 19:39:26 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry: NO	Initial Entry

5.b

Date	Location	User	Value	Reason
Dec-27-2020 19:39:26 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry: Injection Site Reaction:: SW ELL ING Were injection site reacti NO ons present on the last d ay the Subject Diary was completed?:	Initial Entry

5.b Injection Site Reaction:

Date	Location	User	Value	Reason
Dec-27-2020 19:39:26 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry: SWELLING	Initial Entry

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

Date	Location	User	Value	Reason
Dec-27-2020 19:39:26 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry: NO	Initial Entry

5.c

Date	Location	User	Value	Reason
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Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 10-Oct-2020 16:03

Site No: 1126

Subject No: 11261263

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

Dec-27-2020 19:39:26 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Injection Site Reaction: PAIN AT INJECTION SITE Were injection site reactions present on the last day the Subject Diary was completed?: NO	Initial Entry
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5.c Injection Site Reaction:

Date	Location	User	Value	Reason
Dec-27-2020 19:39:26 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: PAIN AT INJECTION SITE	Initial Entry

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

Date	Location	User	Value	Reason
Dec-27-2020 19:39:26 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

090177e196ae4003\Final\Final On: 01-Apr-2021 05:28 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 10-Dec-2020 02:27

Site No: 1126

Subject No: 11261263

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

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1. Date:

Date	Location	User	Value	Reason
Dec-27-2020 19:39:45 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Dec/23/2020	Initial Entry

2.a

Date	Location	User	Value	Reason
Dec-27-2020 19:39:45 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Record Identifier 1 :: Temperature: 98.3 Temperature Unit F : Temperature Loc ORAL CAV ation:: ITY	Initial Entry

2.a Record Identifier:

Date	Location	User	Value	Reason
Dec-27-2020 19:39:45 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 1	Initial Entry

2.a Temperature:

Date	Location	User	Value	Reason
Dec-27-2020 19:39:45 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 98.3	Initial Entry

2.a Unit:

Date	Location	User	Value	Reason
Dec-27-2020 19:39:45 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: F	Initial Entry

090177e196ae4003\Final\Final On: 01-Apr-2021 05:28 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 10-Dec-2020 02:27

Site No: 1126

Subject No: 11261263

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

2.a Temperature Location:

Date	Location	User	Value	Reason
Dec-27-2020 19:39:45 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry: ORAL CAVITY	Initial Entry

Header Text: c4591001**Visit:** V2_VAX2_L**Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB - eCRF
Audit Trail History**Form Version:** 22-Apr-2020 21:03**Form Status:** Data Complete, Frozen, Verified**Site No:** 1126**Site Name:** (1126) Kaiser Permanente Santa Clara**Subject No:** 11261263**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-27-2020 19:40:00 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Dec-27-2020 19:40:00 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: NASAL_SWAB	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Dec-27-2020 19:40:08 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Dec-27-2020 19:40:00 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Dec-27-2020 19:40:00 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry: YES Date of Collection: Dec/23/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Dec-27-2020 19:40:08 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry: Sample ID: BP2928	Initial Entry

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:03

Site No: 1126

Subject No: 11261263

Generated By: (b) (4)

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

Form Status: Data Complete, Frozen, Verified

Site Name: (1126) Kaiser Permanente Santa Clara

Subject Initials: ---

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

5.a Sample ID

Date	Location	User	Value	Reason
Dec-27-2020 19:40:08 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry: BP2928	Initial Entry

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 10-Dec-2020 02:26

Site No: 1126

Subject No: 11261263

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-27-2020 19:40:29 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2. Treatment Name

Date	Location	User	Value	Reason
Dec-27-2020 19:40:29 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: BLINDED THERAPY	Initial Entry

3. Formulation:

Date	Location	User	Value	Reason
Dec-27-2020 19:40:29 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INJECTION	Initial Entry

4. Dose Date Time:

Date	Location	User	Value	Reason
Dec-27-2020 19:40:29 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Dec/23/2020 15:39	Initial Entry

5. Anatomical Location:

Date	Location	User	Value	Reason
Dec-27-2020 19:40:29 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: DELTOID MUSCLE	Initial Entry

6. Body Side:

Date	Location	User	Value	Reason
Dec-27-2020 19:40:29	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Initial Entry

090177e196ae4003\Final\Final On: 01-Apr-2021 05:28 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 10-Dec-2020 02:26

Site No: 1126

Subject No: 11261263

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

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

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

LEFT

7. Route:

Date	Location	User	Value	Reason
Dec-27-2020 19:40:29 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INTRAMUSCULAR	Initial Entry

10. Timeframe Subject Was Observed

Date	Location	User	Value	Reason
Dec-27-2020 19:40:29 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: THE PROTOCOL SPECIFIED O BSERVATION 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-27-2020 19:40:29 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

090177e196ae4003\Final\Final On: 01-Apr-2021 05:28 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 1126

Subject No: 11261263

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-11-2021 13:33:12 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Feb-11-2021 11:23:06 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	DONE
Feb-11-2021 10:55:21 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	CLINQUERY - Visit 3 was completed on 20 Jan 21. However, the EOT page remains BLANK. Per guidelines, it is to be completed the same date. Please review and update.
Feb-11-2021 10:30:28 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Jan/20/2021	Initial Entry

090177e196ae4003\Final\Final On: 01-Apr-2021 05:28 (GMT)

Header Text: c4591001**Visit:** V3_MONTH1_POSTVAX2_L**Form Version:** 10-Oct-2020 16:03**Site No:** 1126**Subject No:** 11261263**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
Feb-11-2021 10:30:59 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry: NO	Initial Entry

2.a

Date	Location	User	Value	Reason
Feb-11-2021 10:30:59 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry: Symptom:: FE VE R Were fever or systemic sy N mptoms present on the las O t day the Subject Diary wa s completed?:	Initial Entry

2.a Symptom:

Date	Location	User	Value	Reason
Feb-11-2021 10:30:59 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry: FEVER	Initial Entry

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

Date	Location	User	Value	Reason
Feb-11-2021 10:30:59 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry: NO	Initial Entry

2.b

Date	Location	User	Value	Reason
Feb-11-2021 10:30:59 (UTC-08:00) Pacific	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry: Symptom:: FA	Initial Entry

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form Version: 10-Oct-2020 16:03

Site No: 1126

Subject No: 11261263

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

Time (US & Canada)		(b) (4), (b) (6)	TI GU E Were fever or systemic sy NO mptoms present on the la st day the Subject Diary was completed?:	
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2.b Symptom:

Date	Location	User	Value	Reason
Feb-11-2021 10:30:59 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> FATIGUE	Initial Entry

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

Date	Location	User	Value	Reason
Feb-11-2021 10:30:59 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

2.c

Date	Location	User	Value	Reason
Feb-11-2021 10:30:59 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Symptom:: HE AD AC HE Were fever or systemic s NO ymptoms present on the l ast day the Subject Diary was completed?:	Initial Entry

090177e196ae4003\Final\Final On: 01-Apr-2021 05:28 (GMT)

Header Text: c4591001**Visit:** V3_MONTH1_POSTVAX2_L**Form Version:** 10-Oct-2020 16:03**Site No:** 1126**Subject No:** 11261263**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**2.c Symptom:**

Date	Location	User	Value	Reason
Feb-11-2021 10:30:59 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: HEADACHE	Initial Entry

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

Date	Location	User	Value	Reason
Feb-11-2021 10:30:59 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2.d

Date	Location	User	Value	Reason
Feb-11-2021 10:30:59 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom:: CH IL LS Were fever or systemic sy NO mptoms present on the las t day the Subject Diary w as completed?:	Initial Entry

2.d Symptom:

Date	Location	User	Value	Reason
Feb-11-2021 10:30:59 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: CHILLS	Initial Entry

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

Date	Location	User	Value	Reason
Feb-11-2021 10:30:59 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2.e

Header Text: c4591001**Visit:** V3_MONTH1_POSTVAX2_L**Form Version:** 10-Oct-2020 16:03**Site No:** 1126**Subject No:** 11261263**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

Date	Location	User	Value	Reason
Feb-11-2021 10:30:59 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom:: VO MIT ING Were fever or systemic s NO ymptoms present on the l ast day the Subject Diary was completed?:	Initial Entry

2.e Symptom:

Date	Location	User	Value	Reason
Feb-11-2021 10:30:59 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: VOMITING	Initial Entry

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

Date	Location	User	Value	Reason
Feb-11-2021 10:30:59 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2.f

Date	Location	User	Value	Reason
Feb-11-2021 10:30:59 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom:: DIA RR HE A Were fever or systemic sy NO mptoms present on the la st day the Subject Diary was completed?:	Initial Entry

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form Version: 10-Oct-2020 16:03

Site No: 1126

Subject No: 11261263

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

2.f Symptom:

Date	Location	User	Value	Reason
Feb-11-2021 10:30:59 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: DIARRHEA	Initial Entry

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

Date	Location	User	Value	Reason
Feb-11-2021 10:30:59 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2.g

Date	Location	User	Value	Reason
Feb-11-2021 10:30:59 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom:: NEW OR WORSE NED MU SCLE PA IN Were fever or syste NO mic symptoms prese nt on the last day th e Subject Diary was completed?:	Initial Entry

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form Version: 10-Oct-2020 16:03

Site No: 1126

Subject No: 11261263

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

2.g Symptom:

Date	Location	User	Value	Reason
Feb-11-2021 10:30:59 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 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
Feb-11-2021 10:30:59 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2.h

Date	Location	User	Value	Reason
Feb-11-2021 10:30:59 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 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

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form Version: 10-Oct-2020 16:03

Site No: 1126

Subject No: 11261263

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

2.h Symptom:

Date	Location	User	Value	Reason
Feb-11-2021 10:30:59 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 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
Feb-11-2021 10:30:59 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

3. Injection Site Location:

Date	Location	User	Value	Reason
Feb-11-2021 10:30:59 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: DELTOID MUSCLE	Initial Entry

4. Injection Site Body Side:

Date	Location	User	Value	Reason
Feb-11-2021 10:30:59 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: LEFT	Initial Entry

5.a

Date	Location	User	Value	Reason
Feb-11-2021 10:30:59 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 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

5.a Injection Site Reaction:

Header Text: c4591001**Visit:** V3_MONTH1_POSTVAX2_L**Form Version:** 10-Oct-2020 16:03**Site No:** 1126**Subject No:** 11261263**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

Date	Location	User	Value	Reason
Feb-11-2021 10:30:59 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: REDNESS	Initial Entry

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

Date	Location	User	Value	Reason
Feb-11-2021 10:30:59 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

5.b

Date	Location	User	Value	Reason
Feb-11-2021 10:30:59 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Injection Site Reaction:: SW ELL ING Were injection site reacti NO ons present on the last d ay the Subject Diary was completed?:	Initial Entry

5.b Injection Site Reaction:

Date	Location	User	Value	Reason
Feb-11-2021 10:30:59 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: SWELLING	Initial Entry

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

Date	Location	User	Value	Reason
Feb-11-2021 10:30:59 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

5.c

Date	Location	User	Value	Reason
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Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form Version: 10-Oct-2020 16:03

Site No: 1126

Subject No: 11261263

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

Feb-11-2021 10:30:59 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Injection Site Reaction: PAIN AT INJECTION SITE Were injection site reactions present on the last day the Subject Diary was completed?: NO	Initial Entry
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5.c Injection Site Reaction:

Date	Location	User	Value	Reason
Feb-11-2021 10:30:59 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: PAIN AT INJECTION SITE	Initial Entry

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

Date	Location	User	Value	Reason
Feb-11-2021 10:30:59 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

090177e196ae4003\Final\Final On: 01-Apr-2021 05:28 (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:** 11261263**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
Feb-11-2021 10:31:33 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Feb-11-2021 10:31:33 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SERUM	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Feb-11-2021 10:31:56 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Feb-11-2021 10:31:33 (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-11-2021 10:31:33 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry: YES Date of Collection: Jan/20/2021	Initial Entry

5.a

Date	Location	User	Value	Reason
Feb-11-2021 10:31:56 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry: Sample ID: BPZZBN	Initial Entry

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form Version: 22-Apr-2020 21:03

Site No: 1126

Subject No: 11261263

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

5.a Sample ID

Date	Location	User	Value	Reason
Feb-11-2021 10:31:56 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BPZZBN	Initial Entry

5.b

Date	Location	User	Value	Reason
Feb-11-2021 10:32:10 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BPZZBP	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Feb-11-2021 10:32:10 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BPZZBP	Initial Entry

5.c

Date	Location	User	Value	Reason
Feb-11-2021 10:32:24 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BS7VN4	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Feb-11-2021 10:32:24 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BS7VN4	Initial Entry

090177e196ae4003\Final\Final On: 01-Apr-2021 05:28 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1126

Subject No: 11261263

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - Audit Trail

Form Status:

Site Name: (1126) Kaiser Permanente Santa Clara

Subject Initials: ---

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

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Date	Location	User	Value	Reason
Dec-30-2020 11:52:15 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Form Created	

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1126

Subject No: 11261263

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - Audit Trail

Form Status:

Site Name: (1126) Kaiser Permanente Santa Clara

Subject Initials: ---

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

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Date	Location	User	Value	Reason
Dec-30-2020 11:53:25 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Form Created	

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1126

Subject No: 11261263

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - Audit Trail

Form Status:

Site Name: (1126) Kaiser Permanente Santa Clara

Subject Initials: ---

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

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Date	Location	User	Value	Reason
Jan-05-2021 13:28:35 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Charlie Chao (b) (4)	Form Created	

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1126

Subject No: 11261263

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Frozen

Site Name: (1126) Kaiser Permanente Santa Clara

Subject Initials: ---

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

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1. Category:

Date	Location	User	Value	Reason
Dec-30-2020 11:52:15 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: ADVERSE EVENT	Initial Entry

2. AE ID:

Date	Location	User	Value	Reason
Dec-30-2020 11:52:15 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 1	Initial Entry

3. Adverse Event:

(If possible specify diagnosis, not individual symptoms)

Date	Location	User	Value	Reason
Dec-30-2020 11:52:15 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: LEFT AXILLA LYMPH NODE SWELLING	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason
Dec-30-2020 11:52:15 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Dec/10/2020 UNK:UNK	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Dec-30-2020 11:52:15 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO End Date Time: Dec/13/2020 UNK:UNK	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
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090177e196ae4003\Final\Final On: 01-Apr-2021 05:28 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1126

Subject No: 11261263

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Frozen

Site Name: (1126) Kaiser Permanente Santa Clara

Subject Initials: ---

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

Dec-30-2020 11:52:15 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 1	Initial Entry
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7. Is the adverse event serious?

If Yes, NOTIFY PFIZER IMMEDIATELY.

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

Date	Location	User	Value	Reason
Dec-30-2020 11:52:24 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

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

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

Date	Location	User	Value	Reason
Dec-30-2020 11:52:15 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Dec-30-2020 11:52:15 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: RELATED	Initial Entry

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Dec-30-2020 11:52:15 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NOT APPLICABLE	Initial Entry

11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
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090177e196ae4003\Final\Final On: 01-Apr-2021 05:28 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1126

Subject No: 11261263

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Frozen

Site Name: (1126) Kaiser Permanente Santa Clara

Subject Initials: ---

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

Dec-30-2020 11:52:15 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry
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12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Dec-30-2020 11:52:15 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

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

Date	Location	User	Value	Reason
Dec-30-2020 11:52:15 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: RECOVERED/RESOLVED	Initial Entry

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

Date	Location	User	Value	Reason
Dec-30-2020 11:52:15 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

090177e196ae4003\Final\Final On: 01-Apr-2021 05:28 (GMT)

Header Text: c4591001

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Form Version: 22-Apr-2020 21:02

Site No: 1126

Subject No: 11261263

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Frozen

Site Name: (1126) Kaiser Permanente Santa Clara

Subject Initials: ---

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1. Category:

Date	Location	User	Value	Reason
Dec-30-2020 11:53:25 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: ADVERSE EVENT	Initial Entry

2. AE ID:

Date	Location	User	Value	Reason
Dec-30-2020 11:53:25 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 2	Initial Entry

3. Adverse Event:

(If possible specify diagnosis, not individual symptoms)

Date	Location	User	Value	Reason
Dec-30-2020 11:53:25 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: RIGHT DISTAL RADIUS TOR US FRACTURE	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason
Dec-30-2020 11:53:25 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Dec/20/2020 UNK:UNK	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Feb-23-2021 13:47:19 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Feb-23-2021 08:33:11 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Closed	Close Auto Query

Header Text: c4591001**Visit:** Logs - Unscheduled**Form Version:** 22-Apr-2020 21:02**Site No:** 1126**Subject No:** 11261263**Generated By:** (b) (4)**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History**Form Status:** Data Complete, Frozen**Site Name:** (1126) Kaiser Permanente Santa Clara**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 11:09

Feb-23-2021 08:33:11 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry: NO End Date Time: Jan/20/2021 UNK:UNK	Transcription Error
Feb-23-2021 08:32:51 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Opened	For RIGHT DISTAL RADIUS TORUS FRACTURE End Date & Time 20/Jan/2020 UNK:UNK is before the Start Date & Time 20/Dec/2020 UNK:UNK.
Feb-23-2021 08:32:51 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	New Information
Feb-23-2021 08:32:51 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry: NO End Date Time: Jan/20/2020 UNK:UNK	New Information
Feb-22-2021 06:40:40 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Query 1: Opened	CLINQUERY - RIGHT DISTAL RADIUS FRACTURE (20 DEC 20) is still reported as ONGOING. Please confirm or enter END DATE if known.
Dec-30-2020 11:53:25 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry: YES	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
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Header Text: c4591001

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Form Version: 22-Apr-2020 21:02

Site No: 1126

Subject No: 11261263

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Frozen

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Subject Initials: ---

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

Dec-30-2020 11:53:25 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 2	Initial Entry
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7. Is the adverse event serious?

If Yes, NOTIFY PFIZER IMMEDIATELY.

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

Date	Location	User	Value	Reason
Dec-30-2020 11:53:25 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

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

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

Date	Location	User	Value	Reason
Dec-30-2020 11:53:25 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Jan-06-2021 13:47:43 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Jan-05-2021 11:02:44 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	AE WILL BE ADDED WHEN PI ASSIGNS CAUSALITY
Jan-04-2021 13:42:59 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	CLINQUERY - Fracture is reported as related to Mechanical Fall. However, the Fall is not reported as an AE. Per guidelines,

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Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Frozen

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				both the Fall and the resulting injury are to be reported. Please update.
Dec-30-2020 11:53:25 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NOT RELATED If Not Related to study treatment(s), this event is due to: OTHER If Other, specify: MECHANICAL FALL	Initial Entry

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Dec-30-2020 11:53:25 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NOT APPLICABLE	Initial Entry

11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
Dec-30-2020 11:53:25 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Dec-30-2020 11:53:25 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

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

Date	Location	User	Value	Reason
Feb-23-2021 08:35:18 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query

090177e196ae4003\Final\Final On: 01-Apr-2021 05:28 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

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Site No: 1126

Subject No: 11261263

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Frozen

Site Name: (1126) Kaiser Permanente Santa Clara

Subject Initials: ---

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

Feb-23-2021 08:35:18 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: RECOVERED/RESOLVED	New Information
Feb-23-2021 08:32:51 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	For AE RIGHT DISTAL RADIUS TORUS FRACTURE: Response to "What was the outcome of this adverse event?" is 'Recovering/Resolving' but AE End Date/Time is present.
Dec-30-2020 11:53:25 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: RECOVERING/RESOLVING	Initial Entry

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

Date	Location	User	Value	Reason
Dec-30-2020 11:53:25 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

090177e196ae4003\Final\Final On: 01-Apr-2021 05:28 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1126

Subject No: 11261263

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Frozen

Site Name: (1126) Kaiser Permanente Santa Clara

Subject Initials: ---

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

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1. Category:

Date	Location	User	Value	Reason
Jan-05-2021 13:28:35 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: ADVERSE EVENT	Initial Entry

2. AE ID:

Date	Location	User	Value	Reason
Jan-05-2021 13:28:35 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 3	Initial Entry

3. Adverse Event:

(If possible specify diagnosis, not individual symptoms)

Date	Location	User	Value	Reason
Jan-05-2021 13:28:35 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Charlie Chao (b) (4)	Data Entry: Mechanical Fall	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason
Jan-05-2021 13:28:35 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Charlie Chao (b) (4)	Data Entry: Dec/20/2020 UNK:UNK	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Jan-05-2021 13:28:35 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Charlie Chao (b) (4)	Data Entry: NO End Date Time: Dec/20/2020 UNK:UNK	Initial Entry

6. Toxicity Grade:

090177e196ae4003\Final\Final On: 01-Apr-2021 05:28 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1126

Subject No: 11261263

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Frozen

Site Name: (1126) Kaiser Permanente Santa Clara

Subject Initials: ---

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

Date	Location	User	Value	Reason
Jan-05-2021 13:28:35 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Charlie Chao (b) (4)	Data Entry: 2	Initial Entry

7. Is the adverse event serious?

If Yes, NOTIFY PFIZER IMMEDIATELY.

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

Date	Location	User	Value	Reason
Jan-05-2021 13:28:35 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Charlie Chao (b) (4)	Data Entry: NO	Initial Entry

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

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

Date	Location	User	Value	Reason
Jan-05-2021 13:28:35 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Charlie Chao (b) (4)	Data Entry: NO	Initial Entry

9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Jan-05-2021 13:28:35 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Charlie Chao (b) (4)	Data Entry: NOT RELATED If Not Related to study treatment (s), this event is due to: OTHER If Other, specify: Snow boarding	Initial Entry

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
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090177e196ae4003\Final\Final On: 01-Apr-2021 05:28 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1126

Subject No: 11261263

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Frozen

Site Name: (1126) Kaiser Permanente Santa Clara

Subject Initials: ---

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

Jan-05-2021 13:28:35 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Charlie Chao (b) (4)	Data Entry: NOT APPLICABLE	Initial Entry
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11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
Jan-05-2021 13:28:35 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Charlie Chao (b) (4)	Data Entry: NO	Initial Entry

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Jan-05-2021 13:28:35 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Charlie Chao (b) (4)	Data Entry: NO	Initial Entry

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

Date	Location	User	Value	Reason
Jan-05-2021 13:28:35 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Charlie Chao (b) (4)	Data Entry: RECOVERED/RESOLVED	Initial Entry

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

Date	Location	User	Value	Reason
Jan-05-2021 13:28:35 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Charlie Chao (b) (4)	Data Entry: NO	Initial Entry

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Header Text: c4591001

Visit: Unplanned 1 - Unscheduled Visit on
Dec/06/2020

Form Version: 22-Apr-2020 21:02

Site No: 1126

Subject No: 11261263

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-10-2020 09:11:34 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry: Dec/6/2020	Initial Entry

Header Text: c4591001**Visit:** Unplanned 1 - Unscheduled Visit on Dec/06/2020**Form:** UNPLANNED VISIT - eCRF Audit Trail History**Form Version:** 22-Apr-2020 21:04**Form Status:** Data Complete, Frozen, Verified**Site No:** 1126**Site Name:** (1126) Kaiser Permanente Santa Clara**Subject No:** 11261263**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 11:09[Back to Form](#)**I. Assessments**

Date	Location	User	Value	Reason
Dec-10-2020 09:12:32 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Dec-10-2020 09:11:45 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Contact Outcome is ticked however 'CONTACT OUTCOME' form is not entered. Please review and update as appropriate.
Dec-10-2020 09:11:45 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry: CONTACT OUTCOME	Initial Entry

Header Text: c4591001**Visit:** Unplanned 1 - Unscheduled Visit on Dec/06/2020**Form Version:** 22-Apr-2020 21:04**Site No:** 1126**Subject No:** 11261263**Generated By:** (b) (4)**Form:** CONTACT OUTCOME - UNPLANNED - 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. Contact Type:**

Date	Location	User	Value	Reason
Dec-10-2020 09:12:12 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: TELEPHONE VISIT	Initial Entry

2. Was contact made?

Date	Location	User	Value	Reason
Dec-10-2020 09:12:32 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Dec-10-2020 09:12:32 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Contact: Dec/6/2020 Contact Outcome: VISIT NOT ARRANGED, R EACTION NO LONGER P RESENT	Transcription Error
Dec-10-2020 09:12:12 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	Response to "Date of Contact" is missing.
Dec-10-2020 09:12:12 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Contact Outcome: VISIT NOT ARRANGED, R EACTION NO LONGER P RESENT	Initial Entry

Header Text: c4591001

Visit: V201_SURVEIL_CONSENT -
Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1126

Subject No: 11261263

Generated By: (b) (4)

Form: DATE OF VISIT - 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. Date of Visit

Date	Location	User	Value	Reason
Mar-12-2021 16:43:30 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Mar/11/2021	Initial Entry

Header Text: c4591001

Visit: V201_SURVEIL_CONSENT -
Unscheduled

Form Version: 14-Jan-2021 02:29

Site No: 1126

Subject No: 11261263

Generated By: (b) (4)

Form: INFORMED CONSENT - ASYMPTOMATIC
SURVEILLANCE - 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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I. Consent Was:

Date	Location	User	Value	Reason
Mar-12-2021 16:43:47 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: OBTAINED Date Written Consent Obtaine d Mar/11/2021	Initial Entry

Header Text: c4591001**Visit:** V201_SURVEIL_CONSENT -
Unscheduled**Form Version:** 22-Apr-2020 21:03**Site No:** 1126**Subject No:** 11261263**Generated By:** (b) (4)**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY -
eCRF Audit Trail History**Form Status:** Data Complete, Queries, 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
Mar-12-2021 16:44:31 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Mar-12-2021 16:44:31 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SERUM	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Mar-13-2021 01:15:43 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (b) (4)	Query 1: Op ened	DMW7698957;Date of Collection is not equal to Date of Visit. Please clarify or correct.
Mar-12-2021 16:44:31 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry : YES Date of C ollec tion: Ma r/1 2/2 02 1	Initial Entry

5.a

Header Text: c4591001**Visit:** V201_SURVEIL_CONSENT -
Unscheduled**Form Version:** 22-Apr-2020 21:03**Site No:** 1126**Subject No:** 11261263**Generated By:** (b) (4)**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY -
eCRF Audit Trail History**Form Status:** Data Complete, Queries, Verified**Site Name:** (1126) Kaiser Permanente Santa Clara**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 11:09

Date	Location	User	Value	Reason
Mar-12-2021 16:43:57 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BR7ZDH	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Mar-12-2021 16:43:57 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BR7ZDH	Initial Entry

5.b

Date	Location	User	Value	Reason
Mar-12-2021 16:44:08 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BR7ZDJ	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Mar-12-2021 16:44:08 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BR7ZDJ	Initial Entry

5.c

Date	Location	User	Value	Reason
Mar-12-2021 16:44:15 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BRYLX2	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Mar-12-2021 16:44:15 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BRYLX2	Initial Entry

Header Text: c4591001**Visit:** V201_SURVEIL_CONSENT -
Unscheduled**Form Version:** 22-Apr-2020 21:03**Site No:** 1126**Subject No:** 11261263**Generated By:** (b) (4)**Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB - 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[Back to Form](#)**1. Data Origin**

Date	Location	User	Value	Reason
Mar-12-2021 16:45:01 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Mar-12-2021 16:45:01 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: NASAL_SWAB	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Mar-12-2021 16:45:01 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry: YES Date of Collection: Mar/11/2021	Initial Entry

5.a

Date	Location	User	Value	Reason
Mar-12-2021 16:44:44 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry: Sample ID: BR7Z18	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Mar-12-2021 16:44:44 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry: BR7Z18	Initial Entry

Header Text: c4591001

Visit: End of Treatment - Unscheduled

Form Version: 10-Dec-2020 02:29

Site No: 1126

Subject No: 11261263

Generated By: (b) (4)

Form: DISPOSITION - TREATMENT - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1126) Kaiser Permanente Santa Clara

Subject Initials: ---

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

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1. Date of Completion/Discontinuation/Death :

Date	Location	User	Value	Reason
Feb-11-2021 11:22:47 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Jan/20/2021	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Feb-11-2021 11:22:47 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: VACCINATION	Initial Entry

3. Status:

Date	Location	User	Value	Reason
Feb-11-2021 11:22:47 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: COMPLETED	Initial Entry

Header Text: c4591001

Visit: Subject Status - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1126

Subject No: 11261263

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
Feb-11-2021 11:22:47 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: FOLLOW-UP	Initial Entry
Dec-07-2020 12:42:51 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: ENROLLED/RANDOMIZED	Initial Entry
Dec-07-2020 12:40:54 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SCREENED	Initial Entry

2. Subject Status Date

Date	Location	User	Value	Reason
Feb-11-2021 11:22:47 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Jan/20/2021	Initial Entry
Dec-07-2020 12:42:51 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Dec/4/2020	Initial Entry
Dec-07-2020 12:40:54 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Dec/4/2020	Initial Entry

090177e196ae4003\Final\Final On: 01-Apr-2021 05:28 (GMT)

Header Text: c4591001

Visit: Investigator Signature - Unscheduled

Form Version: 22-Apr-2020 21:04

Site No: 1126

Subject No: 11261263

Generated By: (b) (4)

Form: CASEBOOK SIGNATURE FORM - 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. Casebook Signature

Date	Location	User	Value	Reason
Mar-11-2021 09:53:54 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry: Click Here to Enable	Initial Entry