

Header Text: c4591001

Visit: COHORT_SELECTION

Form: COHORT_SELECTION

Form Version: 10-Oct-2020 16:01

Form Status: Data Complete, Frozen, Verified

Site No: 1130

Site Name: (1130) Kaiser Permanente Center For Health Research

Subject No: 11301081

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:25

[eCRF Audit Trail History](#)

Cohort Selection

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

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

Header Text: c4591001

Visit: COHORT_SELECTION

Form: MAIN INFORMED CONSENT

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen, Verified

Site No: 1130

Site Name: (1130) Kaiser Permanente Center For Health Research

Subject No: 11301081

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:25

[eCRF Audit Trail History](#)

Informed Consent

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

Header Text: c4591001

Visit: COHORT_SELECTION

Form: DEMOGRAPHY

Form Version: 15-Sep-2020 21:54

Form Status: Data Complete, Frozen, Verified

Site No: 1130

Site Name: (1130) Kaiser Permanente Center For Health Research

Subject No: 11301081

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:25

[eCRF Audit Trail History](#)

Demography

1.	Subject ID	[11301081]
2.	Birth Date:	(b) (6)/1967
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: 1130

Subject No: 11301081

Generated By: (b) (4)

Form: DATE OF VISIT

Form Status: Data Complete, Frozen, Verified

Site Name: (1130) Kaiser Permanente Center For Health Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:25

[eCRF Audit Trail History](#)

Date of Visit

1.	Date of Visit	Oct/16/2020
2.	Erroneous Visit	

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 10-Oct-2020 16:00

Site No: 1130

Subject No: 11301081

Generated By: (b) (4)

Form: INCLUSION/EXCLUSION CRITERIA

Form Status: Data Complete, Frozen, Verified

Site Name: (1130) Kaiser Permanente Center For Health Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:25

Form Comments

Inclusion Criteria Not Met

1.	Description of Inclusion Criterion Not Met	Not Applicable
----	--	----------------

Exclusion Criteria Met

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

Visit: V1_DAY1_VAX1_L

Form Version: 15-Sep-2020 21:52

Site No: 1130

Subject No: 11301081

Generated By: (b) (4)

Form: DISPOSITION - SCREENING

Form Status: Data Complete, Frozen, Verified

Site Name: (1130) Kaiser Permanente Center For Health Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:25

[eCRF Audit Trail History](#)

Disposition - Screening

1.	Date of Completion/Discontinuation /Death	Oct/16/2020
2.	Phase of Disposition:	SCREENING
3.	Status:	COMPLETED
4.	Specify Status:	[]

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1130

Subject No: 11301081

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY

Form Status: Data Complete, Frozen, Verified

Site Name: (1130) Kaiser Permanente Center For Health Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:25

[eCRF Audit Trail History](#)

Medical History Details

1.a	Line/MH Number:	[1]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[History of Alcoholism]
	Start Date:	Mar/28/2000
	Ongoing:	NO End Date: Jun/13/2016
1.b	Line/MH Number:	[2]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Hypertension]
	Start Date:	Apr/1/2003
	Ongoing:	YES
1.c	Line/MH Number:	[3]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Moderate Persistent Asthma]
	Start Date:	Sep/4/2015
	Ongoing:	YES
1.d	Line/MH Number:	[4]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Cough]
	Start Date:	Jan/1/1982
	Ongoing:	YES

090177e196ae3d43\Final\Final On: 01-Apr-2021 04:28 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1130

Subject No: 11301081

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY

Form Status: Data Complete, Frozen, Verified

Site Name: (1130) Kaiser Permanente Center For Health Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:25

1.e	Line/MH Number:	[5]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[obstructive sleep apnea]
	Start Date:	Jun/8/2011
	Ongoing:	YES
1.f	Line/MH Number:	[6]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[LIPID METABOLISM DISORDER]
	Start Date:	Mar/26/2018
	Ongoing:	YES
1.g	Line/MH Number:	[7]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[VASECTOMY]
	Start Date:	Dec/19/2002
	Ongoing:	NO End Date: Dec/19/2002
1.h	Line/MH Number:	[8]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Compression injury dorsum right fifth Carpometacarpal joint]
	Start Date:	Dec/3/2008
	Ongoing:	NO End Date: Dec/3/2009

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Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1130

Subject No: 11301081

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY

Form Status: Data Complete, Frozen, Verified

Site Name: (1130) Kaiser Permanente Center For Health Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:25

1.i	Line/MH Number:	[9]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[focal arthritis of dorsum right fifth Carpometacarpal joint]
	Start Date:	Dec/3/2008
	Ongoing:	NO End Date: Dec/3/2009

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Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 15-Sep-2020 21:57

Site No: 1130

Subject No: 11301081

Generated By: (b) (4)

Form: HIV STATUS

Form Status: Data Complete, Frozen, Verified

Site Name: (1130) Kaiser Permanente Center For Health Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:25

[eCRF Audit Trail History](#)

HIV Status

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

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 10-Oct-2020 16:04

Site No: 1130

Subject No: 11301081

Generated By: (b) (4)

Form: VITAL SIGNS - BASELINE

Form Status: Data Complete, Frozen, Verified

Site Name: (1130) Kaiser Permanente Center For Health Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:25

[eCRF Audit Trail History](#)

Vital Signs

1.	Date:	Oct/16/2020
2.	Weight:	[93.1]
3.	Unit:	kg
4.	Height:	[177.2]
5.	Unit:	cm
6.	Body Mass Index:	[29.6]

Vital Signs Details

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

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Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1130

Subject No: 11301081

Generated By: (b) (4)

Form: RANDOMIZATION

Form Status: Data Complete, Frozen, Verified

Site Name: (1130) Kaiser Permanente Center For Health Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:25

[eCRF Audit Trail History](#)

Disposition

1.	Randomization Date :	Oct/16/2020
2.	Randomization Number:	[109109]
3.	Randomization Group:	[]

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1130

Site Name: (1130) Kaiser Permanente Center For Health Research

Subject No: 11301081

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:25

[eCRF Audit Trail History](#)

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	SERUM
3.	Sample Collected?	YES Date of Collection: Oct/16/2020
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[]

Aliquot

Please enter barcode for each aliquot.

5.a	Sample ID	[BR8MVG]
5.b	Sample ID	[BR8MVH]
5.c	Sample ID	[BPHV1R]
5.d	Sample ID	[BPHV1S]
5.e	Sample ID	[BS6ZSG]

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Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1130

Subject No: 11301081

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB

Form Status: Data Complete, Frozen, Verified

Site Name: (1130) Kaiser Permanente Center For Health Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:25

[eCRF Audit Trail History](#)

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Oct/16/2020
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[]

Aliquot

Please enter barcode for each aliquot.

5.a	Sample ID	[BR8MTZ]
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090177e196ae3d43\Final\Final On: 01-Apr-2021 04:28 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:04

Site No: 1130

Subject No: 11301081

Generated By: (b) (4)

Form: VACCINATION

Form Status: Data Complete, Frozen, Verified

Site Name: (1130) Kaiser Permanente Center For Health Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:25

[eCRF Audit Trail History](#)

Vaccination

1.	Was there a temporary delay of vaccination?	NO
2.	Treatment Name	[BLINDED THERAPY]
3.	Formulation:	INJECTION
4.	Dose Date Time:	Oct/16/2020 11:30
5.	Anatomical Location:	DELTOID MUSCLE
6.	Body Side:	LEFT
7.	Route:	INTRAMUSCULAR
8.	Actual Dose:	[]
9.	Unit:	
10.	Timeframe Subject Was Observed	THE PROTOCOL SPECIFIED OBSERVATION PERIOD
11.	Was the subject observed for at least the protocol specified observation period after investigational product administration?	YES

090177e196ae3d43\Final\Final On: 01-Apr-2021 04:28 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 06-Jul-2020 21:53

Site No: 1130

Subject No: 11301081

Generated By: (b) (4)

Form: REACTOGENICITY DIARY

Form Status: Data Complete, Frozen, Verified

Site Name: (1130) Kaiser Permanente Center For Health Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:25

[eCRF Audit Trail History](#)

Reactogenicity Diary

1.	Select appropriate response - Reactogenicity diary collection	NO - REACTOGENICITY E-DIARY NOT COLLECTED FOR THIS SUBJECT
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Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 1130

Subject No: 11301081

Generated By: (b) (4)

Form: DATE OF VISIT

Form Status: Data Complete, Frozen, Verified

Site Name: (1130) Kaiser Permanente Center For Health Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:25

[eCRF Audit Trail History](#)

Date of Visit

1.	Date of Visit	Nov/6/2020
2.	Erroneous Visit	

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 10-Oct-2020 16:01

Site No: 1130

Subject No: 11301081

Generated By: (b) (4)

Form: VITAL SIGNS - TEMP

Form Status: Data Complete, Frozen, Verified

Site Name: (1130) Kaiser Permanente Center For Health Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:25

[eCRF Audit Trail History](#)

Vital Signs

1.	Date:	Nov/6/2020
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Vital Signs Details

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

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:03

Site No: 1130

Subject No: 11301081

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB

Form Status: Data Complete, Frozen, Verified

Site Name: (1130) Kaiser Permanente Center For Health Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:25

[eCRF Audit Trail History](#)

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Nov/6/2020
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	[BR8MXT]
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090177e196ae3d43\Final\Final On: 01-Apr-2021 04:28 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1130

Subject No: 11301081

Generated By: (b) (4)

Form: VACCINATION

Form Status: Data Complete, Frozen, Verified

Site Name: (1130) Kaiser Permanente Center For Health Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:25

[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:	Nov/6/2020 09:04
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

090177e196ae3d43\Final\Final On: 01-Apr-2021 04:28 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form: DATE OF VISIT

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen, Verified

Site No: 1130

Site Name: (1130) Kaiser Permanente Center For Health Research

Subject No: 11301081

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:25

[eCRF Audit Trail History](#)

Date of Visit

1.	Date of Visit	Dec/4/2020
2.	Erroneous Visit	

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1130

Site Name: (1130) Kaiser Permanente Center For Health Research

Subject No: 11301081

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:25

[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	[BPOX8L]
5.b	Sample ID	[BPOX8M]
5.c	Sample ID	[BS701X]
5.d	Sample ID	[BS701Y]
5.e	Sample ID	[BS701Z]

090177e196ae3d43\Final\Final On: 01-Apr-2021 04:28 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled **Form:** DATE OF VISIT - ILLNESS ONSET
Visit on Feb/10/2021

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1130

Site Name: (1130) Kaiser Permanente Center For Health Research

Subject No: 11301081

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:25

[eCRF Audit Trail History](#)

Date of Visit

1.	Date of Visit	Feb/10/2021
2.	Erroneous Visit	

COVID-19 Illness Visit

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

Visit: POT_COVID_ILL 1 - Unscheduled
Visit on Feb/10/2021

Form: SIGNS AND SYMPTOMS OF POTENTIAL COVID-19

Form Version: 14-Jan-2021 02:23

Form Status: Data Complete

Site No: 1130

Site Name: (1130) Kaiser Permanente Center For Health Research

Subject No: 11301081

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:25

[eCRF Audit Trail History](#)

Signs and Symptoms

1.	Date of Assessment:	Feb/10/2021
2.	Date of First Symptom Started:	Feb/9/2021
3.	Symptoms Ongoing?	NO
	Date of Last Symptom Resolved:	Feb/12/2021

Symptoms

4.a	Symptoms:	FEVER
	Was symptom present?	NO
4.b	Symptoms:	NEW OR INCREASED COUGH
	Was symptom present?	NO
4.c	Symptoms:	NEW OR INCREASED SHORTNESS OF BREATH
	Was symptom present?	NO
4.d	Symptoms:	CHILLS
	Was symptom present?	NO
4.e	Symptoms:	NEW OR INCREASED MUSCLE PAIN
	Was symptom present?	NO
4.f	Symptoms:	NEW LOSS OF TASTE OR SMELL
	Was symptom present?	NO
4.g	Symptoms:	NEW OR INCREASED SORE THROAT
	Was symptom present?	NO

090177e196ae3d43\Final\Final On: 01-Apr-2021 04:28 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled
Visit on Feb/10/2021

Form: SIGNS AND SYMPTOMS OF POTENTIAL COVID-19

Form Version: 14-Jan-2021 02:23

Form Status: Data Complete

Site No: 1130

Site Name: (1130) Kaiser Permanente Center For Health Research

Subject No: 11301081

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:25

4.h	Symptoms:	DIARRHEA
	Was symptom present?	YES
4.i	Symptoms:	VOMITING
	Was symptom present?	NO
Symptoms - Other		
5.	Symptoms - Other Text:	[]

Header Text: c4591001

Visit: POT_COVID_ILL 1

Form: MICROBIOLOGY SPECIMEN

Form Version: 06-Jul-2020 21:54

Site No: 1130

Site Name: (1130) Kaiser Permanente Center For Health Research

Subject No: 11301081

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:25

#	Date of Collection	Specimen Type	Specimen Collection Location	Assay Code and Description	Device Type	Form Instance
1.	Not Applicable	Not Applicable	Not Applicable	Not Applicable	Not Applicable	Repeating Pages

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled **Form:** MICROBIOLOGY SPECIMEN

Visit on Feb/10/2021

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen

Site No: 1130

Site Name: (1130) Kaiser Permanente Center For Health Research

Subject No: 11301081

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:25

[Back to Form](#)

[Form Comments](#)

[eCRF Audit Trail History](#)

Microbiology Specimen

1.	Actual Date of Collection:	Not Applicable _____ //	Comments
2.	Specimen Type:	Not Applicable _____	Comments
3.	Specimen Collection Location:	Not Applicable _____	Comments
4.	Assay Code and Description:	Not Applicable _____	Comments
5.	Device Type:	Not Applicable _____	Comments
6.	Trade Name:	Not Applicable _____	Comments
7.	Test Result:	Not Applicable _____	Comments
8.	Comments/Findings/Details:	Not Applicable _____ []	Comments
9.	Trade Name Other, Specify:	Not Applicable _____ []	Comments

090177e196ae3d43\Final\Final On: 01-Apr-2021 04:28 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled
Visit on Feb/10/2021

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB
SELF

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1130

Site Name: (1130) Kaiser Permanente Center For Health Research

Subject No: 11301081

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:25

[eCRF Audit Trail History](#)

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB_SELF
3.	Sample Collected?	YES Date of Collection: Feb/13/2021
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	[RW84037]
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090177e196ae3d43\Final\Final On: 01-Apr-2021 04:28 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled
Visit on Feb/10/2021

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1130

Site Name: (1130) Kaiser Permanente Center For Health Research

Subject No: 11301081

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:25

[eCRF Audit Trail History](#)

Electronic Sample Tracking

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

Aliquot

Please enter barcode for each aliquot.

5.	Sample ID	[]
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090177e196ae3d43\Final\Final On: 01-Apr-2021 04:28 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled **Form:** HEALTH CARE UTILIZATION

Visit on Feb/10/2021

Form Version: 14-Jan-2021 02:24

Form Status: Data Complete

Site No: 1130

Site Name: (1130) Kaiser Permanente Center For Health Research

Subject No: 11301081

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:25

[eCRF Audit Trail History](#)

Health Care Utilization

1.a	Physician or Healthcare Professional:	SPECIALIST
	Occurrence of Visits or Contacts:	NO
1.b	Physician or Healthcare Professional:	EMERGENCY ROOM
	Occurrence of Visits or Contacts:	NO
1.c	Physician or Healthcare Professional:	PRIMARY CARE PHYSICIAN
	Occurrence of Visits or Contacts:	NO
1.d	Physician or Healthcare Professional:	URGENT CARE
	Occurrence of Visits or Contacts:	NO
1.e	Physician or Healthcare Professional:	TELEPHONE CONSULTATION
	Occurrence of Visits or Contacts:	NO
1.f	Physician or Healthcare Professional:	OTHER
	Occurrence of Visits or Contacts:	NO

Health Care Utilization Other

090177e196ae3d43\Final\Final On: 01-Apr-2021 04:28 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled **Form:** HEALTH CARE UTILIZATION

Visit on Feb/10/2021

Form Version: 14-Jan-2021 02:24

Form Status: Data Complete

Site No: 1130

Site Name: (1130) Kaiser Permanente Center For Health Research

Subject No: 11301081

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:25

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

Health Care Utilization

3.	Has the subject been hospitalized due to potential COVID-19 illness?	NO
----	--	----

Header Text: c4591001

Visit: POT_COVID_ILL 1

Form: RESPIRATORY TREATMENT

Form Version: 06-Jul-2020 21:53

Site No: 1130

Site Name: (1130) Kaiser Permanente Center For Health Research

Subject No: 11301081

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:25

#	Treatment Identifier	Con Non-Drug Treatments Pre-specified	Treatment	Treatment	Start Date	Form Instance
1.						Repeating Pages

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled **Form:** RESPIRATORY TREATMENT

Visit on Feb/10/2021

Form Version: 06-Jul-2020 21:53

Form Status: Not Started

Site No: 1130

Site Name: (1130) Kaiser Permanente Center For Health Research

Subject No: 11301081

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:25

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Respiratory Treatment

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

090177e196ae3d43\Final\Final On: 01-Apr-2021 04:28 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled **Form:** ILLNESS DETAILS

Visit on Feb/10/2021

Form Version: 06-Jul-2020 21:52 **Form Status:** Data Complete

Site No: 1130

Site Name: (1130) Kaiser Permanente Center For Health Research

Subject No: 11301081

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:25

[eCRF Audit Trail History](#)

Illness Details

1.	Category of Clinical Event:	POTENTIAL COVID-19 ILLNESS
2.	Was a diagnosis obtained for Potential COVID-19 Illness?	NO
3.	Toxicity Grade:	2

Header Text: c4591001

Visit: POT_COVID_ILL 1

Form: ILLNESS DETAILS - SEVERE

Form Version: 17-Jul-2020 21:55

Site No: 1130

Site Name: (1130) Kaiser Permanente Center For Health Research

Subject No: 11301081

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:25

#	Category of Clinical Event:	Subcategory of Clinical Event	Diagnosis Obtained	Toxicity Grade	Form Instance
1.					Repeating Pages

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled **Form:** ILLNESS DETAILS - SEVERE

Visit on Feb/10/2021

Form Version: 17-Jul-2020 21:55

Form Status: Not Started

Site No: 1130

Site Name: (1130) Kaiser Permanente Center For Health Research

Subject No: 11301081

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:25

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Illness Details

1.	Category of Clinical Event:	
2.	Subcategory of Clinical Event:	
3.	Was a diagnosis obtained?	
4.	Toxicity Grade:	

Header Text: c4591001

Visit: POT_COVID_ILL 1

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY

Form Version: 10-Oct-2020 15:58

Site No: 1130

Site Name: (1130) Kaiser Permanente Center For Health Research

Subject No: 11301081

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:25

#	Category for Lab Test	Vendor Name	Collection Date:	Specimen Type	Lab Result			Form Instance
1.					Sponsor-Defined Identifier	Test:	Result:	Repeating Pages

090177e196ae3d43\Final\Final On: 01-Apr-2021 04:28 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled
Visit on Feb/10/2021

Form: LOCAL LABORATORY DATA - REPEATING
CHEMISTRY

Form Version: 10-Oct-2020 15:58

Form Status: Not Started

Site No: 1130

Site Name: (1130) Kaiser Permanente Center For Health Research

Subject No: 11301081

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:25

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Lab Chemistry Details

1.	Lab Panel:	
2.	Laboratory Name and Address	[]
3.	Collection Date:	//
4.	Specimen Type:	

Lab Result

5.	Sponsor ID:	[]
	Test:	
	Result:	[]
	Not Done:	
	LNMT	Low [] High [] Unit

090177e196ae3d43\Final\Final On: 01-Apr-2021 04:28 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1

Form: LOCAL LABORATORY DATA - REPEATING
Hematology

Form Version: 10-Oct-2020 16:02

Site No: 1130

Site Name: (1130) Kaiser Permanente Center For Health Research

Subject No: 11301081

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:25

#	Category for Lab Test	Vendor Name (DERIVED)	Collection Date:	Specimen Type	Lab Result			Form Instance
1.					Sponsor-Defined Identifier	Test:	Result:	Repeating Pages

090177e196ae3d43\Final\Final On: 01-Apr-2021 04:28 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled
Visit on Feb/10/2021

Form: LOCAL LABORATORY DATA - REPEATING
Hematology

Form Version: 10-Oct-2020 16:02

Form Status: Not Started

Site No: 1130

Site Name: (1130) Kaiser Permanente Center For Health Research

Subject No: 11301081

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:25

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Laboratory Data Hematology

1.	Lab Panel:	
2.	Laboratory Name and Address	[]
3.	Collection Date:	//
4.	Specimen Type:	

Lab Result

5.	Sponsor ID:	[]
	Test:	
	Result:	[]
	Not Done:	
	LNMT	Low [] High [] Unit

090177e196ae3d43\Final\Final On: 01-Apr-2021 04:28 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1

Form: VITAL SIGNS - COVID

Form Version: 10-Oct-2020 15:59

Site No: 1130

Site Name: (1130) Kaiser Permanente Center For Health Research

Subject No: 11301081

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:25

#	Date:	Vital Signs Details			Form Instance
1.		Record Identifier:	Systolic:	Diastolic:	Repeating Pages

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled **Form:** VITAL SIGNS - COVID

Visit on Feb/10/2021

Form Version: 10-Oct-2020 15:59

Form Status: Not Started

Site No: 1130

Site Name: (1130) Kaiser Permanente Center For Health Research

Subject No: 11301081

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:25

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Vital Signs

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

Vital Signs Details

2.	Record Identifier:	
	Systolic:	[]
	Diastolic:	[]
	Respiratory Rate in respirations/minute:	[]
	Heart Rate in beats/minute:	[]

Header Text: c4591001

Visit: POT_COVID_ILL 1

Form: VITAL SIGNS - PULSE OX ROOM AIR

Form Version: 10-Oct-2020 16:04

Site No: 1130

Site Name: (1130) Kaiser Permanente Center For Health Research

Subject No: 11301081

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:25

#	Date:	Vital Signs Details		Form Instance
1.		Record Identifier:	Oxygen Saturation	Repeating Pages

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled
Visit on Feb/10/2021

Form: VITAL SIGNS - PULSE OX ROOM AIR

Form Version: 10-Oct-2020 16:04

Form Status: Not Started

Site No: 1130

Site Name: (1130) Kaiser Permanente Center For Health Research

Subject No: 11301081

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:25

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Vital Signs

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

Vital Signs Details

2.	Record Identifier:	
	SPO2 Pulse Oximetry %	[]

Header Text: c4591001

Visit: POT_COVID_ILL 1

Form: OXYGENATION PARAMETERS

Form Version: 06-Jul-2020 21:52

Site No: 1130

Site Name: (1130) Kaiser Permanente Center For Health Research

Subject No: 11301081

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:25

#	Date Time of Assessment	Arterial Blood Gases PaO2	FiO2 (Fraction of Inhaled Oxygen)	Form Instance
1.				Repeating Pages

090177e196ae3d43\Final\Final On: 01-Apr-2021 04:28 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled
Visit on Feb/10/2021

Form: OXYGENATION PARAMETERS

Form Version: 06-Jul-2020 21:52

Form Status: Not Started

Site No: 1130

Site Name: (1130) Kaiser Permanente Center For Health Research

Subject No: 11301081

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:25

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Oxygenation Parameters

1.	Date Time of Assessment:	//
2.	Arterial Blood Gases PaO2 (mmHg):	[]
3.	FiO2 (Fraction of Inhaled Oxygen):	[]

Header Text: c4591001

Visit: POT_COVID_ILL 1

Form: CONCOMITANT MEDICATIONS - VASOPRESSORS

Form Version: 06-Jul-2020 21:55

Site No: 1130

Site Name: (1130) Kaiser Permanente Center For Health Research

Subject No: 11301081

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:25

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

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled
Visit on Feb/10/2021

Form: CONCOMITANT MEDICATIONS - VASOPRESSORS

Form Version: 06-Jul-2020 21:55

Form Status: Not Started

Site No: 1130

Site Name: (1130) Kaiser Permanente Center For Health Research

Subject No: 11301081

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:25

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Concomitant Medications

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

090177e196ae3d43\Final\Final On: 01-Apr-2021 04:28 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1

Form: IMAGING

Form Version: 06-Jul-2020 21:53

Site No: 1130

Site Name: (1130) Kaiser Permanente Center For Health Research

Subject No: 11301081

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:25

#	Date of Assessment	Location of Assessment	Imaging Method	Overall Assessment	Form Instance
1.					Repeating Pages

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled **Form:** IMAGING

Visit on Feb/10/2021

Form Version: 06-Jul-2020 21:53

Form Status: Not Started

Site No: 1130

Site Name: (1130) Kaiser Permanente Center For Health Research

Subject No: 11301081

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:25

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Imaging

1.	Date of Assessment:	//
2.	Location of Assessment:	
3.	Type of Imaging Exam:	
4.	Assessment:	

Header Text: c4591001

Visit: POT_COVID_CONVA 1 -
Unscheduled Visit on Mar/12/2021

Form: DATE OF VISIT - ILLNESS CONVALESCENT

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Verified

Site No: 1130

Site Name: (1130) Kaiser Permanente Center For Health Research

Subject No: 11301081

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:25

[eCRF Audit Trail History](#)

Date of Visit

1.	Date of Visit	Mar/12/2021
2.	Erroneous Visit	

COVID-19 Illness Visit

3.	COVID-19 Illness Visit:	COVID_A1
----	-------------------------	----------

Header Text: c4591001

Visit: POT_COVID_CONVA 1 -
Unscheduled Visit on Mar/12/2021

Form Version: 22-Apr-2020 21:03

Site No: 1130

Subject No: 11301081

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING -
IMMUNOGENICITY

Form Status: Data Complete, Verified

Site Name: (1130) Kaiser Permanente Center For Health Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:25

[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	[BPOXKJ]
5.b	Sample ID	[BPOXL0]
5.c	Sample ID	[BPHV8S]
5.d	Sample ID	[BPHV8T]
5.e	Sample ID	[BPHV8V]
5.f	Sample ID	[BPHV8W]

090177e196ae3d43\Final\Final On: 01-Apr-2021 04:28 (GMT)

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: 1130

Site Name: (1130) Kaiser Permanente Center For Health Research

Subject No: 11301081

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:25

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: 1130

Site Name: (1130) Kaiser Permanente Center For Health Research

Subject No: 11301081

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:25

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	[]
----	-----------	-----

090177e196ae3d43\Final\Final On: 01-Apr-2021 04:28 (GMT)

Header Text: c4591001

Visit: Logs

Form: ADVERSE EVENT REPORT

Form Version: 22-Apr-2020 21:02

Site No: 1130

Site Name: (1130) Kaiser Permanente Center For Health Research

Subject No: 11301081

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:25

#	Category	AE Identifier	Adverse Event	Start Date	Is the Adverse Event Still Ongoing	Form Instance
1.	ADVERSE EVENT	1	swollen lymph node - right side of neck	Feb/11/2021 16:00	NO End Date Time: Feb/12/2021 23:00	Repeating Pages

090177e196ae3d43\Final\Final On: 01-Apr-2021 04:28 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1130

Subject No: 11301081

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Frozen

Site Name: (1130) Kaiser Permanente Center For Health Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:25

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

Adverse Event Report

1.	Category:	ADVERSE EVENT
2.	AE ID:	[1]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[swollen lymph node - right side of neck]
4.	Start Date Time:	Feb/11/2021 16:00
5.	Is the adverse event still ongoing?	NO End Date Time: Feb/12/2021 23:00
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

090177e196ae3d43\Final\Final On: 01-Apr-2021 04:28 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1130

Subject No: 11301081

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Frozen

Site Name: (1130) Kaiser Permanente Center For Health Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:25

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

090177e196ae3d43\Final\Final On: 01-Apr-2021 04:28 (GMT)

Header Text: c4591001

Visit: Logs

Form: MEDICATION ERROR

Form Version: 17-Jul-2020 21:54

Site No: 1130

Site Name: (1130) Kaiser Permanente Center For Health Research

Subject No: 11301081

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:25

#	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: 1130

Subject No: 11301081

Generated By: (b) (4)

Form: MEDICATION ERROR

Form Status: Not Started

Site Name: (1130) Kaiser Permanente Center For Health Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:25

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Medication Error

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

090177e196ae3d43\Final\Final On: 01-Apr-2021 04:28 (GMT)

Header Text: c4591001

Visit: Logs

Form: CONCOMITANT MEDICATIONS - NON STUDY
VACCINATIONS

Form Version: 22-Apr-2020 21:03

Site No: 1130

Site Name: (1130) Kaiser Permanente Center For Health Research

Subject No: 11301081

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:25

#	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: 1130

Site Name: (1130) Kaiser Permanente Center For Health Research

Subject No: 11301081

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:25

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Concomitant Medications

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

090177e196ae3d43\Final\Final On: 01-Apr-2021 04:28 (GMT)

Header Text: c4591001

Visit: Logs

Form: CONCOMITANT MEDICATIONS - PROHIBITED

Form Version: 22-Apr-2020 21:03

Site No: 1130

Site Name: (1130) Kaiser Permanente Center For Health Research

Subject No: 11301081

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:25

#	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: 1130

Subject No: 11301081

Generated By: (b) (4)

Form: CONCOMITANT MEDICATIONS - PROHIBITED

Form Status: Not Started

Site Name: (1130) Kaiser Permanente Center For Health Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:25

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Concomitant Medications

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

090177e196ae3d43\Final\Final On: 01-Apr-2021 04:28 (GMT)

Header Text: c4591001

Visit: Logs

Form: RADIATION TREATMENT

Form Version: 22-Apr-2020 21:02

Site No: 1130

Site Name: (1130) Kaiser Permanente Center For Health Research

Subject No: 11301081

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:25

#	Category	Treatment Identifier	Con Non-Drug Treatments Pre-specified	Treatment	Start Date	Form Instance
1.						Repeating Pages

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1130

Subject No: 11301081

Generated By: (b) (4)

Form: RADIATION TREATMENT

Form Status: Not Started

Site Name: (1130) Kaiser Permanente Center For Health Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:25

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Radiation Treatment

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

Header Text: c4591001

Visit: Logs

Form: TRANSFUSIONS

Form Version: 22-Apr-2020 21:03

Site No: 1130

Site Name: (1130) Kaiser Permanente Center For Health Research

Subject No: 11301081

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:25

#	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: 1130

Subject No: 11301081

Generated By: (b) (4)

Form: TRANSFUSIONS

Form Status: Not Started

Site Name: (1130) Kaiser Permanente Center For Health Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:25

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

Header Text: c4591001

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

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

Site No: 1130 **Site Name:** (1130) Kaiser Permanente Center For Health Research

Subject No: 11301081 **Subject Initials:** ---

Generated By: (b) (4) **Generated Time (GMT):** 29-Mar-2021 11:25

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

Header Text: c4591001

Visit: Unplanned - New Unscheduled Visit **Form:** UNPLANNED VISIT

Form Version: 22-Apr-2020 21:04 **Form Status:** Not Started

Site No: 1130 **Site Name:** (1130) Kaiser Permanente Center For Health Research

Subject No: 11301081 **Subject Initials:** ---

Generated By: (b) (4) **Generated Time (GMT):** 29-Mar-2021 11:25

Unplanned Assessments

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

Header Text: c4591001

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

Form Version: 22-Apr-2020 21:02

Form Status: Not Started

Site No: 1130

Site Name: (1130) Kaiser Permanente Center For Health Research

Subject No: 11301081

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:25

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: 1130

Site Name: (1130) Kaiser Permanente Center For Health Research

Subject No: 11301081

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:25

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: 1130

Site Name: (1130) Kaiser Permanente Center For Health Research

Subject No: 11301081

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:25

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?	

090177e196ae3d43\Final\Final On: 01-Apr-2021 04:28 (GMT)

Header Text: c4591001

Visit: Unplanned Vaccination - Unscheduled **Form:** CONTACT OUTCOME - MONTH 1

Form Version: 10-Oct-2020 15:57

Form Status: Not Started

Site No: 1130

Site Name: (1130) Kaiser Permanente Center For Health Research

Subject No: 11301081

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:25

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: 1130

Site Name: (1130) Kaiser Permanente Center For Health Research

Subject No: 11301081

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:25

Contact Outcome

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

Header Text: c4591001

Visit: End of Treatment - Unscheduled

Form: DISPOSITION - TREATMENT

Form Version: 15-Sep-2020 21:55

Form Status: Data Complete, Frozen, Verified

Site No: 1130

Site Name: (1130) Kaiser Permanente Center For Health Research

Subject No: 11301081

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:25

[eCRF Audit Trail History](#)

Disposition - Treatment

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

Header Text: c4591001

Visit: Potential ReVax Initial Contact -
Unscheduled

Form: DATE OF VISIT

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen, Verified

Site No: 1130

Site Name: (1130) Kaiser Permanente Center For Health Research

Subject No: 11301081

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:25

[eCRF Audit Trail History](#)

Date of Visit

1.	Date of Visit	Jan/22/2021
2.	Erroneous Visit	

Header Text: c4591001

Visit: Potential ReVax Initial Contact -
Unscheduled

Form: FURTHER VACCINATION CONFIRMATION

Form Version: 10-Dec-2020 02:25

Form Status: Data Complete, Frozen

Site No: 1130

Site Name: (1130) Kaiser Permanente Center For Health Research

Subject No: 11301081

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:25

[eCRF Audit Trail History](#)

Further Vaccination Confirmation

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

090177e196ae3d43\Final\Final On: 01-Apr-2021 04:28 (GMT)

Header Text: c4591001

Visit: Follow-Up - Unscheduled

Form: DISPOSITION - FOLLOW-UP

Form Version: 15-Sep-2020 21:53

Form Status: Not Started

Site No: 1130

Site Name: (1130) Kaiser Permanente Center For Health Research

Subject No: 11301081

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:25

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: TREATMENT UNBLINDED

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1130

Site Name: (1130) Kaiser Permanente Center For Health Research

Subject No: 11301081

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:25

[eCRF Audit Trail History](#)

Treatment Unblinded

1.	Date Treatment Unblinded :	Jan/22/2021
2.	Primary Reason for Unblinding:	ASSESS ELIGIBILITY FOR ADDITIONAL VACCINATION

Header Text: c4591001

Visit: Disposition - Unscheduled

Form: WITHDRAWAL OF CONSENT

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1130

Site Name: (1130) Kaiser Permanente Center For Health Research

Subject No: 11301081

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:25

Withdrawal Of Consent

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

Header Text: c4591001

Visit: Disposition - Unscheduled

Form: DEATH DETAILS CODED

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1130

Site Name: (1130) Kaiser Permanente Center For Health Research

Subject No: 11301081

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:25

Death Details

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

Cause of Death

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

Header Text: c4591001

Visit: V101_VAX3

Form Version: 22-Apr-2020 21:02

Site No: 1130

Subject No: 11301081

Generated By: (b) (4)

Form: DATE OF VISIT

Form Status: Data Complete, Frozen, Verified

Site Name: (1130) Kaiser Permanente Center For Health Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:25

[eCRF Audit Trail History](#)

Date of Visit

1.	Date of Visit	Jan/28/2021
2.	Erroneous Visit	

Header Text: c4591001

Visit: V101_VAX3

Form Version: 10-Dec-2020 02:31

Site No: 1130

Subject No: 11301081

Generated By: (b) (4)

Form: INFORMED CONSENT - FURTHER VACCINATION

Form Status: Data Complete, Frozen, Verified

Site Name: (1130) Kaiser Permanente Center For Health Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:25

[eCRF Audit Trail History](#)

Informed Consent - Further Vaccination

1.	Consent Was:	OBTAINED Date Written Consent Obtained Jan/28/2021
----	--------------	--

Header Text: c4591001

Visit: V101_VAX3

Form: INCLUSION/EXCLUSION CRITERIA - FURTHER VACCINATION

Form Version: 10-Dec-2020 02:30

Form Status: Data Complete, Frozen, Verified

Site No: 1130

Site Name: (1130) Kaiser Permanente Center For Health Research

Subject No: 11301081

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:25

Form Comments

Inclusion Criteria Not Met

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

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

Header Text: c4591001

Visit: V101_VAX3

Form: DISPOSITION - SCREENING FOR FURTHER VACCINATION

Form Version: 10-Dec-2020 02:31

Form Status: Data Complete, Frozen, Verified

Site No: 1130

Site Name: (1130) Kaiser Permanente Center For Health Research

Subject No: 11301081

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:25

[eCRF Audit Trail History](#)

Disposition - Screening for Further Vaccination

1.	Date of Completion/Discontinuation /Death :	Jan/28/2021
2.	Phase of Disposition:	REPEAT SCREENING 1
3.	Status:	COMPLETED
4.	Specify Status:	[]

Header Text: c4591001

Visit: V101_VAX3

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1130

Site Name: (1130) Kaiser Permanente Center For Health Research

Subject No: 11301081

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:25

[eCRF Audit Trail History](#)

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	SERUM
3.	Sample Collected?	YES Date of Collection: Jan/28/2021
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	[BPOXHD]
5.b	Sample ID	[BPOXHF]
5.c	Sample ID	[BPHV6S]
5.d	Sample ID	[BPHV6T]
5.e	Sample ID	[BPHV6V]

090177e196ae3d43\Final\Final On: 01-Apr-2021 04:28 (GMT)

Header Text: c4591001

Visit: V101_VAX3

Form Version: 22-Apr-2020 21:03

Site No: 1130

Subject No: 11301081

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB

Form Status: Data Complete, Frozen, Verified

Site Name: (1130) Kaiser Permanente Center For Health Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:25

[eCRF Audit Trail History](#)

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Jan/28/2021
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	[BPOXH2]
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090177e196ae3d43\Final\Final On: 01-Apr-2021 04:28 (GMT)

Header Text: c4591001

Visit: V101_VAX3

Form Version: 10-Dec-2020 02:26

Site No: 1130

Subject No: 11301081

Generated By: (b) (4)

Form: VACCINATION

Form Status: Data Complete, Frozen, Verified

Site Name: (1130) Kaiser Permanente Center For Health Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:25

[eCRF Audit Trail History](#)

Vaccination

1.	Was there a temporary delay of vaccination?	NO
2.	Treatment Name	[BNT162b2]
3.	Formulation:	INJECTION
4.	Dose Date Time:	Jan/28/2021 14:18
5.	Anatomical Location:	DELTOID MUSCLE
6.	Body Side:	RIGHT
7.	Route:	INTRAMUSCULAR
8.	Actual Dose:	[30.0]
9.	Unit:	ug
10.	Timeframe Subject Was Observed	30 MINUTES
11.	Was the subject observed for at least the protocol specified observation period after investigational product administration?	YES

090177e196ae3d43\Final\Final On: 01-Apr-2021 04:28 (GMT)

Header Text: c4591001

Visit: V102_VAX4

Form Version: 22-Apr-2020 21:02

Site No: 1130

Subject No: 11301081

Generated By: (b) (4)

Form: DATE OF VISIT

Form Status: Data Complete, Frozen, Verified

Site Name: (1130) Kaiser Permanente Center For Health Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:25

[eCRF Audit Trail History](#)

Date of Visit

1.	Date of Visit	Feb/18/2021
2.	Erroneous Visit	

Header Text: c4591001

Visit: V102_VAX4

Form Version: 22-Apr-2020 21:03

Site No: 1130

Subject No: 11301081

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB

Form Status: Data Complete, Frozen, Verified

Site Name: (1130) Kaiser Permanente Center For Health Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:25

[eCRF Audit Trail History](#)

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Feb/18/2021
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	[BP0XK2]
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090177e196ae3d43\Final\Final On: 01-Apr-2021 04:28 (GMT)

Header Text: c4591001

Visit: V102_VAX4

Form Version: 10-Dec-2020 02:26

Site No: 1130

Subject No: 11301081

Generated By: (b) (4)

Form: VACCINATION

Form Status: Data Complete, Frozen, Verified

Site Name: (1130) Kaiser Permanente Center For Health Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:25

[eCRF Audit Trail History](#)

Vaccination

1.	Was there a temporary delay of vaccination?	NO
2.	Treatment Name	[BNT162b2]
3.	Formulation:	INJECTION
4.	Dose Date Time:	Feb/18/2021 14:06
5.	Anatomical Location:	DELTOID MUSCLE
6.	Body Side:	LEFT
7.	Route:	INTRAMUSCULAR
8.	Actual Dose:	[30.0]
9.	Unit:	ug
10.	Timeframe Subject Was Observed	30 MINUTES
11.	Was the subject observed for at least the protocol specified observation period after investigational product administration?	YES

090177e196ae3d43\Final\Final On: 01-Apr-2021 04:28 (GMT)

Header Text: c4591001

Visit: V103_MONTH1

Form Version: 22-Apr-2020 21:02

Site No: 1130

Subject No: 11301081

Generated By: (b) (4)

Form: DATE OF VISIT

Form Status: Not Started

Site Name: (1130) Kaiser Permanente Center For Health Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:25

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

Header Text: c4591001

Visit: V103_MONTH1

Form Version: 22-Apr-2020 21:04

Site No: 1130

Subject No: 11301081

Generated By: (b) (4)

Form: CONTACT OUTCOME

Form Status: Not Started

Site Name: (1130) Kaiser Permanente Center For Health Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:25

Contact Outcome

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

Header Text: c4591001

Visit: V104_MONTH6

Form Version: 22-Apr-2020 21:02

Site No: 1130

Subject No: 11301081

Generated By: (b) (4)

Form: DATE OF VISIT

Form Status: Not Started

Site Name: (1130) Kaiser Permanente Center For Health Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:25

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

Header Text: c4591001

Visit: V104_MONTH6

Form Version: 22-Apr-2020 21:04

Site No: 1130

Subject No: 11301081

Generated By: (b) (4)

Form: CONTACT OUTCOME

Form Status: Not Started

Site Name: (1130) Kaiser Permanente Center For Health Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:25

Contact Outcome

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

Header Text: c4591001

Visit: V105_MONTH18

Form Version: 22-Apr-2020 21:02

Site No: 1130

Subject No: 11301081

Generated By: (b) (4)

Form: DATE OF VISIT

Form Status: Not Started

Site Name: (1130) Kaiser Permanente Center For Health Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:25

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

Header Text: c4591001

Visit: V105_MONTH18

Form Version: 22-Apr-2020 21:04

Site No: 1130

Subject No: 11301081

Generated By: (b) (4)

Form: CONTACT OUTCOME

Form Status: Not Started

Site Name: (1130) Kaiser Permanente Center For Health Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:25

Contact Outcome

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

Header Text: c4591001

Visit: FURTHER_VACCINATION_EOT - **Form:** DISPOSITION - TREATMENT

Unscheduled

Form Version: 20-Feb-2021 02:26

Form Status: Not Started

Site No: 1130

Site Name: (1130) Kaiser Permanente Center For Health Research

Subject No: 11301081

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:25

Disposition - Treatment

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

Header Text: c4591001

Visit: Subject Status - Unscheduled

Form: SUBJECT STATUS

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Verified

Site No: 1130

Site Name: (1130) Kaiser Permanente Center For Health Research

Subject No: 11301081

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:25

[eCRF Audit Trail History](#)

Subject Status

1.	Subject Status	FOLLOW-UP
2.	Subject Status Date	Dec/4/2020

Header Text: c4591001

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

Form Version: 22-Apr-2020 21:04 **Form Status:** Data Complete, Verified

Site No: 1130 **Site Name:** (1130) Kaiser Permanente Center For Health Research

Subject No: 11301081 **Subject Initials:** ---

Generated By: (b) (4) **Generated Time (GMT):** 29-Mar-2021 11:25

[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: 1130

Site Name: (1130) Kaiser Permanente Center For Health Research

Subject No: 11301081

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:25

[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: 1130

Subject No: 11301081

Generated By: (b) (4)

Form: INCLUSION/EXCLUSION CRITERIA - Comments

Form Status: Data Complete, Frozen, Verified

Site Name: (1130) Kaiser Permanente Center For Health Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:25

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Item	Date	User	Comment
Form	Oct-16-2020 10:41:52 (UTC-08:00) Pacific Time (US & Canada)	Tara Beatty (b) (4)	Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled **Form:** MICROBIOLOGY SPECIMEN - Comments
Visit on Feb/10/2021

Form Version: 06-Jul-2020 21:54 **Form Status:** Data Complete, Frozen

Site No: 1130 **Site Name:** (1130) Kaiser Permanente Center For Health Research

Subject No: 11301081 **Subject Initials:** ---

Generated By: (b) (4) **Generated Time (GMT):** 29-Mar-2021 11:25

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Item	Date	User	Comment
Form	Feb-12-2021 10:32:14 (UTC-08:00) Pacific Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled **Form:** MICROBIOLOGY SPECIMEN - Comments
Visit on Feb/10/2021

Form Version: 06-Jul-2020 21:54 **Form Status:** Data Complete, Frozen

Site No: 1130 **Site Name:** (1130) Kaiser Permanente Center For Health Research

Subject No: 11301081 **Subject Initials:** ---

Generated By: (b) (4) **Generated Time (GMT):** 29-Mar-2021 11:25

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Item	Date	User	Comment
1	Feb-12-2021 10:32:14 (UTC-08:00) Pacific Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled **Form:** MICROBIOLOGY SPECIMEN - Comments
Visit on Feb/10/2021

Form Version: 06-Jul-2020 21:54 **Form Status:** Data Complete, Frozen

Site No: 1130 **Site Name:** (1130) Kaiser Permanente Center For Health Research

Subject No: 11301081 **Subject Initials:** ---

Generated By: (b) (4) **Generated Time (GMT):** 29-Mar-2021 11:25

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Item	Date	User	Comment
2	Feb-12-2021 10:32:14 (UTC-08:00) Pacific Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled **Form:** MICROBIOLOGY SPECIMEN - Comments
Visit on Feb/10/2021

Form Version: 06-Jul-2020 21:54 **Form Status:** Data Complete, Frozen

Site No: 1130 **Site Name:** (1130) Kaiser Permanente Center For Health Research

Subject No: 11301081 **Subject Initials:** ---

Generated By: (b) (4) **Generated Time (GMT):** 29-Mar-2021 11:25

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Item	Date	User	Comment
3	Feb-12-2021 10:32:14 (UTC-08:00) Pacific Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled **Form:** MICROBIOLOGY SPECIMEN - Comments
Visit on Feb/10/2021

Form Version: 06-Jul-2020 21:54 **Form Status:** Data Complete, Frozen

Site No: 1130 **Site Name:** (1130) Kaiser Permanente Center For Health Research

Subject No: 11301081 **Subject Initials:** ---

Generated By: (b) (4) **Generated Time (GMT):** 29-Mar-2021 11:25

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Item	Date	User	Comment
4	Feb-12-2021 10:32:14 (UTC-08:00) Pacific Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled **Form:** MICROBIOLOGY SPECIMEN - Comments
Visit on Feb/10/2021

Form Version: 06-Jul-2020 21:54 **Form Status:** Data Complete, Frozen

Site No: 1130 **Site Name:** (1130) Kaiser Permanente Center For Health Research

Subject No: 11301081 **Subject Initials:** ---

Generated By: (b) (4) **Generated Time (GMT):** 29-Mar-2021 11:25

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Item	Date	User	Comment
5	Feb-12-2021 10:32:14 (UTC-08:00) Pacific Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled **Form:** MICROBIOLOGY SPECIMEN - Comments
Visit on Feb/10/2021

Form Version: 06-Jul-2020 21:54 **Form Status:** Data Complete, Frozen

Site No: 1130 **Site Name:** (1130) Kaiser Permanente Center For Health Research

Subject No: 11301081 **Subject Initials:** ---

Generated By: (b) (4) **Generated Time (GMT):** 29-Mar-2021 11:25

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Item	Date	User	Comment
6	Feb-12-2021 10:32:14 (UTC-08:00) Pacific Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled **Form:** MICROBIOLOGY SPECIMEN - Comments
Visit on Feb/10/2021

Form Version: 06-Jul-2020 21:54 **Form Status:** Data Complete, Frozen

Site No: 1130 **Site Name:** (1130) Kaiser Permanente Center For Health Research

Subject No: 11301081 **Subject Initials:** ---

Generated By: (b) (4) **Generated Time (GMT):** 29-Mar-2021 11:25

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Item	Date	User	Comment
7	Feb-12-2021 10:32:14 (UTC-08:00) Pacific Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled **Form:** MICROBIOLOGY SPECIMEN - Comments
Visit on Feb/10/2021

Form Version: 06-Jul-2020 21:54 **Form Status:** Data Complete, Frozen

Site No: 1130 **Site Name:** (1130) Kaiser Permanente Center For Health Research

Subject No: 11301081 **Subject Initials:** ---

Generated By: (b) (4) **Generated Time (GMT):** 29-Mar-2021 11:25

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Item	Date	User	Comment
8	Feb-12-2021 10:32:14 (UTC-08:00) Pacific Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled **Form:** MICROBIOLOGY SPECIMEN - Comments
Visit on Feb/10/2021

Form Version: 06-Jul-2020 21:54 **Form Status:** Data Complete, Frozen

Site No: 1130 **Site Name:** (1130) Kaiser Permanente Center For Health Research

Subject No: 11301081 **Subject Initials:** ---

Generated By: (b) (4) **Generated Time (GMT):** 29-Mar-2021 11:25

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Item	Date	User	Comment
9	Feb-12-2021 10:32:14 (UTC-08:00) Pacific Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

Header Text: c4591001

Visit: V101_VAX3

Form Version: 10-Dec-2020 02:30

Site No: 1130

Subject No: 11301081

Generated By: (b) (4)

Form: INCLUSION/EXCLUSION CRITERIA - FURTHER VACCINATION - Comments

Form Status: Data Complete, Frozen, Verified

Site Name: (1130) Kaiser Permanente Center For Health Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:25

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Item	Date	User	Comment
Form	Jan-28-2021 13:31:16 (UTC-08:00) Pacific Time (US & Canada)	Dorothy Kurdyla (b) (4)	Not Applicable

Header Text: c4591001

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

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Verified

Site No: 1130

Site Name: (1130) Kaiser Permanente Center For Health Research

Subject No: 11301081

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:25

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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 16:26:03 (UTC-08:00) Pacific Time (US & Canada)		Edit - All signatures invalidated

Affidavit:

N/A

Stephen Fortmann	Approved	Feb-21-2021 16:46:00 (UTC-08:00) Pacific Time (US & Canada)	BOOK	Signed
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Affidavit:

By my dated signature below, I, StephenFortmann, 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.

Kristi Bays	N/A	Feb-17-2021 06:54:04 (UTC-08:00) Pacific Time (US & Canada)		Edit - All signatures invalidated
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Affidavit:

N/A

Stephen Fortmann	Approved	Feb-16-2021 11:24:01 (UTC-08:00) Pacific Time (US & Canada)	BOOK	Signed
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090177e196ae3d43\Final\Final On: 01-Apr-2021 04:28 (GMT)

Header Text: c4591001

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

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Verified

Site No: 1130

Site Name: (1130) Kaiser Permanente Center For Health Research

Subject No: 11301081

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:25

Affidavit:

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

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

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

(b) (6)	N/A	Feb-16-2021 09:59:42 (UTC-08:00) Pacific Time (US & Canada)		Edit - All signatures invalidated
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Affidavit:

N/A

Stephen Fortmann	Approved	Feb-12-2021 17:09:53 (UTC-08:00) Pacific Time (US & Canada)	BOOK	Signed
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Affidavit:

By my dated signature below, I, StephenFortmann, 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.

Tara Beatty	N/A	Feb-10-2021 15:31:34 (UTC-08:00) Pacific Time (US & Canada)		Edit - All signatures invalidated
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Affidavit:

N/A

Stephen Fortmann	Approved	Jan-29-2021 11:55:56 (UTC-08:00) Pacific Time (US & Canada)	BOOK	Signed
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090177e196ae3d43\Final\Final On: 01-Apr-2021 04:28 (GMT)

Header Text: c4591001

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

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Verified

Site No: 1130

Site Name: (1130) Kaiser Permanente Center For Health Research

Subject No: 11301081

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:25

Affidavit:

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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.

Dorothy Kurdyla	N/A	Jan-28-2021 13:30:57 (UTC-08:00) Pacific Time (US & Canada)		Edit - All signatures invalidated
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Affidavit:

N/A

Stephen Fortmann	Approved	Jan-22-2021 22:25:07 (UTC-08:00) Pacific Time (US & Canada)	BOOK	Signed
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Affidavit:

By my dated signature below, I, StephenFortmann, 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.

Sperry Robinson	N/A	Jan-22-2021 09:48:57 (UTC-08:00) Pacific Time (US & Canada)		Edit - All signatures invalidated
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Affidavit:

N/A

Stephen Fortmann	Approved	Dec-04-2020 13:51:24 (UTC-08:00) Pacific Time (US & Canada)	BOOK	Signed
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090177e196ae3d43\Final\Final On: 01-Apr-2021 04:28 (GMT)

Header Text: c4591001

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

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Verified

Site No: 1130

Site Name: (1130) Kaiser Permanente Center For Health Research

Subject No: 11301081

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:25

Affidavit:

By my dated signature below, I, StephenFortmann, 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.

090177e196ae3d43\Final\Final On: 01-Apr-2021 04:28 (GMT)

Header Text: c4591001

Visit: COHORT_SELECTION

Form: COHORT SELECTION - eCRF Audit Trail History

Form Version: 10-Oct-2020 16:01

Form Status: Data Complete, Frozen, Verified

Site No: 1130

Site Name: (1130) Kaiser Permanente Center For Health Research

Subject No: 11301081

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:25

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1. Select appropriate response - Protocol version

Date	Location	User	Value	Reason
Oct-16-2020 10:41:15 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Tara Beatty (b) (4)	Data Entry: 06 OCT 2020	Initial Entry

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

Date	Location	User	Value	Reason
Oct-16-2020 10:41:15 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Tara Beatty (b) (4)	Data Entry: STAGE 3 COHORTS	Initial Entry

090177e196ae3d43\Final\Final On: 01-Apr-2021 04:28 (GMT)

Header Text: c4591001

Visit: COHORT_SELECTION

Form Version: 22-Apr-2020 21:02

Site No: 1130

Subject No: 11301081

Generated By: (b) (4)

Form: MAIN INFORMED CONSENT - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1130) Kaiser Permanente Center For Health Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:25

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I. Consent Was:

Date	Location	User	Value	Reason
Oct-16-2020 10:41:22 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Tara Beatty (b) (4)	Data Entry: OBTAINED Date Written Consent Obtained Oct/16/2020	Initial Entry

090177e196ae3d43\Final\Final On: 01-Apr-2021 04:28 (GMT)

Header Text: c4591001

Visit: COHORT_SELECTION

Form: DEMOGRAPHY - eCRF Audit Trail History

Form Version: 15-Sep-2020 21:54

Form Status: Data Complete, Frozen, Verified

Site No: 1130

Site Name: (1130) Kaiser Permanente Center For Health Research

Subject No: 11301081

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:25

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1. Subject ID

Date	Location	User	Value	Reason
Oct-16-2020 10:41:03 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 11301081	Item copied from previous form

2. Birth Date:

Date	Location	User	Value	Reason
Oct-16-2020 10:41:00 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: (b) (6)/1967	Enrollment Entry

3. Sex:

Date	Location	User	Value	Reason
Oct-16-2020 10:41:30 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Tara Beatty (b) (4)	Data Entry: MALE	Initial Entry

4. Ethnicity:

Date	Location	User	Value	Reason
Oct-16-2020 10:41:30 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Tara Beatty (b) (4)	Data Entry: NOT HISPANIC OR LATIN O(A) OR OF SPANISH ORI GIN	Initial Entry

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

Date	Location	User	Value	Reason
Oct-16-2020 10:41:30 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Tara Beatty (b) (4)	Data Entry: WHITE	Initial Entry

090177e196ae3d43\Final\Final On: 01-Apr-2021 04:28 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:02

Site No: 1130

Subject No: 11301081

Generated By: (b) (4)

Form: DATE OF VISIT - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1130) Kaiser Permanente Center For Health Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:25

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I. Date of Visit

Date	Location	User	Value	Reason
Oct-16-2020 10:41:41 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Tara Beatty (b) (4)	Data Entry: Oct/16/2020	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 15-Sep-2020 21:52

Site No: 1130

Subject No: 11301081

Generated By: (b) (4)

Form: DISPOSITION - SCREENING - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1130) Kaiser Permanente Center For Health Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:25

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1. Date of Completion/Discontinuation/Death

Date	Location	User	Value	Reason
Oct-16-2020 10:42:11 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Tara Beatty (b) (4)	Data Entry: Oct/16/2020	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Oct-16-2020 10:42:11 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SCREENING	Initial Entry

3. Status:

Date	Location	User	Value	Reason
Oct-16-2020 10:42:11 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Tara Beatty (b) (4)	Data Entry: COMPLETED	Initial Entry

090177e196ae3d43\Final\Final On: 01-Apr-2021 04:28 (GMT)

Header Text: c4591001**Visit:** V1_DAY1_VAX1_L**Form:** GENERAL MEDICAL HISTORY - eCRF Audit Trail History**Form Version:** 22-Apr-2020 21:03**Form Status:** Data Complete, Frozen, Verified**Site No:** 1130**Site Name:** (1130) Kaiser Permanente Center For Health Research**Subject No:** 11301081**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 11:25[Back to Form](#)*I.a*

Date	Location	User	Value	Reason
Oct-16-2020 10:45:06 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Nu 1 mber: Medical Hist History of Alc ory Term: oholism Start Date: Mar/28/2000 Ongoing: NO End Date: Jun/13/201 6	Initial Entry

I.a Line/MH Number:

Date	Location	User	Value	Reason
Oct-16-2020 10:45:06 (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
Oct-16-2020 10:45:06 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Tara Beatty (b) (4)	Data Entry: History of Alcoholism	Initial Entry

I.a Start Date:

Date	Location	User	Value	Reason
Oct-16-2020 10:45:06 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Tara Beatty (b) (4)	Data Entry: Mar/28/2000	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1130

Site Name: (1130) Kaiser Permanente Center For Health Research

Subject No: 11301081

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:25

1.a Ongoing:

Date	Location	User	Value	Reason
Oct-16-2020 10:45:06 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Tara Beatty (b) (4)	Data Entry: NO End Date: Jun/13/2016	Initial Entry

1.b

Date	Location	User	Value	Reason
Oct-16-2020 10:45:30 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Numbe 2 r: Medical History Hypertens Term: ion Start Date: Apr/1/200 3 Ongoing: YES	Initial Entry

090177e196ae3d43\Final\Final On: 01-Apr-2021 04:28 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1130

Site Name: (1130) Kaiser Permanente Center For Health Research

Subject No: 11301081

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:25

1.b Line/MH Number:

Date	Location	User	Value	Reason
Oct-16-2020 10:45:30 (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
Oct-16-2020 10:45:30 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Tara Beatty (b) (4)	Data Entry: Hypertension	Initial Entry

1.b Start Date:

Date	Location	User	Value	Reason
Oct-16-2020 10:45:30 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Tara Beatty (b) (4)	Data Entry: Apr/1/2003	Initial Entry

1.b Ongoing:

Date	Location	User	Value	Reason
Oct-16-2020 10:45:30 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Tara Beatty (b) (4)	Data Entry: YES	Initial Entry

1.c

Date	Location	User	Value	Reason
Oct-16-2020 10:45:56 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Nu 3 mber: Medical Hist Moderate Persi ory Term: stent Asthma Start Date: Sep/4/2015	Initial Entry

090177e196ae3d43\Final\Final On: 01-Apr-2021 04:28 (GMT)

Header Text: c4591001**Visit:** V1_DAY1_VAX1_L**Form:** GENERAL MEDICAL HISTORY - eCRF Audit Trail History**Form Version:** 22-Apr-2020 21:03**Form Status:** Data Complete, Frozen, Verified**Site No:** 1130**Site Name:** (1130) Kaiser Permanente Center For Health Research**Subject No:** 11301081**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 11:25**Ongoing:** YES***1.c Line/MH Number:***

Date	Location	User	Value	Reason
Oct-16-2020 10:45:56 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 3	Initial Entry

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

Date	Location	User	Value	Reason
Oct-16-2020 10:45:56 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Tara Beatty (b) (4)	Data Entry: Moderate Persistent Asthma	Initial Entry

1.c Start Date:

Date	Location	User	Value	Reason
Oct-16-2020 10:45:56 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Tara Beatty (b) (4)	Data Entry: Sep/4/2015	Initial Entry

1.c Ongoing:

Date	Location	User	Value	Reason
Oct-16-2020 10:45:56 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Tara Beatty (b) (4)	Data Entry: YES	Initial Entry

1.d

Date	Location	User	Value	Reason
Oct-16-2020 10:46:23 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number 4 :	Initial Entry

Header Text: c4591001
Visit: V1_DAY1_VAX1_L
Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History
Form Version: 22-Apr-2020 21:03
Form Status: Data Complete, Frozen, Verified
Site No: 1130
Site Name: (1130) Kaiser Permanente Center For Health Research
Subject No: 11301081
Subject Initials: ---
Generated By: (b) (4)
Generated Time (GMT): 29-Mar-2021 11:25

			Medical History Term: Start Date: Jan/1/1982 Ongoing: YES
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1.d Line/MH Number:

Date	Location	User	Value	Reason
Oct-16-2020 10:46:23 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 4	Initial Entry

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

Date	Location	User	Value	Reason
Oct-16-2020 10:46:23 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Tara Beatty (b) (4)	Data Entry: Cough	Initial Entry

1.d Start Date:

Date	Location	User	Value	Reason
Oct-16-2020 10:46:23 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Tara Beatty (b) (4)	Data Entry: Jan/1/1982	Initial Entry

1.d Ongoing:

Date	Location	User	Value	Reason
Oct-16-2020 10:46:23 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Tara Beatty (b) (4)	Data Entry: YES	Initial Entry

1.e

Date	Location	User	Value	Reason
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090177e196ae3d43\Final\Final On: 01-Apr-2021 04:28 (GMT)

Header Text: c4591001**Visit:** V1_DAY1_VAX1_L**Form:** GENERAL MEDICAL HISTORY - eCRF Audit Trail History**Form Version:** 22-Apr-2020 21:03**Form Status:** Data Complete, Frozen, Verified**Site No:** 1130**Site Name:** (1130) Kaiser Permanente Center For Health Research**Subject No:** 11301081**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 11:25

Oct-22-2020 12:45:22 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Dorothy Kurdyla (b) (4)	Data Entry: Line/MH N 5 umber: Medical Hi obstructive story Term: sleep apnea Start Date: Jun/8/2011 Ongoing: YES	Transcription Error
Oct-19-2020 16:23:09 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Line/MH N 5 umber: Medical Hi Obstructive story Term: sleep apnea Start Date: Jun/8/2011 Ongoing: YES	re-typed. Unclear what the error is.
Oct-19-2020 09:57:06 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Line/MH N 5 umber: Medical Hi Obstructive story Term: sleep apnea Start Date: Jun/8/2011 Ongoing: YES	Changed Information
Oct-16-2020 15:23:30 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Tara Beatty (b) (4)	Data Entry: Line/MH N 5 umber: Medical Hi Obstructive story Term Sleep Apnea : a Start Date: Jun/8/2011 Ongoing: YES	Transcription Error
Oct-16-2020 10:46:52 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH 5 Number:	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1130

Subject No: 11301081

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1130) Kaiser Permanente Center For Health Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:25

			Medical History Term: OBSTRUCTIVE SLEEP APNEA	
			Start Date: Jun/8/2011	
			Ongoing: YES	

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1130

Site Name: (1130) Kaiser Permanente Center For Health Research

Subject No: 11301081

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:25

I.e Line/MH Number:

Date	Location	User	Value	Reason
Oct-16-2020 10:46:52 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 5	Initial Entry

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

Date	Location	User	Value	Reason
Oct-22-2020 21:01:33 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 4: Closed	Response satisfies query
Oct-22-2020 12:45:22 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 4: Answered	Transcription Error
Oct-22-2020 12:45:22 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Dorothy Kurdyla (b) (4)	Data Entry: obstructive sleep apnea	Transcription Error
Oct-22-2020 05:50:43 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 4: Opened	DM: A carriage is identified. To avoid processing errors, please remove the identified character by

090177e196ae3d43\Final\Final On: 01-Apr-2021 04:28 (GMT)

Header Text: c4591001**Visit:** V1_DAY1_VAX1_L**Form:** GENERAL MEDICAL HISTORY - eCRF Audit Trail History**Form Version:** 22-Apr-2020 21:03**Form Status:** Data Complete, Frozen, Verified**Site No:** 1130**Site Name:** (1130) Kaiser Permanente Center For Health Research**Subject No:** 11301081**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 11:25

				deleting the entry and re-entering the data (without using copy and paste).
Oct-19-2020 22:36:19 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	PFETMS Oracle (b) (4)	Query 3: Closed	Discrepancy has been closed.
Oct-19-2020 16:23:09 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 3: Answered	re-typed. Unclear what the error is.
Oct-19-2020 16:23:09 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Obstructive sleep apnea	re-typed. Unclear what the error is.
Oct-19-2020 14:51:02 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	PFETMS Oracle (b) (4)	Query 3: Opened	Special Characters: Verbatim Term contains embedded non-compliant characters.
Oct-19-2020 12:44:15 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	PFETMS Oracle (b) (4)	Query 2: Closed	Discrepancy has been closed.

Header Text: c4591001**Visit:** V1_DAY1_VAX1_L**Form:** GENERAL MEDICAL HISTORY - eCRF Audit Trail History**Form Version:** 22-Apr-2020 21:03**Form Status:** Data Complete, Frozen, Verified**Site No:** 1130**Site Name:** (1130) Kaiser Permanente Center For Health Research**Subject No:** 11301081**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 11:25

Oct-19-2020 09:57:06 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Ans wered	Changed Information
Oct-19-2020 09:57:06 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Obstruc tive sle ep apne a	Changed Information
Oct-16-2020 18:58:54 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	PFETMS Oracle (b) (4)	Query 2: Ope ned	Special Characters: Verbatim Term contains embedded non-compliant characters.
Oct-16-2020 18:51:10 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	PFETMS Oracle (b) (4)	Query 1: Clos ed	Discrepancy has been closed.
Oct-16-2020 15:23:30 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Ans wered	Transcription Error
Oct-16-2020 15:23:30 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Tara Beatty (b) (4)	Data Entry: Obstruc tive Sle ep Apn ea	Transcription Error

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1130

Site Name: (1130) Kaiser Permanente Center For Health Research

Subject No: 11301081

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:25

Oct-16-2020 14:15:05 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	PFETMS Oracle (b) (4)	Query 1: Opened	Special Characters: Verbatim Term contains embedded non-compliant characters.
Oct-16-2020 10:46:52 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Tara Beatty (b) (4)	Data Entry: OBST RUCTI VE SL EEP A PNEA	Initial Entry

1.e Start Date:

Date	Location	User	Value	Reason
Oct-16-2020 10:46:52 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Tara Beatty (b) (4)	Data Entry: Jun/8/2011	Initial Entry

1.e Ongoing:

Date	Location	User	Value	Reason
Oct-16-2020 10:46:52 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Tara Beatty (b) (4)	Data Entry: YES	Initial Entry

1.f

Date	Location	User	Value	Reason
Oct-16-2020 10:47:16 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH 6 Number:	Initial Entry

090177e196ae3d43\Final\Final On: 01-Apr-2021 04:28 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

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Form Status: Data Complete, Frozen, Verified

Site No: 1130

Site Name: (1130) Kaiser Permanente Center For Health Research

Subject No: 11301081

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:25

			Medical Hi story Term OLISM DISOR : DER Start Date: Mar/26/2018 Ongoing: YES	
--	--	--	---	--

1.f Line/MH Number:

Date	Location	User	Value	Reason
Oct-16-2020 10:47:16 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 6	Initial Entry

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

Date	Location	User	Value	Reason
Oct-16-2020 10:47:16 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Tara Beatty (b) (4)	Data Entry: LIPID METABOLISM DIS ORDER	Initial Entry

1.f Start Date:

Date	Location	User	Value	Reason
Oct-16-2020 10:47:16 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Tara Beatty (b) (4)	Data Entry: Mar/26/2018	Initial Entry

1.f Ongoing:

Date	Location	User	Value	Reason
Oct-16-2020 10:47:16 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Tara Beatty (b) (4)	Data Entry: YES	Initial Entry

090177e196ae3d43\Final\Final On: 01-Apr-2021 04:28 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1130

Site Name: (1130) Kaiser Permanente Center For Health Research

Subject No: 11301081

Subject Initials: ---

Generated By: (b) (4)

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<i>I.g</i>				
Date	Location	User	Value	Reason
Oct-16-2020 10:47:48 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 7 Medical History Term: VASECTOMY Start Date: Dec/19/2002 Ongoing: NO End Date: Dec/19/2002	Initial Entry

090177e196ae3d43\Final\Final On: 01-Apr-2021 04:28 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1130

Site Name: (1130) Kaiser Permanente Center For Health Research

Subject No: 11301081

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:25

1.g Line/MH Number:

Date	Location	User	Value	Reason
Oct-16-2020 10:47:48 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 7	Initial Entry

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

Date	Location	User	Value	Reason
Oct-16-2020 10:47:48 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Tara Beatty (b) (4)	Data Entry: VASECTOMY	Initial Entry

1.g Start Date:

Date	Location	User	Value	Reason
Oct-16-2020 10:47:48 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Tara Beatty (b) (4)	Data Entry: Dec/19/2002	Initial Entry

1.g Ongoing:

Date	Location	User	Value	Reason
Oct-16-2020 10:47:48 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Tara Beatty (b) (4)	Data Entry: NO End Date: Dec/19/2002	Initial Entry

1.h

Date	Location	User	Value	Reason
Oct-19-2020 14:15:21 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Dorothy Kurdyla (b) (4)	Data Entry: Line/ 8 MH N umber	Transcription Error

090177e196ae3d43\Final\Final On: 01-Apr-2021 04:28 (GMT)

Header Text: c4591001
Visit: V1_DAY1_VAX1_L
Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History
Form Version: 22-Apr-2020 21:03
Form Status: Data Complete, Frozen, Verified
Site No: 1130
Site Name: (1130) Kaiser Permanente Center For Health Research
Subject No: 11301081
Subject Initials: ---
Generated By: (b) (4)
Generated Time (GMT): 29-Mar-2021 11:25

			<p>:</p> <p>Medic al Hist ory Term: Compression inju ry dorsum right fi fth Carpometacar pal joint</p> <p>Start Date: Dec/3/2008</p> <p>Ongoi ng: NO End Date: Dec/3/2009</p>	
<p>Oct-16-2020 15:24:03 (UTC-08:00) Pacific Time (US & Canada)</p>	ACV0PFEINFP6000	<p>Tara Beatty (b) (4)</p>	<p>Data Entry:</p> <p>Line/M H Num ber: 8</p> <p>Medica l Histor y Term: Compression inj ury dorsum right 5th CMC joint</p> <p>Start D ate: Dec/3/2008</p> <p>Ongoin g: NO End Date: Dec/3/2009</p>	Transcription Error
<p>Oct-16-2020 10:48:38 (UTC-08:00) Pacific Time (US & Canada)</p>	ACV0PFEINFP6000	<p>auto calc (autocalc)</p>	<p>Data Entry:</p> <p>Line/ MH N umber: 8</p> <p>:</p> <p>Medic al Hist ory Term: Compression injur y dorsum right 5th CMC joint with fo cal arthritis</p> <p>Start Date: Dec/3/2008</p>	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

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Site No: 1130

Subject No: 11301081

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1130) Kaiser Permanente Center For Health Research

Subject Initials: ---

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			Ongoi NO	
			ng: End Date:	
			Dec/3/2009	

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

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Form Status: Data Complete, Frozen, Verified

Site No: 1130

Site Name: (1130) Kaiser Permanente Center For Health Research

Subject No: 11301081

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:25

1.h Line/MH Number:

Date	Location	User	Value	Reason
Oct-16-2020 10:48:38 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 8	Initial Entry

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

Date	Location	User	Value	Reason
Oct-19-2020 14:15:21 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Dorothy Kurdyla (b) (4)	Data Entry : Comp ressio n inju ry dor sum ri ght fif th Car pomet acarp al join t	Transcription Error
Oct-16-2020 18:51:26 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	PFETMS Oracle (b) (4)	Query 1: Closed	Discrepancy has been closed.
Oct-16-2020 15:24:03 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Transcription Error
Oct-16-2020	ACV0PFEINFP6000	Tara Beatty	Data	Transcription

090177e196ae3d43\Final\Final On: 01-Apr-2021 04:28 (GMT)

Header Text: c4591001**Visit:** V1_DAY1_VAX1_L**Form:** GENERAL MEDICAL HISTORY - eCRF Audit Trail History**Form Version:** 22-Apr-2020 21:03**Form Status:** Data Complete, Frozen, Verified**Site No:** 1130**Site Name:** (1130) Kaiser Permanente Center For Health Research**Subject No:** 11301081**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 11:25

15:24:03 (UTC-08:00) Pacific Time (US & Canada)		(b) (4)	Entry : Comp ressio n inju ry dor sum ri ght 5t h CM C join t	Error
Oct-16-2020 14:15:21 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	PFETMS Oracle (b) (4)	Query 1: Op ened	Multiple concepts in the term COMPRESSION INJURY DORSUM RIGHT 5TH CMC JOINT WITH FOCAL ARTHRITIS. Split the term into COMPRESSION INJURY DORSUM RIGHT 5TH CMC JOINT and FOCAL ARTHRITIS and report as separate entries. Thank you.
Oct-16-2020 10:48:38 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Tara Beatty (b) (4)	Data Entry : Comp ressio n inju	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

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Form Status: Data Complete, Frozen, Verified

Site No: 1130

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Subject No: 11301081

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:25

				ry dor sum ri ght 5t h CM C join t with focal arthritis
--	--	--	--	--

I.h Start Date:

Date	Location	User	Value	Reason
Oct-16-2020 10:48:38 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Tara Beatty (b) (4)	Data Entry: Dec/3/2008	Initial Entry

I.h Ongoing:

Date	Location	User	Value	Reason
Oct-16-2020 10:48:38 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Tara Beatty (b) (4)	Data Entry: NO End Date: Dec/3/2009	Initial Entry

I.i

Date	Location	User	Value	Reason
Oct-19-2020 14:15:37 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Dorothy Kurdyla (b) (4)	Data Entry: Line/ 9 MH N umber : Medic focal arthritis of al Hist dorsum right fifth ory Te Carpometacarpal rm: joint	Transcription Error

090177e196ae3d43\Final\Final On: 01-Apr-2021 04:28 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1130

Site Name: (1130) Kaiser Permanente Center For Health Research

Subject No: 11301081

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:25

			Start Date: Dec/3/2008 Ongoing: NO End Date: Dec/3/2009	
Oct-16-2020 15:25:11 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Tara Beatty (b) (4)	Data Entry: Line/Marker Number: 9 Medical History Term: focal arthritis of dorsum right 5th CMC joint Start Date: Dec/3/2008 Ongoing: NO End Date: Dec/3/2009	Transcription Error
Oct-16-2020 15:24:54 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/Marker Number: 9 Medical History Term: dorsum right 5th CMC joint with focal arthritis Start Date: Dec/3/2008 Ongoing: NO End Date: Dec/3/2009	Initial Entry

090177e196ae3d43\Final\Final On: 01-Apr-2021 04:28 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

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Form Status: Data Complete, Frozen, Verified

Site No: 1130

Site Name: (1130) Kaiser Permanente Center For Health Research

Subject No: 11301081

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:25

1.i Line/MH Number:

Date	Location	User	Value	Reason
Oct-16-2020 15:24:54 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 9	Initial Entry

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

Date	Location	User	Value	Reason
Oct-19-2020 14:15:37 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Dorothy Kurdyla (b) (4)	Data Entry: focal arthritis of dorsum right fifth Carpometacarpal joint	Transcription Error
Oct-16-2020 15:25:11 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Tara Beatty (b) (4)	Data Entry: focal arthritis of dorsum right 5th CMC joint	Transcription Error
Oct-16-2020 15:24:54 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Tara Beatty (b) (4)	Data Entry: dorsum right 5th CMC joint with focal arthritis	Initial Entry

1.i Start Date:

Date	Location	User	Value	Reason
Oct-16-2020 15:24:54 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Tara Beatty (b) (4)	Data Entry: Dec/3/2008	Initial Entry

1.i Ongoing:

Date	Location	User	Value	Reason
Oct-16-2020 15:24:54 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Tara Beatty (b) (4)	Data Entry: NO End Date:	Initial Entry

090177e196ae3d43\Final\Final On: 01-Apr-2021 04:28 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1130

Subject No: 11301081

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1130) Kaiser Permanente Center For Health Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:25

Dec/3/2009

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 15-Sep-2020 21:57

Site No: 1130

Subject No: 11301081

Generated By: (b) (4)

Form: HIV STATUS - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1130) Kaiser Permanente Center For Health Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:25

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

Date	Location	User	Value	Reason
Oct-16-2020 10:48:53 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Tara Beatty (b) (4)	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: 1130

Subject No: 11301081

Generated By: (b) (4)

Form: VITAL SIGNS - BASELINE - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1130) Kaiser Permanente Center For Health Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:25

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1. Date:

Date	Location	User	Value	Reason
Oct-16-2020 10:49:36 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Tara Beatty (b) (4)	Data Entry: Oct/16/2020	Initial Entry

2. Weight:

Date	Location	User	Value	Reason
Oct-16-2020 10:49:36 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Tara Beatty (b) (4)	Data Entry: 93.1	Initial Entry

3. Unit:

Date	Location	User	Value	Reason
Oct-16-2020 10:49:36 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Tara Beatty (b) (4)	Data Entry: kg	Initial Entry

4. Height:

Date	Location	User	Value	Reason
Oct-16-2020 10:49:36 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Tara Beatty (b) (4)	Data Entry: 177.2	Initial Entry

5. Unit:

Date	Location	User	Value	Reason
Oct-16-2020 10:49:36 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Tara Beatty (b) (4)	Data Entry: cm	Initial Entry

6. Body Mass Index:

090177e196ae3d43\Final\Final On: 01-Apr-2021 04:28 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 10-Oct-2020 16:04

Site No: 1130

Subject No: 11301081

Generated By: (b) (4)

Form: VITAL SIGNS - BASELINE - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1130) Kaiser Permanente Center For Health Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:25

Date	Location	User	Value	Reason
Oct-16-2020 10:49:36 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 29.6	Initial Entry

7.a

Date	Location	User	Value	Reason
Oct-16-2020 10:49:36 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Tara Beatty (b) (4)	Data Entry: Record Identifier: 1 Temperature: 98.3 Temperature Unit: Temperature Location: ORAL CAVITY	Initial Entry

7.a Record Identifier:

Date	Location	User	Value	Reason
Oct-16-2020 10:49:36 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Tara Beatty (b) (4)	Data Entry: 1	Initial Entry

7.a Temperature:

Date	Location	User	Value	Reason
Oct-16-2020 10:49:36 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Tara Beatty (b) (4)	Data Entry: 98.3	Initial Entry

7.a Unit:

Date	Location	User	Value	Reason
Oct-16-2020 10:49:36 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Tara Beatty (b) (4)	Data Entry: F	Initial Entry

090177e196ae3d43\Final\Final On: 01-Apr-2021 04:28 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 10-Oct-2020 16:04

Site No: 1130

Subject No: 11301081

Generated By: (b) (4)

Form: VITAL SIGNS - BASELINE - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1130) Kaiser Permanente Center For Health Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:25

7.a Temperature Location:

Date	Location	User	Value	Reason
Oct-16-2020 10:49:36 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Tara Beatty (b) (4)	Data Entry: ORAL CAVITY	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1130

Subject No: 11301081

Generated By: (b) (4)

Form: RANDOMIZATION - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1130) Kaiser Permanente Center For Health Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:25

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1. Randomization Date :

Date	Location	User	Value	Reason
Oct-16-2020 12:30:32 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Sperry Robinson (b) (4)	Data Entry: Oct/16/2020	Initial Entry

2. Randomization Number:

Date	Location	User	Value	Reason
Oct-16-2020 12:30:32 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Sperry Robinson (b) (4)	Data Entry: 109109	Initial Entry

090177e196ae3d43\Final\Final On: 01-Apr-2021 04:28 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1130

Site Name: (1130) Kaiser Permanente Center For Health Research

Subject No: 11301081

Subject Initials: ---

Generated By: (b) (4)

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1. Data Origin

Date	Location	User	Value	Reason
Oct-16-2020 10:55:09 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Oct-16-2020 10:55:09 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SERUM	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Oct-16-2020 10:55:18 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Oct-16-2020 10:55:09 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Oct-16-2020 10:55:09 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Kristi Bays (b) (4)	Data Entry: YES Date of Collection: Oct/16/2020	Initial Entry

090177e196ae3d43\Final\Final On: 01-Apr-2021 04:28 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1130

Site Name: (1130) Kaiser Permanente Center For Health Research

Subject No: 11301081

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:25

5.a

Date	Location	User	Value	Reason
Oct-16-2020 10:55:18 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Kristi Bays (b) (4)	<u>Data Entry:</u> Sample ID: BR8MVG	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Oct-16-2020 10:55:18 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Kristi Bays (b) (4)	<u>Data Entry:</u> BR8MVG	Initial Entry

5.b

Date	Location	User	Value	Reason
Oct-16-2020 10:55:28 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Kristi Bays (b) (4)	<u>Data Entry:</u> Sample ID: BR8MVH	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Oct-16-2020 10:55:28 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Kristi Bays (b) (4)	<u>Data Entry:</u> BR8MVH	Initial Entry

5.c

Date	Location	User	Value	Reason
Oct-16-2020 10:55:38 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Kristi Bays (b) (4)	<u>Data Entry:</u> Sample ID: BPHV1R	Initial Entry

090177e196ae3d43\Final\Final On: 01-Apr-2021 04:28 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1130

Site Name: (1130) Kaiser Permanente Center For Health Research

Subject No: 11301081

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:25

5.c Sample ID

Date	Location	User	Value	Reason
Oct-16-2020 10:55:38 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Kristi Bays (b) (4)	<u>Data Entry:</u> BPHV1R	Initial Entry

5.d

Date	Location	User	Value	Reason
Oct-16-2020 10:55:49 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Kristi Bays (b) (4)	<u>Data Entry:</u> Sample ID: BPHV1S	Initial Entry

5.d Sample ID

Date	Location	User	Value	Reason
Oct-16-2020 10:55:49 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Kristi Bays (b) (4)	<u>Data Entry:</u> BPHV1S	Initial Entry

5.e

Date	Location	User	Value	Reason
Oct-16-2020 10:55:59 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Kristi Bays (b) (4)	<u>Data Entry:</u> Sample ID: BS6ZSG	Initial Entry

5.e Sample ID

Date	Location	User	Value	Reason
Oct-16-2020 10:55:59 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Kristi Bays (b) (4)	<u>Data Entry:</u> BS6ZSG	Initial Entry

090177e196ae3d43\Final\Final On: 01-Apr-2021 04:28 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1130

Site Name: (1130) Kaiser Permanente Center For Health Research

Subject No: 11301081

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:25

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1. Data Origin

Date	Location	User	Value	Reason
Oct-16-2020 10:52:09 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Oct-16-2020 10:52:09 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: NASAL_SWAB	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Oct-16-2020 10:52:21 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Oct-16-2020 10:52:09 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Oct-16-2020 10:52:09 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Kristi Bays (b) (4)	Data Entry: YES Date of Collection: Oct/16/2020	Initial Entry

090177e196ae3d43\Final\Final On: 01-Apr-2021 04:28 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1130

Site Name: (1130) Kaiser Permanente Center For Health Research

Subject No: 11301081

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:25

5.a

Date	Location	User	Value	Reason
Oct-16-2020 10:52:21 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Kristi Bays (b) (4)	Data Entry: Sample ID: BR8MTZ	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Oct-16-2020 10:52:21 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Kristi Bays (b) (4)	Data Entry: BR8MTZ	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:04

Site No: 1130

Subject No: 11301081

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1130) Kaiser Permanente Center For Health Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:25

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1. Was there a temporary delay of vaccination?

Date	Location	User	Value	Reason
Oct-16-2020 12:30:08 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Sperry Robinson (b) (4)	Data Entry: NO	Initial Entry

2. Treatment Name

Date	Location	User	Value	Reason
Oct-16-2020 12:30:08 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: BLINDED THERAPY	Initial Entry

3. Formulation:

Date	Location	User	Value	Reason
Oct-16-2020 12:30:08 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INJECTION	Initial Entry

4. Dose Date Time:

Date	Location	User	Value	Reason
Oct-16-2020 12:30:08 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Sperry Robinson (b) (4)	Data Entry: Oct/16/2020 11:30	Initial Entry

5. Anatomical Location:

Date	Location	User	Value	Reason
Oct-16-2020 12:30:08 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: DELTOID MUSCLE	Initial Entry

6. Body Side:

090177e196ae3d43\Final\Final On: 01-Apr-2021 04:28 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:04

Site No: 1130

Subject No: 11301081

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1130) Kaiser Permanente Center For Health Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:25

Date	Location	User	Value	Reason
Oct-16-2020 12:30:08 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Sperry Robinson (b) (4)	Data Entry: LEFT	Initial Entry

7. Route:

Date	Location	User	Value	Reason
Oct-16-2020 12:30:08 (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
Oct-16-2020 12:30:08 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: THE PROTOCOL SPECIFIE D OBSERVATION PERIOD	Initial Entry

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

Date	Location	User	Value	Reason
Oct-16-2020 12:30:08 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Sperry Robinson (b) (4)	Data Entry: YES	Initial Entry

090177e196ae3d43\Final\Final On: 01-Apr-2021 04:28 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 06-Jul-2020 21:53

Site No: 1130

Subject No: 11301081

Generated By: (b) (4)

Form: REACTOGENICITY DIARY - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1130) Kaiser Permanente Center For Health Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:25

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1. Select appropriate response - Reactogenicity diary collection

Date	Location	User	Value	Reason
Oct-16-2020 12:30:15 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Sperry Robinson (b) (4)	Data Entry: NO - REACTOGENICITY E-DIARY NOT COLLECT ED FOR THIS SUBJECT	Initial Entry

090177e196ae3d43\Final\Final On: 01-Apr-2021 04:28 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 1130

Subject No: 11301081

Generated By: (b) (4)

Form: DATE OF VISIT - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1130) Kaiser Permanente Center For Health Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:25

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I. Date of Visit

Date	Location	User	Value	Reason
Nov-06-2020 08:23:07 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Kristi Bays (b) (4)	Data Entry: Nov/6/2020	Initial Entry

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 10-Oct-2020 16:01

Site No: 1130

Subject No: 11301081

Generated By: (b) (4)

Form: VITAL SIGNS - TEMP - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1130) Kaiser Permanente Center For Health Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:25

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1. Date:

Date	Location	User	Value	Reason
Nov-06-2020 08:26:18 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Tara Beatty (b) (4)	Data Entry: Nov/6/2020	Initial Entry

2.a

Date	Location	User	Value	Reason
Nov-06-2020 08:26:08 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Tara Beatty (b) (4)	Data Entry: Record Identifier: Temperature: 98.4 Temperature Unit: Temperature Location: ORAL CAVITY	Initial Entry

2.a Record Identifier:

Date	Location	User	Value	Reason
Nov-06-2020 08:26:08 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Tara Beatty (b) (4)	Data Entry: 1	Initial Entry

2.a Temperature:

Date	Location	User	Value	Reason
Nov-06-2020 08:26:08 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Tara Beatty (b) (4)	Data Entry: 98.4	Initial Entry

2.a Unit:

Date	Location	User	Value	Reason
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090177e196ae3d43\Final\Final On: 01-Apr-2021 04:28 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 10-Oct-2020 16:01

Site No: 1130

Subject No: 11301081

Generated By: (b) (4)

Form: VITAL SIGNS - TEMP - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1130) Kaiser Permanente Center For Health Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:25

Nov-06-2020 08:26:08 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Tara Beatty (b) (4)	Data Entry: F	Initial Entry
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2.a Temperature Location:

Date	Location	User	Value	Reason
Nov-06-2020 08:26:08 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Tara Beatty (b) (4)	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: 1130

Site Name: (1130) Kaiser Permanente Center For Health Research

Subject No: 11301081

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:25

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1. Data Origin

Date	Location	User	Value	Reason
Nov-06-2020 08:23:17 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Nov-06-2020 08:23:17 (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
Nov-06-2020 08:23:30 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Nov-06-2020 08:23:17 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Nov-06-2020 08:23:17 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Kristi Bays (b) (4)	Data Entry: YES Date of Collection: Nov/6/2020	Initial Entry

090177e196ae3d43\Final\Final On: 01-Apr-2021 04:28 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1130

Site Name: (1130) Kaiser Permanente Center For Health Research

Subject No: 11301081

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:25

5.a

Date	Location	User	Value	Reason
Nov-06-2020 08:23:30 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Kristi Bays (b) (4)	Data Entry: Sample ID: BR8MXT	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Nov-06-2020 08:23:30 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Kristi Bays (b) (4)	Data Entry: BR8MXT	Initial Entry

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1130

Subject No: 11301081

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1130) Kaiser Permanente Center For Health Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:25

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1. Was there a temporary delay of vaccination?

Date	Location	User	Value	Reason
Nov-06-2020 13:10:27 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Sperry Robinson (b) (4)	Data Entry: NO	Initial Entry

2. Treatment Name

Date	Location	User	Value	Reason
Nov-06-2020 13:10:27 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: BLINDED THERAPY	Initial Entry

3. Formulation:

Date	Location	User	Value	Reason
Nov-06-2020 13:10:27 (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
Nov-06-2020 13:10:27 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Sperry Robinson (b) (4)	Data Entry: Nov/6/2020 09:04	Initial Entry

5. Anatomical Location:

Date	Location	User	Value	Reason
Nov-06-2020 13:10:27 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: DELTOID MUSCLE	Initial Entry

090177e196ae3d43\Final\Final On: 01-Apr-2021 04:28 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1130

Subject No: 11301081

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1130) Kaiser Permanente Center For Health Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:25

6. Body Side:

Date	Location	User	Value	Reason
Nov-06-2020 13:10:27 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Sperry Robinson (b) (4)	Data Entry: LEFT	Initial Entry

7. Route:

Date	Location	User	Value	Reason
Nov-06-2020 13:10:27 (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
Nov-06-2020 13:10:27 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: THE PROTOCOL SPECIFIED OBSERVATION PERIOD	Initial Entry

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

Date	Location	User	Value	Reason
Nov-06-2020 13:10:27 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Sperry Robinson (b) (4)	Data Entry: YES	Initial Entry

090177e196ae3d43\Final\Final On: 01-Apr-2021 04:28 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form: DATE OF VISIT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen, Verified

Site No: 1130

Site Name: (1130) Kaiser Permanente Center For Health Research

Subject No: 11301081

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:25

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I. Date of Visit

Date	Location	User	Value	Reason
Dec-04-2020 08:07:27 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Tara Beatty (b) (4)	Data Entry: Dec/4/2020	Initial Entry

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1130

Site Name: (1130) Kaiser Permanente Center For Health Research

Subject No: 11301081

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:25

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1. Data Origin

Date	Location	User	Value	Reason
Dec-04-2020 11:02:04 (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-04-2020 11:02:04 (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-04-2020 11:02:28 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Dec-04-2020 11:02:04 (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-04-2020 11:02:04 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Collection: Dec/4/2020	Initial Entry

090177e196ae3d43\Final\Final On: 01-Apr-2021 04:28 (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: 1130

Site Name: (1130) Kaiser Permanente Center For Health Research

Subject No: 11301081

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:25

5.a

Date	Location	User	Value	Reason
Dec-04-2020 11:02:28 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BPOX8L	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Dec-04-2020 11:02:28 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BPOX8L	Initial Entry

5.b

Date	Location	User	Value	Reason
Dec-04-2020 11:04:29 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BPOX8M	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Dec-04-2020 11:04:29 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BPOX8M	Initial Entry

5.c

Date	Location	User	Value	Reason
Dec-04-2020 11:05:11 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BS701X	Initial Entry

090177e196ae3d43\Final\Final On: 01-Apr-2021 04:28 (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: 1130

Site Name: (1130) Kaiser Permanente Center For Health Research

Subject No: 11301081

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:25

5.c Sample ID

Date	Location	User	Value	Reason
Dec-04-2020 11:05:11 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BS701X	Initial Entry

5.d

Date	Location	User	Value	Reason
Dec-04-2020 11:05:21 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BS701Y	Initial Entry

5.d Sample ID

Date	Location	User	Value	Reason
Dec-04-2020 11:05:21 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BS701Y	Initial Entry

5.e

Date	Location	User	Value	Reason
Dec-04-2020 11:05:32 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BS701Z	Initial Entry

5.e Sample ID

Date	Location	User	Value	Reason
Dec-04-2020 11:05:32 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BS701Z	Initial Entry

090177e196ae3d43\Final\Final On: 01-Apr-2021 04:28 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Feb/10/2021

Form: DATE OF VISIT - ILLNESS ONSET - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1130

Site Name: (1130) Kaiser Permanente Center For Health Research

Subject No: 11301081

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:25

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1. Date of Visit

Date	Location	User	Value	Reason
Feb-16-2021 20:31:36 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Feb-16-2021 10:00:52 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Answer Auto Query
Feb-15-2021 15:06:15 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued:Opened	Please provide the details of the self swab once received.
Feb-15-2021 09:24:11 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	self swab to be performed on 2/13/21, but not yet received in lab for scanning. Is it preferable to add the expected swab date or wait until the self swab is received in the lab for scanning?
Feb-15-2021 01:11:43 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	Date of Visit is completed but Date of Collection in both Nasal Swab Self and Nasal Swab are missing.

090177e196ae3d43\Final\Final On: 01-Apr-2021 04:28 (GMT)

Header Text: c4591001**Visit:** POT_COVID_ILL 1 - Unscheduled
Visit on Feb/10/2021**Form:** DATE OF VISIT - ILLNESS ONSET - eCRF Audit Trail
History**Form Version:** 22-Apr-2020 21:03**Form Status:** Data Complete, Frozen, Verified**Site No:** 1130**Site Name:** (1130) Kaiser Permanente Center For Health Research**Subject No:** 11301081**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 11:25

				Please review and update as appropriate.
Feb-14-2021 22:47:31 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Closed	Response satisfies query
Feb-12-2021 10:34:41 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Answered	Changed data per query
Feb-12-2021 10:34:03 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	Date of Visit is completed but Date of Collection in both Nasal Swab Self and Nasal Swab are missing. Please review and update as appropriate.
Feb-11-2021 03:58:18 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Opened	DM: Kindly review and complete 'Health Care Utilization, Microbiology Specimen, Illness Details form' at this visit. Thank you.
Feb-11-2021 01:56:59 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	Date of Visit is completed but Date of Collection in both Nasal Swab Self and Nasal Swab are missing.

Header Text: c4591001
Visit: POT_COVID_ILL 1 - Unscheduled Visit on Feb/10/2021
Form Version: 22-Apr-2020 21:03
Site No: 1130
Subject No: 11301081
Generated By: (b) (4)
Form: DATE OF VISIT - ILLNESS ONSET - eCRF Audit Trail History
Form Status: Data Complete, Frozen, Verified
Site Name: (1130) Kaiser Permanente Center For Health Research
Subject Initials: ---
Generated Time (GMT): 29-Mar-2021 11:25

				Please review and update as appropriate.
Feb-10-2021 15:32:46 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Deleted	Close Auto Query
Feb-10-2021 15:31:33 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Candidate	Date of Visit is completed but Date of Assessment in the Signs and Symptoms form is missing. Please review and update as appropriate.
Feb-10-2021 15:31:33 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	Date of Visit is completed but Date of Collection in both Nasal Swab Self and Nasal Swab are missing. Please review and update as appropriate.
Feb-10-2021 15:31:33 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Tara Beatty (b) (4)	Data Entry: Feb/10/2021	Initial Entry

3. COVID-19 Illness Visit:

Date	Location	User	Value	Reason
Feb-10-2021 15:31:33 (UTC-08:00) Pacific	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: COVID_A	Initial Entry

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled
Visit on Feb/10/2021

Form: DATE OF VISIT - ILLNESS ONSET - eCRF Audit Trail
History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1130

Site Name: (1130) Kaiser Permanente Center For Health Research

Subject No: 11301081

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:25

Time (US & Canada)

Header Text: c4591001**Visit:** POT_COVID_ILL 1 - Unscheduled
Visit on Feb/10/2021**Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 -
eCRF Audit Trail History**Form Version:** 14-Jan-2021 02:23**Form Status:** Data Complete**Site No:** 1130**Site Name:** (1130) Kaiser Permanente Center For Health Research**Subject No:** 11301081**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 11:25[Back to Form](#)**1. Date of Assessment:**

Date	Location	User	Value	Reason
Feb-10-2021 15:32:46 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Tara Beatty (b) (4)	Data Entry: Feb/10/2021	Initial Entry

2. Date of First Symptom Started:

Date	Location	User	Value	Reason
Feb-10-2021 15:32:46 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Tara Beatty (b) (4)	Data Entry: Feb/9/2021	Initial Entry

3. Symptoms Ongoing?

Date	Location	User	Value	Reason
Feb-18-2021 13:33:52 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Dorothy Kurdyla (b) (4)	Data Entry: NO Date of Last Symptom Re- solved: Feb/12/2021	New Information
Feb-10-2021 15:32:46 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Tara Beatty (b) (4)	Data Entry: YES	Initial Entry

4.a

Date	Location	User	Value	Reason
Feb-10-2021 15:32:46 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Tara Beatty (b) (4)	Data Entry: Symptoms: FEVER Symptom Present: NO	Initial Entry

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled
Visit on Feb/10/2021

Form: SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 -
eCRF Audit Trail History

Form Version: 14-Jan-2021 02:23

Form Status: Data Complete

Site No: 1130

Site Name: (1130) Kaiser Permanente Center For Health Research

Subject No: 11301081

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:25

4.a Symptoms:

Date	Location	User	Value	Reason
Feb-10-2021 15:32:46 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Tara Beatty (b) (4)	Data Entry: FEVER	Initial Entry

4.a Was symptom present?

Date	Location	User	Value	Reason
Feb-10-2021 15:32:46 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Tara Beatty (b) (4)	Data Entry: NO	Initial Entry

4.b

Date	Location	User	Value	Reason
Feb-10-2021 15:32:46 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Tara Beatty (b) (4)	Data Entry: Symptom NEW OR INCR s: EASED COUG H Symptom NO Present:	Initial Entry

4.b Symptoms:

Date	Location	User	Value	Reason
Feb-10-2021 15:32:46 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Tara Beatty (b) (4)	Data Entry: NEW OR INCREASED CO UGH	Initial Entry

4.b Was symptom present?

Date	Location	User	Value	Reason
Feb-10-2021 15:32:46 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Tara Beatty (b) (4)	Data Entry: NO	Initial Entry

090177e196ae3d43\Final\Final On: 01-Apr-2021 04:28 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Feb/10/2021

Form: SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF Audit Trail History

Form Version: 14-Jan-2021 02:23

Form Status: Data Complete

Site No: 1130

Site Name: (1130) Kaiser Permanente Center For Health Research

Subject No: 11301081

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:25

4.c

Date	Location	User	Value	Reason
Feb-10-2021 15:32:46 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Tara Beatty (b) (4)	Data Entry: Symptom: NEW OR INCREASED SHORTNESS OF BREATH Symptom Present: NO	Initial Entry

4.c Symptoms:

Date	Location	User	Value	Reason
Feb-10-2021 15:32:46 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Tara Beatty (b) (4)	Data Entry: NEW OR INCREASED SHORTNESS OF BREATH	Initial Entry

4.c Was symptom present?

Date	Location	User	Value	Reason
Feb-10-2021 15:32:46 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Tara Beatty (b) (4)	Data Entry: NO	Initial Entry

4.d

Date	Location	User	Value	Reason
Feb-10-2021 15:32:46 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Tara Beatty (b) (4)	Data Entry: Symptoms: CHILLS Symptom Present: NO	Initial Entry

090177e196ae3d43\Final\Final On: 01-Apr-2021 04:28 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled
Visit on Feb/10/2021

Form: SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 -
eCRF Audit Trail History

Form Version: 14-Jan-2021 02:23

Form Status: Data Complete

Site No: 1130

Site Name: (1130) Kaiser Permanente Center For Health Research

Subject No: 11301081

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:25

4.d Symptoms:

Date	Location	User	Value	Reason
Feb-10-2021 15:32:46 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Tara Beatty (b) (4)	Data Entry: CHILLS	Initial Entry

4.d Was symptom present?

Date	Location	User	Value	Reason
Feb-10-2021 15:32:46 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Tara Beatty (b) (4)	Data Entry: NO	Initial Entry

4.e

Date	Location	User	Value	Reason
Feb-10-2021 15:32:46 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Tara Beatty (b) (4)	Data Entry: Symptom: NEW OR INCREASED MUSCLE PAIN Symptom Present: NO	Initial Entry

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled
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Form: SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 -
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Form Version: 14-Jan-2021 02:23

Form Status: Data Complete

Site No: 1130

Site Name: (1130) Kaiser Permanente Center For Health Research

Subject No: 11301081

Subject Initials: ---

Generated By: (b) (4)

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4.e Symptoms:

Date	Location	User	Value	Reason
Feb-10-2021 15:32:46 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Tara Beatty (b) (4)	Data Entry: NEW OR INCREASED MU SCLE PAIN	Initial Entry

4.e Was symptom present?

Date	Location	User	Value	Reason
Feb-10-2021 15:32:46 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Tara Beatty (b) (4)	Data Entry: NO	Initial Entry

4.f

Date	Location	User	Value	Reason
Feb-10-2021 15:32:46 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Tara Beatty (b) (4)	Data Entry: Symptom: NEW LOSS OF TASTE OR SME LL Symptom Present: NO	Initial Entry

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Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled
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Generated By: (b) (4)

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4.f Symptoms:

Date	Location	User	Value	Reason
Feb-10-2021 15:32:46 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Tara Beatty (b) (4)	Data Entry: NEW LOSS OF TASTE OR SMELL	Initial Entry

4.f Was symptom present?

Date	Location	User	Value	Reason
Feb-10-2021 15:32:46 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Tara Beatty (b) (4)	Data Entry: NO	Initial Entry

4.g

Date	Location	User	Value	Reason
Feb-10-2021 15:32:46 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Tara Beatty (b) (4)	Data Entry: Symptom: NEW OR INCREASED SORE THROAT Symptom Present: NO	Initial Entry

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled
Visit on Feb/10/2021

Form: SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 -
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Form Version: 14-Jan-2021 02:23

Form Status: Data Complete

Site No: 1130

Site Name: (1130) Kaiser Permanente Center For Health Research

Subject No: 11301081

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:25

4.g Symptoms:

Date	Location	User	Value	Reason
Feb-10-2021 15:32:46 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Tara Beatty (b) (4)	Data Entry: NEW OR INCREASED SO RE THROAT	Initial Entry

4.g Was symptom present?

Date	Location	User	Value	Reason
Feb-10-2021 15:32:46 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Tara Beatty (b) (4)	Data Entry: NO	Initial Entry

4.h

Date	Location	User	Value	Reason
Feb-10-2021 15:32:46 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Tara Beatty (b) (4)	Data Entry: Symptoms: DIARRHE A Symptom Prese nt: YES	Initial Entry

4.h Symptoms:

Date	Location	User	Value	Reason
Feb-10-2021 15:32:46 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Tara Beatty (b) (4)	Data Entry: DIARRHEA	Initial Entry

4.h Was symptom present?

Date	Location	User	Value	Reason
Feb-10-2021 15:32:46 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Tara Beatty (b) (4)	Data Entry: YES	Initial Entry

090177e196ae3d43\Final\Final On: 01-Apr-2021 04:28 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled
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Form: SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 -
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Form Status: Data Complete

Site No: 1130

Site Name: (1130) Kaiser Permanente Center For Health Research

Subject No: 11301081

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:25

4.i

Date	Location	User	Value	Reason
Feb-10-2021 15:32:46 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Tara Beatty (b) (4)	Data Entry: Symptoms: VOMITIN G Symptom Present: NO	Initial Entry

4.i Symptoms:

Date	Location	User	Value	Reason
Feb-10-2021 15:32:46 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Tara Beatty (b) (4)	Data Entry: VOMITING	Initial Entry

4.i Was symptom present?

Date	Location	User	Value	Reason
Feb-10-2021 15:32:46 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Tara Beatty (b) (4)	Data Entry: NO	Initial Entry

090177e196ae3d43\Final\Final On: 01-Apr-2021 04:28 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled
Visit on Feb/10/2021

Form: MICROBIOLOGY SPECIMEN - eCRF Audit Trail History

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen

Site No: 1130

Site Name: (1130) Kaiser Permanente Center For Health Research

Subject No: 11301081

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:25

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1. Actual Date of Collection:

Date	Location	User	Value	Reason
Feb-12-2021 10:32:14 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

2. Specimen Type:

Date	Location	User	Value	Reason
Feb-12-2021 10:32:14 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

3. Specimen Collection Location:

Date	Location	User	Value	Reason
Feb-12-2021 10:32:14 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

4. Assay Code and Description:

Date	Location	User	Value	Reason
Feb-12-2021 10:32:14 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5. Device Type:

Date	Location	User	Value	Reason
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090177e196ae3d43\Final\Final On: 01-Apr-2021 04:28 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled **Form:** MICROBIOLOGY SPECIMEN - eCRF Audit Trail History
Visit on Feb/10/2021

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen

Site No: 1130

Site Name: (1130) Kaiser Permanente Center For Health Research

Subject No: 11301081

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:25

Feb-12-2021 10:32:14 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry
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6. Trade Name:

Date	Location	User	Value	Reason
Feb-12-2021 10:32:14 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

7. Test Result:

Date	Location	User	Value	Reason
Feb-12-2021 10:32:14 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

8. Comments/Findings/Details:

Date	Location	User	Value	Reason
Feb-12-2021 10:32:14 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

9. Trade Name Other, Specify:

Date	Location	User	Value	Reason
Feb-12-2021 10:32:14 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

090177e196ae3d43\Final\Final On: 01-Apr-2021 04:28 (GMT)

Header Text: c4591001**Visit:** POT_COVID_ILL 1 - Unscheduled
Visit on Feb/10/2021**Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB
SELF - eCRF Audit Trail History**Form Version:** 22-Apr-2020 21:03**Form Status:** Data Complete, Frozen, Verified**Site No:** 1130**Site Name:** (1130) Kaiser Permanente Center For Health Research**Subject No:** 11301081**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 11:25[Back to Form](#)**1. Data Origin**

Date	Location	User	Value	Reason
Feb-16-2021 10:00:52 (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-16-2021 10:00:52 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: NASAL_SWAB_SELF	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Feb-17-2021 06:54:04 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Feb-17-2021 04:57:08 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Feb-16-2021 10:00:52 (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

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled
Visit on Feb/10/2021

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1130

Site Name: (1130) Kaiser Permanente Center For Health Research

Subject No: 11301081

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:25

				correct as appropriate.
Feb-16-2021 10:00:52 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Collection: Feb/13/2021	Initial Entry

5.a

Date	Location	User	Value	Reason
Feb-17-2021 06:54:04 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Kristi Bays (b) (4)	Data Entry: Sample ID: RW84037	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Feb-17-2021 06:54:04 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Kristi Bays (b) (4)	Data Entry: RW84037	Initial Entry

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Header Text: c4591001**Visit:** POT_COVID_ILL 1 - Unscheduled
Visit on Feb/10/2021**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:** 1130**Site Name:** (1130) Kaiser Permanente Center For Health Research**Subject No:** 11301081**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 11:25[Back to Form](#)**1. Data Origin**

Date	Location	User	Value	Reason
Feb-12-2021 10:34:03 (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-12-2021 10:34:03 (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
Feb-16-2021 23:07:04 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Feb-16-2021 10:01:16 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Changed data per query
Feb-15-2021 15:04:41 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued:Open ed	The data has not been updated on the SELF SWAB form within this visit. Please record the details of the self swab else clarify.

Header Text: c4591001**Visit:** POT_COVID_ILL 1 - Unscheduled
Visit on Feb/10/2021**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:** 1130**Site Name:** (1130) Kaiser Permanente Center For Health Research**Subject No:** 11301081**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 11:25

Feb-15-2021 09:22:48 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Changed data per query
Feb-14-2021 21:58:33 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	DM: Per comment Self swab performed. However, Self Swab CRF is not initiated. Kindly review and update the Self swab details in the corresponding CRF. Thanks
Feb-12-2021 10:34:03 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

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

Date	Location	User	Value	Reason
Feb-12-2021 10:34:03 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: self swab performed	Initial Entry

Header Text: c4591001**Visit:** POT_COVID_ILL 1 - Unscheduled
Visit on Feb/10/2021**Form:** HEALTH CARE UTILIZATION - eCRF Audit Trail
History**Form Version:** 14-Jan-2021 02:24**Form Status:** Data Complete**Site No:** 1130**Site Name:** (1130) Kaiser Permanente Center For Health Research**Subject No:** 11301081**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 11:25[Back to Form](#)**I.a**

Date	Location	User	Value	Reason
Feb-12-2021 10:31:56 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Type of Practitioner: SPECIALIST Occurrence of Visits or Contacts: NO	Initial Entry

I.a Physician or Healthcare Professional:

Date	Location	User	Value	Reason
Feb-12-2021 10:31:56 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: SPECIALIST	Initial Entry

I.a Occurrence of Visits or Contacts:

Date	Location	User	Value	Reason
Feb-12-2021 10:31:56 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

I.b

Date	Location	User	Value	Reason
Feb-12-2021 10:31:56 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Type of Practitioner: EMERGENCY ROOM	Initial Entry

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled
Visit on Feb/10/2021

Form: HEALTH CARE UTILIZATION - eCRF Audit Trail
History

Form Version: 14-Jan-2021 02:24

Form Status: Data Complete

Site No: 1130

Site Name: (1130) Kaiser Permanente Center For Health Research

Subject No: 11301081

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:25

			Occurrence of NO Visits or Contacts:	
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1.b Physician or Healthcare Professional:

Date	Location	User	Value	Reason
Feb-12-2021 10:31:56 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: EMERGENCY ROOM	Initial Entry

1.b Occurrence of Visits or Contacts:

Date	Location	User	Value	Reason
Feb-12-2021 10:31:56 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

1.c

Date	Location	User	Value	Reason
Feb-12-2021 10:31:56 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Type of Practitioner: PRIMARY CARE PHYSICIAN Occurrence of Visits or Contacts: NO	Initial Entry

090177e196ae3d43\Final\Final On: 01-Apr-2021 04:28 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled
Visit on Feb/10/2021

Form: HEALTH CARE UTILIZATION - eCRF Audit Trail
History

Form Version: 14-Jan-2021 02:24

Form Status: Data Complete

Site No: 1130

Site Name: (1130) Kaiser Permanente Center For Health Research

Subject No: 11301081

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:25

I.c Physician or Healthcare Professional:

Date	Location	User	Value	Reason
Feb-12-2021 10:31:56 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: PRIMARY CARE PHYSI CIAN	Initial Entry

I.c Occurrence of Visits or Contacts:

Date	Location	User	Value	Reason
Feb-12-2021 10:31:56 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

I.d

Date	Location	User	Value	Reason
Feb-12-2021 10:31:56 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Type of Practiti URGEN oner: T CAR E Occurrence of NO Visits or Conta cts:	Initial Entry

090177e196ae3d43\Final\Final On: 01-Apr-2021 04:28 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled
Visit on Feb/10/2021

Form: HEALTH CARE UTILIZATION - eCRF Audit Trail
History

Form Version: 14-Jan-2021 02:24

Form Status: Data Complete

Site No: 1130

Site Name: (1130) Kaiser Permanente Center For Health Research

Subject No: 11301081

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:25

1.d Physician or Healthcare Professional:

Date	Location	User	Value	Reason
Feb-12-2021 10:31:56 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: URGENT CARE	Initial Entry

1.d Occurrence of Visits or Contacts:

Date	Location	User	Value	Reason
Feb-12-2021 10:31:56 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

1.e

Date	Location	User	Value	Reason
Feb-12-2021 10:31:56 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Type of Practitioner: TELEPHONE CONSULTATION Occurrence of Visits or Contacts: NO	Initial Entry

090177e196ae3d43\Final\Final On: 01-Apr-2021 04:28 (GMT)

Header Text: c4591001
Visit: POT_COVID_ILL 1 - Unscheduled Visit on Feb/10/2021
Form Version: 14-Jan-2021 02:24
Site No: 1130
Subject No: 11301081
Generated By: (b) (4)

Form: HEALTH CARE UTILIZATION - eCRF Audit Trail History
Form Status: Data Complete
Site Name: (1130) Kaiser Permanente Center For Health Research
Subject Initials: ---
Generated Time (GMT): 29-Mar-2021 11:25

I.e Physician or Healthcare Professional:

Date	Location	User	Value	Reason
Feb-12-2021 10:31:56 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: TELEPHONE CONSULTATION	Initial Entry

I.e Occurrence of Visits or Contacts:

Date	Location	User	Value	Reason
Feb-12-2021 10:31:56 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

I.f

Date	Location	User	Value	Reason
Feb-12-2021 10:31:56 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Type of Practitioner: OTH ER Occurrence of Visits or Contacts: NO	Initial Entry

090177e196ae3d43\Final\Final On: 01-Apr-2021 04:28 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled
Visit on Feb/10/2021

Form: HEALTH CARE UTILIZATION - eCRF Audit Trail
History

Form Version: 14-Jan-2021 02:24

Form Status: Data Complete

Site No: 1130

Site Name: (1130) Kaiser Permanente Center For Health Research

Subject No: 11301081

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:25

1.f Physician or Healthcare Professional:

Date	Location	User	Value	Reason
Feb-12-2021 10:31:56 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: OTHER	Initial Entry

1.f Occurrence of Visits or Contacts:

Date	Location	User	Value	Reason
Feb-12-2021 10:31:56 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

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

Date	Location	User	Value	Reason
Feb-12-2021 10:31:56 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

090177e196ae3d43\Final\Final On: 01-Apr-2021 04:28 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled **Form:** ILLNESS DETAILS - eCRF Audit Trail History
Visit on Feb/10/2021

Form Version: 06-Jul-2020 21:52 **Form Status:** Data Complete

Site No: 1130 **Site Name:** (1130) Kaiser Permanente Center For Health Research

Subject No: 11301081 **Subject Initials:** ---

Generated By: (b) (4) **Generated Time (GMT):** 29-Mar-2021 11:25

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1. Category of Clinical Event:

Date	Location	User	Value	Reason
Feb-12-2021 10:33:43 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: POTENTIAL COVID-19 ILL NESS	Initial Entry

2. Was a diagnosis obtained for Potential COVID-19 Illness?

Date	Location	User	Value	Reason
Feb-12-2021 10:33:43 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

3. Toxicity Grade:

Date	Location	User	Value	Reason
Feb-12-2021 10:33:43 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 2	Initial Entry

090177e196ae3d43\Final\Final On: 01-Apr-2021 04:28 (GMT)

Header Text: c4591001

Visit: POT_COVID_CONVA 1 -
Unscheduled Visit on Mar/12/2021

Form Version: 22-Apr-2020 21:04

Site No: 1130

Subject No: 11301081

Generated By: (b) (4)

Form: DATE OF VISIT - ILLNESS CONVALESCENT - eCRF
Audit Trail History

Form Status: Data Complete, Verified

Site Name: (1130) Kaiser Permanente Center For Health Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:25

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1. Date of Visit

Date	Location	User	Value	Reason
Mar-12-2021 16:26:02 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Mar/12/2021	Initial Entry

3. COVID-19 Illness Visit:

Date	Location	User	Value	Reason
Mar-12-2021 16:26:02 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: COVID_A1	Initial Entry

090177e196ae3d43\Final\Final On: 01-Apr-2021 04:28 (GMT)

Header Text: c4591001

Visit: POT_COVID_CONVA 1 -
Unscheduled Visit on Mar/12/2021

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Verified

Site No: 1130

Site Name: (1130) Kaiser Permanente Center For Health Research

Subject No: 11301081

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:25

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1. Data Origin

Date	Location	User	Value	Reason
Mar-12-2021 16:26:18 (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 16:26:18 (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-12-2021 16:26:31 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Mar-12-2021 16:26:18 (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.
Mar-12-2021 16:26:18 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Collection: Mar/12/2021	Initial Entry

090177e196ae3d43\Final\Final On: 01-Apr-2021 04:28 (GMT)

Header Text: c4591001

Visit: POT_COVID_CONVA 1 -
Unscheduled Visit on Mar/12/2021

Form Version: 22-Apr-2020 21:03

Site No: 1130

Subject No: 11301081

Generated By: (b) (4)

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

Form Status: Data Complete, Verified

Site Name: (1130) Kaiser Permanente Center For Health Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:25

5.a

Date	Location	User	Value	Reason
Mar-12-2021 16:26:31 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BPOXKJ	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Mar-12-2021 16:26:31 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BPOXKJ	Initial Entry

5.b

Date	Location	User	Value	Reason
Mar-12-2021 16:26:43 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BPOXL0	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Mar-12-2021 16:26:43 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BPOXL0	Initial Entry

5.c

Date	Location	User	Value	Reason
Mar-12-2021 16:27:01 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BPHV8S	Initial Entry

090177e196ae3d43\Final\Final On: 01-Apr-2021 04:28 (GMT)

Header Text: c4591001

Visit: POT_COVID_CONVA 1 -
Unscheduled Visit on Mar/12/2021

Form Version: 22-Apr-2020 21:03

Site No: 1130

Subject No: 11301081

Generated By: (b) (4)

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

Form Status: Data Complete, Verified

Site Name: (1130) Kaiser Permanente Center For Health Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:25

5.c Sample ID

Date	Location	User	Value	Reason
Mar-12-2021 16:27:01 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BPHV8S	Initial Entry

5.d

Date	Location	User	Value	Reason
Mar-12-2021 16:27:12 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BPHV8T	Initial Entry

5.d Sample ID

Date	Location	User	Value	Reason
Mar-12-2021 16:27:12 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BPHV8T	Initial Entry

5.e

Date	Location	User	Value	Reason
Mar-12-2021 16:27:22 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BPHV8V	Initial Entry

5.e Sample ID

Date	Location	User	Value	Reason
Mar-12-2021 16:27:22 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BPHV8V	Initial Entry

5.f

Date	Location	User	Value	Reason
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090177e196ae3d43\Final\Final On: 01-Apr-2021 04:28 (GMT)

Header Text: c4591001

Visit: POT_COVID_CONVA 1 -
Unscheduled Visit on Mar/12/2021

Form Version: 22-Apr-2020 21:03

Site No: 1130

Subject No: 11301081

Generated By: (b) (4)

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

Form Status: Data Complete, Verified

Site Name: (1130) Kaiser Permanente Center For Health Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:25

Mar-12-2021 16:27:33 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BPHV8W	Initial Entry
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5.f Sample ID

Date	Location	User	Value	Reason
Mar-12-2021 16:27:33 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BPHV8W	Initial Entry

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - Audit Trail

Form Version: 22-Apr-2020 21:02

Form Status:

Site No: 1130

Site Name: (1130) Kaiser Permanente Center For Health Research

Subject No: 11301081

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:25

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Date	Location	User	Value	Reason
Feb-12-2021 14:44:08 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

090177e196ae3d43\Final\Final On: 01-Apr-2021 04:28 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1130

Subject No: 11301081

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Frozen

Site Name: (1130) Kaiser Permanente Center For Health Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:25

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1. Category:

Date	Location	User	Value	Reason
Feb-12-2021 14:44:08 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: ADVERSE EVENT	Initial Entry

2. AE ID:

Date	Location	User	Value	Reason
Feb-12-2021 14:44:08 (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
Feb-12-2021 14:44:08 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: swollen lymph node - right side of neck	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason
Feb-12-2021 14:44:08 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Feb/11/2021 16:00	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Feb-18-2021 13:33:03 (UTC-08:00) Pacific	ACV0PFEINFP6000	Dorothy Kurdyla (b) (4)	Data Entry: NO End Date Time:	New Information

090177e196ae3d43\Final\Final On: 01-Apr-2021 04:28 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1130

Subject No: 11301081

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Frozen

Site Name: (1130) Kaiser Permanente Center For Health Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:25

Time (US & Canada)			Feb/12/2021 23:00	
Feb-12-2021 14:44:08 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
Feb-17-2021 00:38:24 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Feb-16-2021 09:59:42 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Initial Entry
Feb-16-2021 09:59:42 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 1	Initial Entry
Feb-15-2021 21:50:54 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	DM: The response for "Toxicity Grade" is missing. Kindly review and update.

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).

090177e196ae3d43\Final\Final On: 01-Apr-2021 04:28 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1130

Subject No: 11301081

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Frozen

Site Name: (1130) Kaiser Permanente Center For Health Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:25

Date	Location	User	Value	Reason
Feb-17-2021 00:39:48 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Feb-16-2021 09:59:42 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Initial Entry
Feb-16-2021 09:59:42 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry
Feb-15-2021 21:51:36 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	DM: The response for "Is the adverse event serious?" is missing. Kindly review and update.

8. Is this adverse event the result of a study Medication Error?
If Yes, record the type of medication error on the Medication Error Log.

Date	Location	User	Value	Reason
Feb-12-2021 14:44:08 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Feb-17-2021 00:39:02 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query

090177e196ae3d43\Final\Final On: 01-Apr-2021 04:28 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1130

Subject No: 11301081

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Frozen

Site Name: (1130) Kaiser Permanente Center For Health Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:25

Feb-16-2021 09:59:42 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Initial Entry
Feb-16-2021 09:59:42 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NOT RELATED If Not Related to study tr eatment(s), this event is d ue to: OTHER <i>If Other, specify:</i> unknown	Initial Entry
Feb-15-2021 21:52:05 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	DM: The response for "Is this event related to study treatment" is missing. Kindly review and update.

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Feb-12-2021 14:44:08 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NOT APPLICABLE	Initial Entry

11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
Feb-12-2021 14:44:08 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

090177e196ae3d43\Final\Final On: 01-Apr-2021 04:28 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1130

Subject No: 11301081

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Frozen

Site Name: (1130) Kaiser Permanente Center For Health Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:25

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Feb-12-2021 14:44:08 (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-18-2021 13:35:20 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Feb-18-2021 13:35:20 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Dorothy Kurdyla (b) (4)	Data Entry: RECOVERED/RESOLVED	New Information
Feb-18-2021 13:33:03 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	For AE swollen lymph node - right side of neck: Response to "What was the outcome of this adverse event?" is 'Not Recovered/Not Resolved' but AE End Date/Time is present.
Feb-12-2021 14:44:08 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NOT RECOVERED/NOT RESOLVED	Initial Entry

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

090177e196ae3d43\Final\Final On: 01-Apr-2021 04:28 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1130

Subject No: 11301081

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Frozen

Site Name: (1130) Kaiser Permanente Center For Health Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:25

Date	Location	User	Value	Reason
Feb-12-2021 14:44:08 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

Header Text: c4591001

Visit: End of Treatment - Unscheduled

Form: DISPOSITION - TREATMENT - eCRF Audit Trail History

Form Version: 15-Sep-2020 21:55

Form Status: Data Complete, Frozen, Verified

Site No: 1130

Site Name: (1130) Kaiser Permanente Center For Health Research

Subject No: 11301081

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:25

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1. Date of Completion/Discontinuation/Death :

Date	Location	User	Value	Reason
Dec-04-2020 08:07:45 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Tara Beatty (b) (4)	Data Entry: Dec/4/2020	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Dec-04-2020 08:07:45 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: VACCINATION	Initial Entry

3. Status:

Date	Location	User	Value	Reason
Dec-04-2020 08:07:45 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Tara Beatty (b) (4)	Data Entry: COMPLETED	Initial Entry

090177e196ae3d43\Final\Final On: 01-Apr-2021 04:28 (GMT)

Header Text: c4591001

Visit: Potential ReVax Initial Contact -
Unscheduled

Form: DATE OF VISIT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen, Verified

Site No: 1130

Site Name: (1130) Kaiser Permanente Center For Health Research

Subject No: 11301081

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:25

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1. Date of Visit

Date	Location	User	Value	Reason
Jan-22-2021 09:48:57 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Sperry Robinson (b) (4)	Data Entry: Jan/22/2021	Initial Entry

Header Text: c4591001**Visit:** Potential ReVax Initial Contact -
Unscheduled**Form Version:** 10-Dec-2020 02:25**Site No:** 1130**Subject No:** 11301081**Generated By:** (b) (4)**Form:** FURTHER VACCINATION CONFIRMATION - eCRF
Audit Trail History**Form Status:** Data Complete, Frozen**Site Name:** (1130) Kaiser Permanente Center For Health Research**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 11:25[Back to Form](#)***1. Select appropriate response - Is participant willing to return for Vaccination 3?***

Date	Location	User	Value	Reason
Jan-22-2021 09:49:20 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Jan-22-2021 09:49:10 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	The response indicates participant was unblinded, however the TREATMENT UNBLINDED date is missing in the DISP visit. Please complete this date.
Jan-22-2021 09:49:10 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Sperry Robinson (b) (4)	Data Entry: Participant is willing to return for Vaccination 3 Participant is: eligible per other protocol allowance(s) and confirmed to have received only placebo at Vaccination 1/2	Initial Entry

Header Text: c4591001

Visit: Disposition - Unscheduled

Form: TREATMENT UNBLINDED - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1130

Site Name: (1130) Kaiser Permanente Center For Health Research

Subject No: 11301081

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:25

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1. Date Treatment Unblinded :

Date	Location	User	Value	Reason
Jan-22-2021 09:49:20 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Sperry Robinson (b) (4)	Data Entry: Jan/22/2021	Initial Entry

2. Primary Reason for Unblinding:

Date	Location	User	Value	Reason
Jan-22-2021 09:49:20 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Sperry Robinson (b) (4)	Data Entry: ASSESS ELIGIBILITY F OR ADDITIONAL VACCI NATION	Initial Entry

090177e196ae3d43\Final\Final On: 01-Apr-2021 04:28 (GMT)

Header Text: c4591001

Visit: V101_VAX3

Form Version: 22-Apr-2020 21:02

Site No: 1130

Subject No: 11301081

Generated By: (b) (4)

Form: DATE OF VISIT - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1130) Kaiser Permanente Center For Health Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:25

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I. Date of Visit

Date	Location	User	Value	Reason
Jan-28-2021 13:30:57 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Dorothy Kurdyla (b) (4)	Data Entry: Jan/28/2021	Initial Entry

Header Text: c4591001

Visit: V101_VAX3

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

Form Version: 10-Dec-2020 02:31

Form Status: Data Complete, Frozen, Verified

Site No: 1130

Site Name: (1130) Kaiser Permanente Center For Health Research

Subject No: 11301081

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:25

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I. Consent Was:

Date	Location	User	Value	Reason
Jan-28-2021 13:31:06 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Dorothy Kurdyla (b) (4)	<u>Data Entry:</u> OBTAINED Date Written Consent Obtained Jan/28/2021	Initial Entry

Header Text: c4591001

Visit: V101_VAX3

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

Form Version: 10-Dec-2020 02:31

Form Status: Data Complete, Frozen, Verified

Site No: 1130

Site Name: (1130) Kaiser Permanente Center For Health Research

Subject No: 11301081

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:25

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1. Date of Completion/Discontinuation/Death :

Date	Location	User	Value	Reason
Jan-28-2021 13:31:29 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Dorothy Kurdyla (b) (4)	Data Entry: Jan/28/2021	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Jan-28-2021 13:31:29 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: REPEAT SCREENING 1	Initial Entry

3. Status:

Date	Location	User	Value	Reason
Jan-28-2021 13:31:29 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Dorothy Kurdyla (b) (4)	Data Entry: COMPLETED	Initial Entry

090177e196ae3d43\Final\Final On: 01-Apr-2021 04:28 (GMT)

Header Text: c4591001

Visit: V101_VAX3

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1130

Site Name: (1130) Kaiser Permanente Center For Health Research

Subject No: 11301081

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:25

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1. Data Origin

Date	Location	User	Value	Reason
Jan-28-2021 14:10:45 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Jan-28-2021 14:10:45 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SERUM	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Jan-28-2021 14:10:56 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Jan-28-2021 14:10:45 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Jan-28-2021 14:10:45 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Kristi Bays (b) (4)	Data Entry: YES Date of Collection: Jan/28/2021	Initial Entry

090177e196ae3d43\Final\Final On: 01-Apr-2021 04:28 (GMT)

Header Text: c4591001

Visit: V101_VAX3

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1130

Site Name: (1130) Kaiser Permanente Center For Health Research

Subject No: 11301081

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:25

5.a

Date	Location	User	Value	Reason
Jan-28-2021 14:10:56 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Kristi Bays (b) (4)	Data Entry: Sample ID: BPOXHD	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Jan-28-2021 14:10:56 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Kristi Bays (b) (4)	Data Entry: BPOXHD	Initial Entry

5.b

Date	Location	User	Value	Reason
Jan-28-2021 14:11:05 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Kristi Bays (b) (4)	Data Entry: Sample ID: BPOXHF	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Jan-28-2021 14:11:05 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Kristi Bays (b) (4)	Data Entry: BPOXHF	Initial Entry

5.c

Date	Location	User	Value	Reason
Jan-28-2021 14:11:16 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Kristi Bays (b) (4)	Data Entry: Sample ID: BPHV6S	Initial Entry

090177e196ae3d43\Final\Final On: 01-Apr-2021 04:28 (GMT)

Header Text: c4591001

Visit: V101_VAX3

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1130

Site Name: (1130) Kaiser Permanente Center For Health Research

Subject No: 11301081

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:25

5.c Sample ID

Date	Location	User	Value	Reason
Jan-28-2021 14:11:16 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Kristi Bays (b) (4)	<u>Data Entry:</u> BPHV6S	Initial Entry

5.d

Date	Location	User	Value	Reason
Jan-28-2021 14:11:25 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Kristi Bays (b) (4)	<u>Data Entry:</u> Sample ID: BPHV6T	Initial Entry

5.d Sample ID

Date	Location	User	Value	Reason
Jan-28-2021 14:11:25 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Kristi Bays (b) (4)	<u>Data Entry:</u> BPHV6T	Initial Entry

5.e

Date	Location	User	Value	Reason
Jan-28-2021 14:11:35 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Kristi Bays (b) (4)	<u>Data Entry:</u> Sample ID: BPHV6V	Initial Entry

5.e Sample ID

Date	Location	User	Value	Reason
Jan-28-2021 14:11:35 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Kristi Bays (b) (4)	<u>Data Entry:</u> BPHV6V	Initial Entry

090177e196ae3d43\Final\Final On: 01-Apr-2021 04:28 (GMT)

Header Text: c4591001

Visit: V101_VAX3

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1130

Site Name: (1130) Kaiser Permanente Center For Health Research

Subject No: 11301081

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:25

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1. Data Origin

Date	Location	User	Value	Reason
Jan-28-2021 13:43:33 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Jan-28-2021 13:43:33 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: NASAL_SWAB	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Jan-28-2021 13:43:45 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Jan-28-2021 13:43:33 (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.
Jan-28-2021 13:43:33 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Kristi Bays (b) (4)	Data Entry: YES Date of Collection: Jan/28/2021	Initial Entry

090177e196ae3d43\Final\Final On: 01-Apr-2021 04:28 (GMT)

Header Text: c4591001

Visit: V101_VAX3

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1130

Site Name: (1130) Kaiser Permanente Center For Health Research

Subject No: 11301081

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:25

5.a

Date	Location	User	Value	Reason
Jan-28-2021 13:43:45 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Kristi Bays (b) (4)	Data Entry: Sample ID: BPOXH2	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Jan-28-2021 13:43:45 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Kristi Bays (b) (4)	Data Entry: BPOXH2	Initial Entry

090177e196ae3d43\Final\Final On: 01-Apr-2021 04:28 (GMT)

Header Text: c4591001

Visit: V101_VAX3

Form Version: 10-Dec-2020 02:26

Site No: 1130

Subject No: 11301081

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1130) Kaiser Permanente Center For Health Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:25

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1. Was there a temporary delay of vaccination?

Date	Location	User	Value	Reason
Jan-28-2021 15:05:04 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2. Treatment Name

Date	Location	User	Value	Reason
Jan-28-2021 15:05:04 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: BNT162b2	Initial Entry

3. Formulation:

Date	Location	User	Value	Reason
Jan-28-2021 15:05:04 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INJECTION	Initial Entry

4. Dose Date Time:

Date	Location	User	Value	Reason
Jan-28-2021 15:05:04 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Jan/28/2021 14:18	Initial Entry

5. Anatomical Location:

Date	Location	User	Value	Reason
Jan-28-2021 15:05:04 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: DELTOID MUSCLE	Initial Entry

6. Body Side:

090177e196ae3d43\Final\Final On: 01-Apr-2021 04:28 (GMT)

Header Text: c4591001

Visit: V101_VAX3

Form Version: 10-Dec-2020 02:26

Site No: 1130

Subject No: 11301081

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1130) Kaiser Permanente Center For Health Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:25

Date	Location	User	Value	Reason
Jan-28-2021 15:05:04 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: RIGHT	Initial Entry

7. Route:

Date	Location	User	Value	Reason
Jan-28-2021 15:05:04 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INTRAMUSCULAR	Initial Entry

8. Actual Dose:

Date	Location	User	Value	Reason
Jan-28-2021 15:05:04 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 30.0	Initial Entry

9. Unit:

Date	Location	User	Value	Reason
Jan-28-2021 15:05:04 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: ug	Initial Entry

10. Timeframe Subject Was Observed

Date	Location	User	Value	Reason
Jan-28-2021 15:05:04 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 30 MINUTES	Initial Entry

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

Date	Location	User	Value	Reason
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090177e196ae3d43\Final\Final On: 01-Apr-2021 04:28 (GMT)

Header Text: c4591001

Visit: V101_VAX3

Form Version: 10-Dec-2020 02:26

Site No: 1130

Subject No: 11301081

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1130) Kaiser Permanente Center For Health Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:25

Jan-28-2021 15:05:04 (UTC-08:00) Pacific Time (US & Canada)	ACVOPFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry
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Header Text: c4591001

Visit: V102_VAX4

Form Version: 22-Apr-2020 21:02

Site No: 1130

Subject No: 11301081

Generated By: (b) (4)

Form: DATE OF VISIT - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1130) Kaiser Permanente Center For Health Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:25

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I. Date of Visit

Date	Location	User	Value	Reason
Feb-18-2021 13:29:59 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Kristi Bays (b) (4)	Data Entry: Feb/18/2021	Initial Entry

090177e196ae3d43\Final\Final On: 01-Apr-2021 04:28 (GMT)

Header Text: c4591001**Visit:** V102_VAX4**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:** 1130**Site Name:** (1130) Kaiser Permanente Center For Health Research**Subject No:** 11301081**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 11:25[Back to Form](#)**1. Data Origin**

Date	Location	User	Value	Reason
Feb-18-2021 13:30:13 (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-18-2021 13:30:13 (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
Feb-18-2021 13:30:24 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Feb-18-2021 13:30:13 (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-18-2021 13:30:13 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Kristi Bays (b) (4)	Data Entry: YES Date of Collection: Feb/18/2021	Initial Entry

Header Text: c4591001

Visit: V102_VAX4

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: 1130

Site Name: (1130) Kaiser Permanente Center For Health Research

Subject No: 11301081

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:25

5.a

Date	Location	User	Value	Reason
Feb-18-2021 13:30:24 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Kristi Bays (b) (4)	Data Entry: Sample ID: BP0XK2	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Feb-18-2021 13:30:24 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Kristi Bays (b) (4)	Data Entry: BP0XK2	Initial Entry

090177e196ae3d43\Final\Final On: 01-Apr-2021 04:28 (GMT)

Header Text: c4591001

Visit: V102_VAX4

Form Version: 10-Dec-2020 02:26

Site No: 1130

Subject No: 11301081

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1130) Kaiser Permanente Center For Health Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:25

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1. Was there a temporary delay of vaccination?

Date	Location	User	Value	Reason
Feb-18-2021 16:27:04 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Sperry Robinson (b) (4)	Data Entry: NO	Initial Entry

2. Treatment Name

Date	Location	User	Value	Reason
Feb-18-2021 16:27:04 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: BNT162b2	Initial Entry

3. Formulation:

Date	Location	User	Value	Reason
Feb-18-2021 16:27:04 (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
Feb-18-2021 16:27:04 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Sperry Robinson (b) (4)	Data Entry: Feb/18/2021 14:06	Initial Entry

5. Anatomical Location:

Date	Location	User	Value	Reason
Feb-18-2021 16:27:04 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: DELTOID MUSCLE	Initial Entry

090177e196ae3d43\Final\Final On: 01-Apr-2021 04:28 (GMT)

Header Text: c4591001

Visit: V102_VAX4

Form Version: 10-Dec-2020 02:26

Site No: 1130

Subject No: 11301081

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1130) Kaiser Permanente Center For Health Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:25

6. Body Side:

Date	Location	User	Value	Reason
Feb-18-2021 16:27:04 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Sperry Robinson (b) (4)	Data Entry: LEFT	Initial Entry

7. Route:

Date	Location	User	Value	Reason
Feb-18-2021 16:27:04 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INTRAMUSCULAR	Initial Entry

8. Actual Dose:

Date	Location	User	Value	Reason
Feb-18-2021 16:27:04 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 30.0	Initial Entry

9. Unit:

Date	Location	User	Value	Reason
Feb-18-2021 16:27:04 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: ug	Initial Entry

10. Timeframe Subject Was Observed

Date	Location	User	Value	Reason
Feb-18-2021 16:27:04 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 30 MINUTES	Initial Entry

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

090177e196ae3d43\Final\Final On: 01-Apr-2021 04:28 (GMT)

Header Text: c4591001

Visit: V102_VAX4

Form Version: 10-Dec-2020 02:26

Site No: 1130

Subject No: 11301081

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1130) Kaiser Permanente Center For Health Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:25

Date	Location	User	Value	Reason
Feb-18-2021 16:27:04 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Sperry Robinson (b) (4)	Data Entry: YES	Initial Entry

Header Text: c4591001

Visit: Subject Status - Unscheduled

Form: SUBJECT STATUS - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Verified

Site No: 1130

Site Name: (1130) Kaiser Permanente Center For Health Research

Subject No: 11301081

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:25

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1. Subject Status

Date	Location	User	Value	Reason
Dec-04-2020 08:07:45 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: FOLLOW-UP	Initial Entry
Oct-16-2020 12:30:32 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: ENROLLED/RANDOMIZED	Initial Entry
Oct-16-2020 10:42:11 (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
Dec-04-2020 08:07:45 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Dec/4/2020	Initial Entry
Oct-16-2020 12:30:32 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Oct/16/2020	Initial Entry
Oct-16-2020 10:42:11 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Oct/16/2020	Initial Entry

090177e196ae3d43\Final\Final On: 01-Apr-2021 04:28 (GMT)

Header Text: c4591001

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

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Verified

Site No: 1130

Site Name: (1130) Kaiser Permanente Center For Health Research

Subject No: 11301081

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:25

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1. Casebook Signature

Date	Location	User	Value	Reason
Dec-04-2020 12:22:59 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Click Here to Enable	Initial Entry