

Header Text: c4591001

Visit: COHORT_SELECTION

Form Version: 30-Jul-2020 21:29

Site No: 1130

Subject No: 11301031

Generated By: (b) (4)

Form: COHORT_SELECTION

Form Status: Data Complete, Locked, 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](#)

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	24 JUL 2020
2.	Select appropriate response - What cohort does the subject belong to?	STAGE 3 COHORTS

Header Text: c4591001

Visit: COHORT_SELECTION

Form Version: 22-Apr-2020 21:02

Site No: 1130

Subject No: 11301031

Generated By: (b) (4)

Form: MAIN INFORMED CONSENT

Form Status: Data Complete, Locked, 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

1.	Consent Was:	OBTAINED Date Written Consent Obtained Sep/2/2020
----	--------------	---

Header Text: c4591001

Visit: COHORT_SELECTION

Form Version: 06-Jul-2020 21:55

Site No: 1130

Subject No: 11301031

Generated By: (b) (4)

Form: DEMOGRAPHY

Form Status: Data Complete, Locked, 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](#)

Demography

1.	Subject ID	[11301031]
2.	Birth Date:	(b) (6)/1939
3.	Sex:	FEMALE
4.	Ethnicity:	NOT HISPANIC OR LATINO(A) OR OF SPANISH ORIGIN
5.	Race: (Check X all that apply):	WHITE
6.	Racial Designation:	

090177e196ae3d44\Final\Final On: 01-Apr-2021 04:29 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:02

Site No: 1130

Subject No: 11301031

Generated By: (b) (4)

Form: DATE OF VISIT

Form Status: Data Complete, Locked, 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	Sep/2/2020
2.	Erroneous Visit	

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 30-Jul-2020 21:29

Site No: 1130

Subject No: 11301031

Generated By: (b) (4)

Form: INCLUSION/EXCLUSION CRITERIA

Form Status: Data Complete, Locked, 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 _____
----	--	-------------------------

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1130

Subject No: 11301031

Generated By: (b) (4)

Form: DISPOSITION - SCREENING

Form Status: Data Complete, Locked, 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	Sep/2/2020
2.	Phase of Disposition:	SCREENING
3.	Status:	COMPLETED
4.	Specify Status:	[]

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1130

Subject No: 11301031

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY

Form Status: Data Complete, Locked, 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:	[Right Breast Cancer]
	Start Date:	UNK/UNK/2000
	Ongoing:	NO End Date: UNK/UNK/2000
1.b	Line/MH Number:	[2]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Lumpectomy Right breast]
	Start Date:	UNK/UNK/2000
	Ongoing:	NO End Date: UNK/UNK/2000
1.c	Line/MH Number:	[3]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Left Breast Cancer]
	Start Date:	UNK/UNK/2005
	Ongoing:	NO End Date: UNK/UNK/2005

090177e196ae3d44\Final\Final On: 01-Apr-2021 04:29 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1130

Subject No: 11301031

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

1.d	Line/MH Number:	[4]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Lumpectomy, Left breast]
	Start Date:	UNK/UNK/2005
	Ongoing:	NO End Date: UNK/UNK/2005
1.e	Line/MH Number:	[5]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[ATHEROSCLEROSIS OF AORTA (Chronic)]
	Start Date:	Nov/9/2019
	Ongoing:	YES
1.f	Line/MH Number:	[6]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Chronic RHINOSINUSITIS]
	Start Date:	Mar/2/2000
	Ongoing:	YES
1.g	Line/MH Number:	[7]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[HYPERCHOLESTEROLEMIA]
	Start Date:	Apr/26/2016
	Ongoing:	YES

090177e196ae3d44\Final\Final On: 01-Apr-2021 04:29 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1130

Subject No: 11301031

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

1.h	Line/MH Number:	[8]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[HYPOTHYROIDISM]
	Start Date:	Aug/14/2017
	Ongoing:	YES
1.i	Line/MH Number:	[9]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Bilateral hands, PERIPHERAL NEUROPATHY]
	Start Date:	Dec/17/2009
	Ongoing:	YES
1.j	Line/MH Number:	[10]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[OSTEOARTHRITIS bilateral hands]
	Start Date:	Feb/25/2000
	Ongoing:	YES
1.k	Line/MH Number:	[11]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Osteoporosis of back]
	Start Date:	Apr/25/2007
	Ongoing:	YES

090177e196ae3d44\Final\Final On: 01-Apr-2021 04:29 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1130

Subject No: 11301031

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

1.1	Line/MH Number:	[12]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[ROSACEA]
	Start Date:	Nov/17/2000
	Ongoing:	YES
1.m	Line/MH Number:	[13]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[SPINAL STENOSIS OF LUMBAR SPINE]
	Start Date:	Jul/30/2019
	Ongoing:	YES
1.n	Line/MH Number:	[14]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[SPONDYLOSIS CERVICAL JOINT Without MYELOPATHY]
	Start Date:	Nov/26/2003
	Ongoing:	YES
1.o	Line/MH Number:	[15]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[GASTROESOPHAGEAL REFLUX DISEASE]
	Start Date:	Mar/24/1995
	Ongoing:	YES

090177e196ae3d44\Final\Final On: 01-Apr-2021 04:29 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1130

Subject No: 11301031

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

1.p	Line/MH Number:	[16]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[BASAL CELL CARCINOMA, FACE LEFT FOREHEAD ABOVE EYEBROW]
	Start Date:	Feb/5/2002
	Ongoing:	NO End Date: Feb/5/2002
1.q	Line/MH Number:	[17]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Mohs micrographic surgery to Left face basal cell carcinoma]
	Start Date:	Feb/5/2002
	Ongoing:	NO End Date: Feb/5/2002

090177e196ae3d44\Final\Final On: 01-Apr-2021 04:29 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 21-Aug-2020 02:51

Site No: 1130

Subject No: 11301031

Generated By: (b) (4)

Form: VITAL SIGNS - BASELINE

Form Status: Data Complete, Locked, 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:	Sep/2/2020
2.	Weight:	[50.8]
3.	Unit:	kg
4.	Height:	[152.4]
5.	Unit:	cm
6.	Body Mass Index:	[21.9]

Vital Signs Details

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

090177e196ae3d44\Final\Final On: 01-Apr-2021 04:29 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 21-Aug-2020 02:49

Site No: 1130

Subject No: 11301031

Generated By: (b) (4)

Form: LAB URINALYSIS - PREGNANCY TEST

Form Status: Data Complete, Locked, 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](#)

Lab Urinalysis

1.	Lab Panel:	URINALYSIS
2.	Lab Sub-Panel:	PREGNANCY
3.	Collection Date:	Sep/2/2020
4.	Laboratory Name and Address (Derived)	[STUDY SITE]
5.	Specimen Type:	URINE

Lab Result

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

090177e196ae3d44\Final\Final On: 01-Apr-2021 04:29 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1130

Subject No: 11301031

Generated By: (b) (4)

Form: RANDOMIZATION

Form Status: Data Complete, Locked, 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 :	Sep/2/2020
2.	Randomization Number:	[250094]
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, Locked, Frozen, Verified

Site No: 1130

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

Subject No: 11301031

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: Sep/2/2020
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[]

Aliquot

Please enter barcode for each aliquot.

5.a	Sample ID	[BP0X1D]
5.b	Sample ID	[BP0X1F]
5.c	Sample ID	[BP0X1G]
5.d	Sample ID	[BPHTTW]
5.e	Sample ID	[BPHTTV]
5.f	Sample ID	[BPHTTT]
5.g	Sample ID	[BPHTTS]

090177e196ae3d44\Final\Final On: 01-Apr-2021 04:29 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1130

Subject No: 11301031

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB

Form Status: Data Complete, Locked, 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: Sep/2/2020
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[]

Aliquot

Please enter barcode for each aliquot.

5.a	Sample ID	[BPOX1L]
-----	-----------	----------

090177e196ae3d44\Final\Final On: 01-Apr-2021 04:29 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:04

Site No: 1130

Subject No: 11301031

Generated By: (b) (4)

Form: VACCINATION

Form Status: Data Complete, Locked, 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:	Sep/2/2020 14:18
5.	Anatomical Location:	DELTOID MUSCLE
6.	Body Side:	LEFT
7.	Route:	INTRAMUSCULAR
8.	Actual Dose:	[]
9.	Unit:	
10.	Timeframe Subject Was Observed	THE PROTOCOL SPECIFIED OBSERVATION PERIOD
11.	Was the subject observed for at least the protocol specified observation period after investigational product administration?	YES

090177e196ae3d44\Final\Final On: 01-Apr-2021 04:29 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 06-Jul-2020 21:53

Site No: 1130

Subject No: 11301031

Generated By: (b) (4)

Form: REACTOGENICITY DIARY

Form Status: Data Complete, Locked, 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
----	---	--

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 1130

Subject No: 11301031

Generated By: (b) (4)

Form: DATE OF VISIT

Form Status: Data Complete, Locked, 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	Sep/21/2020
2.	Erroneous Visit	

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 15-Sep-2020 21:54

Site No: 1130

Subject No: 11301031

Generated By: (b) (4)

Form: VITAL SIGNS - TEMP

Form Status: Data Complete, Locked, 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:	Sep/21/2020
----	-------	-------------

Vital Signs Details

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

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 21-Aug-2020 02:49

Site No: 1130

Subject No: 11301031

Generated By: (b) (4)

Form: LAB URINALYSIS - PREGNANCY TEST

Form Status: Data Complete, Locked, 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](#)

Lab Urinalysis

1.	Lab Panel:	URINALYSIS
2.	Lab Sub-Panel:	PREGNANCY
3.	Collection Date:	Sep/21/2020
4.	Laboratory Name and Address (Derived)	[STUDY SITE]
5.	Specimen Type:	URINE

Lab Result

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

090177e196ae3d44\Final\Final On: 01-Apr-2021 04:29 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:03

Site No: 1130

Subject No: 11301031

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB

Form Status: Data Complete, Locked, 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: Sep/21/2020
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	[BPOX7H]
-----	-----------	----------

090177e196ae3d44\Final\Final On: 01-Apr-2021 04:29 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1130

Subject No: 11301031

Generated By: (b) (4)

Form: VACCINATION

Form Status: Data Complete, Locked, 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:	Sep/21/2020 10:24
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

090177e196ae3d44\Final\Final On: 01-Apr-2021 04:29 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form: DATE OF VISIT

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1130

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

Subject No: 11301031

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	Oct/19/2020
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, Locked, Frozen, Verified

Site No: 1130

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

Subject No: 11301031

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/19/2020
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	[BR8MW5]
5.b	Sample ID	[BR8MW6]
5.c	Sample ID	[BS6ZSR]
5.d	Sample ID	[BS6ZSS]
5.e	Sample ID	[BS6ZST]

090177e196ae3d44\Final\Final On: 01-Apr-2021 04:29 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL - New
Unscheduled Visit

Form: DATE OF VISIT - ILLNESS ONSET

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1130

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

Subject No: 11301031

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 Illness Visit

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

Header Text: c4591001

Visit: POT_COVID_ILL - New
Unscheduled Visit

Form: SIGNS AND SYMPTOMS OF POTENTIAL COVID-19

Form Version: 20-Feb-2021 02:17

Form Status: Not Started

Site No: 1130

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

Subject No: 11301031

Subject Initials: ---

Generated By: (b) (4)

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

Signs and Symptoms

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

Symptoms

4.	Symptoms:	
	Was symptom present?	

Symptoms - Other

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

090177e196ae3d44\Final\Final On: 01-Apr-2021 04:29 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL - New
Unscheduled Visit

Form Version: 22-Apr-2020 21:03

Site No: 1130

Subject No: 11301031

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB
SELF

Form Status: Not Started

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

Subject Initials: ---

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

090177e196ae3d44\Final\Final On: 01-Apr-2021 04:29 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL - New
Unscheduled Visit

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1130

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

Subject No: 11301031

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

090177e196ae3d44\Final\Final On: 01-Apr-2021 04:29 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL - New
Unscheduled Visit

Form: HEALTH CARE UTILIZATION

Form Version: 20-Feb-2021 02:19

Form Status: Not Started

Site No: 1130

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

Subject No: 11301031

Subject Initials: ---

Generated By: (b) (4)

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

Health Care Utilization

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

Health Care Utilization Other

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

Health Care Utilization

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

090177e196ae3d44\Final\Final On: 01-Apr-2021 04:29 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL - New
Unscheduled Visit

Form: ILLNESS DETAILS

Form Version: 06-Jul-2020 21:52

Form Status: Not Started

Site No: 1130

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

Subject No: 11301031

Subject Initials: ---

Generated By: (b) (4)

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

Illness Details

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

Header Text: c4591001

Visit: POT_COVID_CONVA - New
Unscheduled Visit

Form: DATE OF VISIT - ILLNESS CONVALESCENT

Form Version: 22-Apr-2020 21:04

Form Status: Not Started

Site No: 1130

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

Subject No: 11301031

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 Illness Visit

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

Header Text: c4591001

Visit: POT_COVID_CONVA - New
Unscheduled Visit

Form Version: 22-Apr-2020 21:03

Site No: 1130

Subject No: 11301031

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING -
IMMUNOGENICITY

Form Status: Not Started

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

Subject Initials: ---

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

090177e196ae3d44\Final\Final On: 01-Apr-2021 04:29 (GMT)

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: 11301031 **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: 11301031 **Subject Initials:** ---

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

Unplanned Assessments

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

Header Text: c4591001

Visit: End of Treatment - Unscheduled

Form: DISPOSITION - TREATMENT

Form Version: 15-Sep-2020 21:55

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1130

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

Subject No: 11301031

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 :	Oct/19/2020
2.	Phase of Disposition:	VACCINATION
3.	Status:	COMPLETED
4.	Specify Status:	[]

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: 11301031

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: 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: 11301031

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: 11301031

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

090177e196ae3d44\Final\Final On: 01-Apr-2021 04:29 (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: 11301031

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	Rash - injection site	Feb/9/2021 19:00	NO End Date Time: Feb/19/2021 UNK:UNK	Repeating Pages
2.	ADVERSE EVENT	2	Rash- various places on body	Feb/9/2021 19:00	NO End Date Time: Feb/19/2021 UNK:UNK	Repeating Pages
3.	ADVERSE EVENT	3	Transient Ischemic Attack	Mar/7/2021 08:00	NO End Date Time: Mar/7/2021 10:07	Repeating Pages
4.	ADVERSE EVENT	4	Urinary Tract Infection	Mar/7/2021 09:48	YES	Repeating Pages

090177e196ae3d44\Final\Final On: 01-Apr-2021 04:29 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1130

Subject No: 11301031

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Answered Queries

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

Subject Initials: ---

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

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

Adverse Event Report

1.	Category:	ADVERSE EVENT
2.	AE ID:	[1]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[Rash - injection site]
4.	Start Date Time:	Feb/9/2021 19:00
5.	Is the adverse event still ongoing?	NO End Date Time: Feb/19/2021 UNK:UNK
6.	Toxicity Grade:	1
7.	Is the adverse event serious? If Yes, NOTIFY PFIZER IMMEDIATELY. Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).	NO
8.	Is this adverse event the result of a study Medication Error? If Yes, record the type of medication error on the Medication Error Log.	NO

090177e196ae3d44\Final\Final On: 01-Apr-2021 04:29 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1130

Subject No: 11301031

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Answered Queries

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:	RELATED
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	[]

090177e196ae3d44\Final\Final On: 01-Apr-2021 04:29 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1130

Subject No: 11301031

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Answered Queries

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

Subject Initials: ---

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

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

Adverse Event Report

1.	Category:	ADVERSE EVENT
2.	AE ID:	[2]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[Rash- various places on body]
4.	Start Date Time:	Feb/9/2021 19:00
5.	Is the adverse event still ongoing?	NO End Date Time: Feb/19/2021 UNK:UNK
6.	Toxicity Grade:	1
7.	Is the adverse event serious? If Yes, NOTIFY PFIZER IMMEDIATELY. Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).	NO

090177e196ae3d44\Final\Final On: 01-Apr-2021 04:29 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1130

Subject No: 11301031

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Answered Queries

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

Subject Initials: ---

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

8.	Is this adverse event the result of a study Medication Error? If Yes, record the type of medication error on the Medication Error Log.	NO
9.	Is this event related to study treatment:	RELATED
10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE
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	[]

090177e196ae3d44\Final\Final On: 01-Apr-2021 04:29 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1130

Subject No: 11301031

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete

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

Subject Initials: ---

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

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

Adverse Event Report

1.	Category:	ADVERSE EVENT
2.	AE ID:	[3]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[Transient Ischemic Attack]
4.	Start Date Time:	Mar/7/2021 08:00
5.	Is the adverse event still ongoing?	NO End Date Time: Mar/7/2021 10:07
6.	Toxicity Grade:	2

090177e196ae3d44\Final\Final On: 01-Apr-2021 04:29 (GMT)

Header Text: c4591001**Visit:** Logs - Unscheduled**Form Version:** 22-Apr-2020 21:02**Site No:** 1130**Subject No:** 11301031**Generated By:** (b) (4)**Form:** ADVERSE EVENT REPORT**Form Status:** Data Complete**Site Name:** (1130) Kaiser Permanente Center For Health Research**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 11:25

7.	<p>Is the adverse event serious? If Yes, NOTIFY PFIZER IMMEDIATELY.</p> <p>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).</p>	<p>YES</p> <p>Is this serious event associated with congenital anomaly or birth defect? NO</p> <p>Did this serious event result in death? NO</p> <p>Did this serious event require or prolong hospitalization? YES</p> <p>Did this serious event result in persistent or significant disability/incapacity? NO</p> <p>Is this serious event life threatening? NO</p> <p>Other medically important serious event YES</p>
8.	<p>Is this adverse event the result of a study Medication Error? If Yes, record the type of medication error on the Medication Error Log.</p>	NO
9.	<p>Is this event related to study treatment:</p>	<p>NOT RELATED</p> <p>If Not Related to study treatment(s), this event is due to: OTHER</p> <p>If Other, specify: [Related to hypercholesterolemia]</p>
10.	<p>Latest Action Taken with Study Treatment:</p>	NOT APPLICABLE
11.	<p>Was a Concomitant Medication given?</p>	YES
12.	<p>Was a Non-Drug Treatment given?</p>	NO

Header Text: c4591001
Visit: Logs - Unscheduled
Form Version: 22-Apr-2020 21:02
Site No: 1130
Subject No: 11301031
Generated By: (b) (4)

Form: ADVERSE EVENT REPORT
Form Status: Data Complete
Site Name: (1130) Kaiser Permanente Center For Health Research
Subject Initials: ---
Generated Time (GMT): 29-Mar-2021 11:25

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	[2021264920]

Header Text: c4591001**Visit:** Logs - Unscheduled**Form Version:** 22-Apr-2020 21:02**Site No:** 1130**Subject No:** 11301031**Generated By:** (b) (4)**Form:** ADVERSE EVENT REPORT**Form Status:** Data Complete**Site Name:** (1130) Kaiser Permanente Center For Health Research**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 11:25

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

Adverse Event Report

1.	Category:	ADVERSE EVENT
2.	AE ID:	[4]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[Urinary Tract Infection]
4.	Start Date Time:	Mar/7/2021 09:48
5.	Is the adverse event still ongoing?	YES
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

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1130

Subject No: 11301031

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete

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

090177e196ae3d44\Final\Final On: 01-Apr-2021 04:29 (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: 11301031

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: 11301031

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

[Back to Form](#)

Medication Error

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

090177e196ae3d44\Final\Final On: 01-Apr-2021 04:29 (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: 11301031

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.	1	VACCINATIONS	NO	INfs Pres Free High Dose (FLUZONE) (influenza)	Oct/15/2020	Repeating Pages

Header Text: c4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - NON STUDY VACCINATIONS

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1130

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

Subject No: 11301031

Subject Initials: ---

Generated By: (b) (4)

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

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

Concomitant Medications

1.	What is the medication identifier?	[1]
2.	Category:	VACCINATIONS
3.	Concomitant Medications Pre-specified:	NO
4.	Medication: Provide the complete generic drug name (including salt form, where applicable). Where generic name is unknown, enter the full trade or proprietary name. Include clarifying information in the Medication text (e.g., Ingredient(s), route, use, formulation).	[INFs Pres Free High Dose (FLUZONE) (influenza)]
5.	Date:	Oct/15/2020

090177e196ae3d44\Final\Final On: 01-Apr-2021 04:29 (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: 11301031

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: 11301031

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

[Back to Form](#)

Concomitant Medications

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

090177e196ae3d44\Final\Final On: 01-Apr-2021 04:29 (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: 11301031

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: 11301031

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

[Back to Form](#)

Radiation Treatment

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

090177e196ae3d44\Final\Final On: 01-Apr-2021 04:29 (GMT)

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: 11301031

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: 11301031

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

[Back to Form](#)

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

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: 11301031

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: 11301031

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:	

090177e196ae3d44\Final\Final On: 01-Apr-2021 04:29 (GMT)

Header Text: c4591001

Visit: Unplanned Vaccination -
Unscheduled

Form: LAB URINALYSIS - PREGNANCY TEST

Form Version: 20-Feb-2021 02:14

Form Status: Not Started

Site No: 1130

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

Subject No: 11301031

Subject Initials: ---

Generated By: (b) (4)

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

Lab Urinalysis

1.	Lab Panel:	
2.	Lab Sub-Panel:	
3.	Collection Date:	//
4.	Laboratory Name and Address (Derived)	[]
5.	Specimen Type:	

Lab Result

6.	Sponsor ID:	[]
	Test:	
	Result:	
	Not Done:	

090177e196ae3d44\Final\Final On: 01-Apr-2021 04:29 (GMT)

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: 11301031

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?	

090177e196ae3d44\Final\Final On: 01-Apr-2021 04:29 (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: 11301031

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: 11301031

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: 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: 11301031

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/15/2021
2.	Erroneous Visit	

Header Text: c4591001

Visit: Potential ReVax Initial Contact -
Unscheduled

Form: FURTHER VACCINATION CONFIRMATION

Form Version: 10-Dec-2020 02:25

Form Status: Data Complete, Frozen, Verified

Site No: 1130

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

Subject No: 11301031

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
----	---	--

Header Text: c4591001

Visit: Disposition - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1130

Subject No: 11301031

Generated By: (b) (4)

Form: TREATMENT UNBLINDED

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](#)

Treatment Unblinded

1.	Date Treatment Unblinded :	Jan/15/2021
2.	Primary Reason for Unblinding:	ASSESS ELIGIBILITY FOR ADDITIONAL VACCINATION

Header Text: c4591001

Visit: Disposition - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1130

Subject No: 11301031

Generated By: (b) (4)

Form: WITHDRAWAL OF CONSENT

Form Status: Not Started

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

Subject Initials: ---

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

Withdrawal Of Consent

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

Header Text: c4591001

Visit: Disposition - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1130

Subject No: 11301031

Generated By: (b) (4)

Form: DEATH DETAILS CODED

Form Status: Not Started

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

Subject Initials: ---

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: 11301031

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/20/2021
2.	Erroneous Visit	

Header Text: c4591001

Visit: V101_VAX3

Form Version: 10-Dec-2020 02:31

Site No: 1130

Subject No: 11301031

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/20/2021
----	--------------	--

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: 11301031

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

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: 11301031

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/20/2021
2.	Phase of Disposition:	REPEAT SCREENING 1
3.	Status:	COMPLETED
4.	Specify Status:	[]

Header Text: c4591001

Visit: V101_VAX3

Form Version: 14-Jan-2021 02:21

Site No: 1130

Subject No: 11301031

Generated By: (b) (4)

Form: LAB URINALYSIS - PREGNANCY TEST

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](#)

Lab Urinalysis

1.	Lab Panel:	URINALYSIS
2.	Lab Sub-Panel:	PREGNANCY
3.	Collection Date:	Jan/20/2021
4.	Laboratory Name and Address (Derived)	[STUDY SITE]
5.	Specimen Type:	URINE

Lab Result

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

090177e196ae3d44\Final\Final On: 01-Apr-2021 04:29 (GMT)

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: 11301031

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/20/2021
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[]

Aliquot

Please enter barcode for each aliquot.

5.a	Sample ID	[BP0XDS]
5.b	Sample ID	[BP0XF7]
5.c	Sample ID	[BPHV4J]
5.d	Sample ID	[BPHV4K]
5.e	Sample ID	[BPHV4L]

090177e196ae3d44\Final\Final On: 01-Apr-2021 04:29 (GMT)

Header Text: c4591001

Visit: V101_VAX3

Form Version: 22-Apr-2020 21:03

Site No: 1130

Subject No: 11301031

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/20/2021
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[]

Aliquot

Please enter barcode for each aliquot.

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

090177e196ae3d44\Final\Final On: 01-Apr-2021 04:29 (GMT)

Header Text: c4591001

Visit: V101_VAX3

Form: VACCINATION

Form Version: 10-Dec-2020 02:26

Form Status: Data Complete, Frozen, Verified

Site No: 1130

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

Subject No: 11301031

Subject Initials: ---

Generated By: (b) (4)

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/20/2021 10:29
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

090177e196ae3d44\Final\Final On: 01-Apr-2021 04:29 (GMT)

Header Text: c4591001

Visit: V102_VAX4

Form Version: 22-Apr-2020 21:02

Site No: 1130

Subject No: 11301031

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/9/2021
2.	Erroneous Visit	

Header Text: c4591001

Visit: V102_VAX4

Form Version: 14-Jan-2021 02:21

Site No: 1130

Subject No: 11301031

Generated By: (b) (4)

Form: LAB URINALYSIS - PREGNANCY TEST

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](#)

Lab Urinalysis

1.	Lab Panel:	URINALYSIS
2.	Lab Sub-Panel:	PREGNANCY
3.	Collection Date:	Feb/9/2021
4.	Laboratory Name and Address (Derived)	[STUDY SITE]
5.	Specimen Type:	URINE

Lab Result

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

090177e196ae3d44\Final\Final On: 01-Apr-2021 04:29 (GMT)

Header Text: c4591001

Visit: V102_VAX4

Form Version: 22-Apr-2020 21:03

Site No: 1130

Subject No: 11301031

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/9/2021
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	[BPOXJD]
-----	-----------	----------

090177e196ae3d44\Final\Final On: 01-Apr-2021 04:29 (GMT)

Header Text: c4591001

Visit: V102_VAX4

Form Version: 10-Dec-2020 02:26

Site No: 1130

Subject No: 11301031

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/9/2021 10:26
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

090177e196ae3d44\Final\Final On: 01-Apr-2021 04:29 (GMT)

Header Text: c4591001

Visit: V103_MONTH1

Form Version: 22-Apr-2020 21:02

Site No: 1130

Subject No: 11301031

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	Mar/9/2021
2.	Erroneous Visit	

Header Text: c4591001

Visit: V103_MONTH1

Form Version: 22-Apr-2020 21:04

Site No: 1130

Subject No: 11301031

Generated By: (b) (4)

Form: CONTACT OUTCOME

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](#)

Contact Outcome

1.	Contact Type:	TELEPHONE VISIT
2.	Was contact made?	YES Date of Contact: Mar/9/2021
3.	Comments:	[]

Header Text: c4591001

Visit: V104_MONTH6

Form Version: 22-Apr-2020 21:02

Site No: 1130

Subject No: 11301031

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: 11301031

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: 11301031

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: 11301031

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: Data Complete, Frozen, Verified

Site No: 1130

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

Subject No: 11301031

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 :	Mar/9/2021
2.	Phase of Disposition:	OPEN LABEL TREATMENT
3.	Status:	COMPLETED
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: 11301031

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	Oct/19/2020

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: 11301031

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: 11301031

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

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 30-Jul-2020 21:29

Site No: 1130

Subject No: 11301031

Generated By: (b) (4)

Form: INCLUSION/EXCLUSION CRITERIA - Comments

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

[Back to Form](#)

Item	Date	User	Comment
Form	Sep-02-2020 13:46:03 (UTC-08:00) Pacific Time (US & Canada)	Tara Beatty (b) (4)	Not Applicable

Header Text: c4591001

Visit: V101_VAX3

Form: INCLUSION/EXCLUSION CRITERIA - FURTHER VACCINATION - Comments

Form Version: 10-Dec-2020 02:30

Form Status: Data Complete, Frozen, Verified

Site No: 1130

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

Subject No: 11301031

Subject Initials: ---

Generated By: (b) (4)

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

[Back to Form](#)

Item	Date	User	Comment
Form	Jan-20-2021 10:17:41 (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: 11301031 **Subject Initials:** ---
Generated By: (b) (4) **Generated Time (GMT):** 29-Mar-2021 11:25

[Back to Form](#)

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

- CRF_Sign
- CRF_Sign_1

Name	Signature Meaning	Date	Type	Action
Tara Beatty	N/A	Mar-09-2021 11:27:13 (UTC-08:00) Pacific Time (US & Canada)		Edit - All signatures invalidated

Affidavit:
N/A

Stephen Fortmann	Approved	Feb-21-2021 16:40:14 (UTC-08:00) Pacific Time (US & Canada)	BOOK	Signed
------------------	----------	--	------	--------

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.

Dorothy Kurdyla	N/A	Feb-17-2021 10:39:54 (UTC-08:00) Pacific Time (US & Canada)		Edit - All signatures invalidated
-----------------	-----	--	--	-----------------------------------

Affidavit:
N/A

Stephen Fortmann	Approved	Feb-16-2021 11:21:09 (UTC-08:00) Pacific Time (US & Canada)	BOOK	Signed
------------------	----------	--	------	--------

090177e196ae3d44\Final\Final On: 01-Apr-2021 04:29 (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: 11301031

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 10:29:42 (UTC-08:00) Pacific Time (US & Canada)		Edit - All signatures invalidated
---------	-----	--	--	-----------------------------------

Affidavit:

N/A

Stephen Fortmann	Approved	Feb-10-2021 10:32:37 (UTC-08:00) Pacific Time (US & Canada)	BOOK	Signed
------------------	----------	--	------	--------

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-09-2021 10:28:25 (UTC-08:00) Pacific Time (US & Canada)		Edit - All signatures invalidated
-------------	-----	--	--	-----------------------------------

Affidavit:

N/A

Stephen Fortmann	Approved	Jan-22-2021 22:11:57 (UTC-08:00) Pacific Time (US & Canada)	BOOK	Signed
------------------	----------	--	------	--------

090177e196ae3d44\Final\Final On: 01-Apr-2021 04:29 (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: 11301031

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.

Dorothy Kurdyla	N/A	Jan-20-2021 10:17:20 (UTC-08:00) Pacific Time (US & Canada)		Edit - All signatures invalidated
-----------------	-----	--	--	-----------------------------------

Affidavit:

N/A

Stephen Fortmann	Approved	Jan-18-2021 22:18:27 (UTC-08:00) Pacific Time (US & Canada)	BOOK	Signed
------------------	----------	--	------	--------

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-15-2021 09:24:29 (UTC-08:00) Pacific Time (US & Canada)		Edit - All signatures invalidated
-----------------	-----	--	--	-----------------------------------

Affidavit:

N/A

Stephen Fortmann	Approved	Nov-16-2020 09:46:31 (UTC-08:00) Pacific Time (US & Canada)	BOOK	Signed
------------------	----------	--	------	--------

090177e196ae3d44\Final\Final On: 01-Apr-2021 04:29 (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: 11301031

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.

Tara Beatty	N/A	Nov-13-2020 17:11:31 (UTC-08:00) Pacific Time (US & Canada)		Edit - All signatures invalidated
-------------	-----	--	--	-----------------------------------

Affidavit:

N/A

Stephen Fortmann	Approved	Oct-27-2020 10:04:38 (UTC-08:00) Pacific Time (US & Canada)	BOOK	Signed
------------------	----------	--	------	--------

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.

090177e196ae3d44\Final\Final On: 01-Apr-2021 04:29 (GMT)

Header Text: c4591001

Visit: COHORT_SELECTION

Form Version: 30-Jul-2020 21:29

Site No: 1130

Subject No: 11301031

Generated By: (b) (4)

Form: COHORT SELECTION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

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 - Protocol version

Date	Location	User	Value	Reason
Sep-02-2020 13:45:23 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Tara Beatty (b) (4)	Data Entry: 24 JUL 2020	Initial Entry

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

Date	Location	User	Value	Reason
Sep-02-2020 13:45:23 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Tara Beatty (b) (4)	Data Entry: STAGE 3 COHORTS	Initial Entry

090177e196ae3d44\Final\Final On: 01-Apr-2021 04:29 (GMT)

Header Text: c4591001

Visit: COHORT_SELECTION

Form: MAIN INFORMED CONSENT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1130

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

Subject No: 11301031

Subject Initials: ---

Generated By: (b) (4)

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

[Back to Form](#)

1. Consent Was:

Date	Location	User	Value	Reason
Sep-02-2020 13:45:30 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Tara Beatty (b) (4)	Data Entry: OBTAINED Date Written Consent Obtained Sep/2/2020	Initial Entry

Header Text: c4591001**Visit:** COHORT_SELECTION**Form Version:** 06-Jul-2020 21:55**Site No:** 1130**Subject No:** 11301031**Generated By:** (b) (4)**Form:** DEMOGRAPHY - eCRF Audit Trail History**Form Status:** Data Complete, Locked, Frozen, Verified**Site Name:** (1130) Kaiser Permanente Center For Health Research**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 11:25[Back to Form](#)**1. Subject ID**

Date	Location	User	Value	Reason
Sep-02-2020 13:45:16 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 11301031	Item copied from previous form

2. Birth Date:

Date	Location	User	Value	Reason
Sep-02-2020 13:45:12 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: (b) (6)/1939	Enrollment Entry

3. Sex:

Date	Location	User	Value	Reason
Sep-02-2020 13:45:38 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Tara Beatty (b) (4)	Data Entry: FEMALE	Initial Entry

4. Ethnicity:

Date	Location	User	Value	Reason
Sep-02-2020 13:45:38 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Tara Beatty (b) (4)	Data Entry: NOT HISPANIC OR LATI NO(A) OR OF SPANISH O RIGIN	Initial Entry

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

Date	Location	User	Value	Reason
Sep-02-2020 13:45:38 (UTC-08:00) Pacific	ACV0PFEINFP6000	Tara Beatty (b) (4)	Data Entry: WHITE	Initial Entry

Header Text: c4591001

Visit: COHORT_SELECTION

Form Version: 06-Jul-2020 21:55

Site No: 1130

Subject No: 11301031

Generated By: (b) (4)

Form: DEMOGRAPHY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

Time (US & Canada)				
--------------------	--	--	--	--

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:02

Site No: 1130

Subject No: 11301031

Generated By: (b) (4)

Form: DATE OF VISIT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

[Back to Form](#)

1. Date of Visit

Date	Location	User	Value	Reason
Sep-02-2020 13:45:52 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Tara Beatty (b) (4)	Data Entry: Sep/2/2020	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1130

Subject No: 11301031

Generated By: (b) (4)

Form: DISPOSITION - SCREENING - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

[Back to Form](#)

1. Date of Completion/Discontinuation/Death

Date	Location	User	Value	Reason
Sep-02-2020 13:46:20 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Tara Beatty (b) (4)	Data Entry: Sep/2/2020	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Sep-02-2020 13:46:20 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SCREENING	Initial Entry

3. Status:

Date	Location	User	Value	Reason
Sep-02-2020 13:46:20 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Tara Beatty (b) (4)	Data Entry: COMPLETED	Initial Entry

090177e196ae3d44\Final\Final On: 01-Apr-2021 04:29 (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, Locked, Frozen, Verified**Site No:** 1130**Site Name:** (1130) Kaiser Permanente Center For Health Research**Subject No:** 11301031**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 11:25[Back to Form](#)*1.a*

Date	Location	User	Value	Reason
Sep-02-2020 13:55:18 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 1 Medical History Term: Right Breast Cancer Start Date: UNK/UNK/2000 Ongoing: NO End Date: UNK/UNK/2000	Initial Entry

1.a Line/MH Number:

Date	Location	User	Value	Reason
Sep-02-2020 13:55:18 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 1	Initial Entry

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

Date	Location	User	Value	Reason
Sep-02-2020 13:55:18 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Tara Beatty (b) (4)	Data Entry: Right Breast Cancer	Initial Entry

1.a Start Date:

Date	Location	User	Value	Reason
------	----------	------	-------	--------

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, Locked, Frozen, Verified

Site No: 1130

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

Subject No: 11301031

Subject Initials: ---

Generated By: (b) (4)

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

Sep-02-2020 13:55:18 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Tara Beatty (b) (4)	Data Entry: UNK/UNK/2000	Initial Entry
---	-----------------	------------------------	------------------------------------	---------------

1.a Ongoing:

Date	Location	User	Value	Reason
Sep-02-2020 13:55:18 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Tara Beatty (b) (4)	Data Entry: NO End Date: UNK/UNK/2000	Initial Entry

1.b

Date	Location	User	Value	Reason
Sep-02-2020 13:56:39 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH N umber: 2 Medical His tory Term: Lumpectomy Right breast Start Date: UNK/UNK/2000 Ongoing: NO End Date: UNK/UNK/ 2000	Initial Entry

090177e196ae3d44\Final\Final On: 01-Apr-2021 04:29 (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, Locked, Frozen, Verified

Site No: 1130

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

Subject No: 11301031

Subject Initials: ---

Generated By: (b) (4)

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

1.b Line/MH Number:

Date	Location	User	Value	Reason
Sep-02-2020 13:56:39 (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
Sep-02-2020 13:56:39 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Tara Beatty (b) (4)	Data Entry: Lumpectomy Right breast	Initial Entry

1.b Start Date:

Date	Location	User	Value	Reason
Sep-02-2020 13:56:39 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Tara Beatty (b) (4)	Data Entry: UNK/UNK/2000	Initial Entry

1.b Ongoing:

Date	Location	User	Value	Reason
Sep-02-2020 13:56:39 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Tara Beatty (b) (4)	Data Entry: NO End Date: UNK/UNK/2000	Initial Entry

1.c

Date	Location	User	Value	Reason
Sep-02-2020 13:57:09 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 3	Initial Entry

090177e196ae3d44\Final\Final On: 01-Apr-2021 04:29 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1130

Subject No: 11301031

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

			Medical History Term: Left Breast Cancer	
			Start Date: UNK/UNK/2005	
			Ongoing: NO	
			End Date:	
			UNK/UNK/2005	

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, Locked, Frozen, Verified

Site No: 1130

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

Subject No: 11301031

Subject Initials: ---

Generated By: (b) (4)

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

I.c Line/MH Number:

Date	Location	User	Value	Reason
Sep-02-2020 13:57:09 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 3	Initial Entry

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

Date	Location	User	Value	Reason
Sep-02-2020 13:57:09 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Tara Beatty (b) (4)	Data Entry: Left Breast Cancer	Initial Entry

I.c Start Date:

Date	Location	User	Value	Reason
Sep-02-2020 13:57:09 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Tara Beatty (b) (4)	Data Entry: UNK/UNK/2005	Initial Entry

I.c Ongoing:

Date	Location	User	Value	Reason
Sep-02-2020 13:57:09 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Tara Beatty (b) (4)	Data Entry: NO End Date: UNK/UNK/2005	Initial Entry

I.d

Date	Location	User	Value	Reason
Sep-02-2020 13:57:46 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 4	Initial Entry

090177e196ae3d44\Final\Final On: 01-Apr-2021 04:29 (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, Locked, Frozen, Verified

Site No: 1130

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

Subject No: 11301031

Subject Initials: ---

Generated By: (b) (4)

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

			Medical History Term: Lumpectomy, Left breast Start Date: UNK/UNK/2005 Ongoing: NO End Date: UNK/UNK/2005	
--	--	--	--	--

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, Locked, Frozen, Verified

Site No: 1130

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

Subject No: 11301031

Subject Initials: ---

Generated By: (b) (4)

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

1.d Line/MH Number:

Date	Location	User	Value	Reason
Sep-02-2020 13:57:46 (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
Sep-02-2020 13:57:46 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Tara Beatty (b) (4)	Data Entry: Lumpectomy, Left breast	Initial Entry

1.d Start Date:

Date	Location	User	Value	Reason
Sep-02-2020 13:57:46 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Tara Beatty (b) (4)	Data Entry: UNK/UNK/2005	Initial Entry

1.d Ongoing:

Date	Location	User	Value	Reason
Sep-02-2020 13:57:46 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Tara Beatty (b) (4)	Data Entry: NO End Date: UNK/UNK/2005	Initial Entry

1.e

Date	Location	User	Value	Reason
Sep-02-2020 13:58:37 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH 5 Number:	Initial Entry

090177e196ae3d44\Final\Final On: 01-Apr-2021 04:29 (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, Locked, Frozen, Verified**Site No:** 1130**Site Name:** (1130) Kaiser Permanente Center For Health Research**Subject No:** 11301031**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 11:25

			Medical History Term: ATHEROSCLEROSIS OF AORTA (Chronic) Start Date: Nov/9/2019 Ongoing: YES	
--	--	--	---	--

I.e Line/MH Number:

Date	Location	User	Value	Reason
Sep-02-2020 13:58:37 (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
Sep-02-2020 13:58:37 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Tara Beatty (b) (4)	Data Entry: ATHEROSCLEROSIS OF AORTA (Chronic)	Initial Entry

I.e Start Date:

Date	Location	User	Value	Reason
Sep-02-2020 13:58:37 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Tara Beatty (b) (4)	Data Entry: Nov/9/2019	Initial Entry

I.e Ongoing:

Date	Location	User	Value	Reason
Sep-02-2020 13:58:37 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Tara Beatty (b) (4)	Data Entry: YES	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, Locked, Frozen, Verified
Site No: 1130
Site Name: (1130) Kaiser Permanente Center For Health Research
Subject No: 11301031
Subject Initials: ---
Generated By: (b) (4)
Generated Time (GMT): 29-Mar-2021 11:25

1.f

Date	Location	User	Value	Reason
Sep-02-2020 13:59:12 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 6 Medical History Term: Chronic RHINOSINUSITIS Start Date: Mar/2/2000 Ongoing: YES	Initial Entry

090177e196ae3d44\Final\Final On: 01-Apr-2021 04:29 (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, Locked, Frozen, Verified**Site No:** 1130**Site Name:** (1130) Kaiser Permanente Center For Health Research**Subject No:** 11301031**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 11:25**1.f Line/MH Number:**

Date	Location	User	Value	Reason
Sep-02-2020 13:59:12 (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
Sep-02-2020 13:59:12 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Tara Beatty (b) (4)	Data Entry: Chronic RHINOSINUSITIS	Initial Entry

1.f Start Date:

Date	Location	User	Value	Reason
Sep-02-2020 13:59:12 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Tara Beatty (b) (4)	Data Entry: Mar/2/2000	Initial Entry

1.f Ongoing:

Date	Location	User	Value	Reason
Sep-02-2020 13:59:12 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Tara Beatty (b) (4)	Data Entry: YES	Initial Entry

1.g

Date	Location	User	Value	Reason
Sep-02-2020 13:59:36 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH N 7 umber:	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, Locked, Frozen, Verified

Site No: 1130

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

Subject No: 11301031

Subject Initials: ---

Generated By: (b) (4)

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

			Medical History Term : HYPERCHOLESTEROLEMIA Start Date : Apr/26/2016 Ongoing : YES	
--	--	--	--	--

1.g Line/MH Number:

Date	Location	User	Value	Reason
Sep-02-2020 13:59:36 (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
Sep-02-2020 13:59:36 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Tara Beatty (b) (4)	Data Entry: HYPERCHOLESTEROLEMIA	Initial Entry

1.g Start Date:

Date	Location	User	Value	Reason
Sep-02-2020 13:59:36 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Tara Beatty (b) (4)	Data Entry: Apr/26/2016	Initial Entry

1.g Ongoing:

Date	Location	User	Value	Reason
Sep-02-2020 13:59:36 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Tara Beatty (b) (4)	Data Entry: YES	Initial Entry

1.h

090177e196ae3d44\Final\Final On: 01-Apr-2021 04:29 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1130

Subject No: 11301031

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, 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
Sep-02-2020 14:00:01 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 8 Medical History Term: HYPOTHYROIDISM Start Date: Aug/14/2017 Ongoing: YES	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, Locked, Frozen, Verified**Site No:** 1130**Site Name:** (1130) Kaiser Permanente Center For Health Research**Subject No:** 11301031**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 11:25***1.h Line/MH Number:***

Date	Location	User	Value	Reason
Sep-02-2020 14:00:01 (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
Sep-02-2020 14:00:01 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Tara Beatty (b) (4)	Data Entry: HYPOTHYROIDISM	Initial Entry

1.h Start Date:

Date	Location	User	Value	Reason
Sep-02-2020 14:00:01 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Tara Beatty (b) (4)	Data Entry: Aug/14/2017	Initial Entry

1.h Ongoing:

Date	Location	User	Value	Reason
Sep-02-2020 14:00:01 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Tara Beatty (b) (4)	Data Entry: YES	Initial Entry

1.i

Date	Location	User	Value	Reason
Sep-02-2020 14:00:50 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH 9 Number:	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, Locked, Frozen, Verified

Site No: 1130

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

Subject No: 11301031

Subject Initials: ---

Generated By: (b) (4)

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

			Medical History Term: Bilateral hands, PERIPHERAL NEUROPATHY Start Date: Dec/17/2009 Ongoing: YES	
--	--	--	--	--

1.i Line/MH Number:

Date	Location	User	Value	Reason
Sep-02-2020 14:00:50 (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
Sep-02-2020 14:00:50 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Tara Beatty (b) (4)	Data Entry: Bilateral hands, PERIPHERAL NEUROPATHY	Initial Entry

1.i Start Date:

Date	Location	User	Value	Reason
Sep-02-2020 14:00:50 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Tara Beatty (b) (4)	Data Entry: Dec/17/2009	Initial Entry

1.i Ongoing:

Date	Location	User	Value	Reason
Sep-02-2020 14:00:50 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Tara Beatty (b) (4)	Data Entry: YES	Initial Entry

090177e196ae3d44\Final\Final On: 01-Apr-2021 04:29 (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, Locked, Frozen, Verified

Site No: 1130

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

Subject No: 11301031

Subject Initials: ---

Generated By: (b) (4)

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

I,j

Date	Location	User	Value	Reason
Sep-02-2020 14:01:28 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH 10 Number: Medical Hi OSTEOARTHRO story Term ITIS bilateral ha : nds Start Date: Feb/25/2000 Ongoing: YES	Initial Entry

090177e196ae3d44\Final\Final On: 01-Apr-2021 04:29 (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, Locked, Frozen, Verified

Site No: 1130

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

Subject No: 11301031

Subject Initials: ---

Generated By: (b) (4)

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

1.j Line/MH Number:

Date	Location	User	Value	Reason
Sep-02-2020 14:01:28 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 10	Initial Entry

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

Date	Location	User	Value	Reason
Sep-02-2020 14:01:28 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Tara Beatty (b) (4)	Data Entry: OSTEOARTHRITIS bilater al hands	Initial Entry

1.j Start Date:

Date	Location	User	Value	Reason
Sep-02-2020 14:01:28 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Tara Beatty (b) (4)	Data Entry: Feb/25/2000	Initial Entry

1.j Ongoing:

Date	Location	User	Value	Reason
Sep-02-2020 14:01:28 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Tara Beatty (b) (4)	Data Entry: YES	Initial Entry

090177e196ae3d44\Final\Final On: 01-Apr-2021 04:29 (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, Locked, Frozen, Verified

Site No: 1130

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

Subject No: 11301031

Subject Initials: ---

Generated By: (b) (4)

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

[Back to Form](#)

1.k

Date	Location	User	Value	Reason
Sep-02-2020 14:02:11 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 11 Medical History Term: Osteoporosis of back Start Date: Apr/25/2007 Ongoing: YES	Initial Entry

090177e196ae3d44\Final\Final On: 01-Apr-2021 04:29 (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, Locked, Frozen, Verified

Site No: 1130

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

Subject No: 11301031

Subject Initials: ---

Generated By: (b) (4)

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

1.k Line/MH Number:

Date	Location	User	Value	Reason
Sep-02-2020 14:02:11 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> 11	Initial Entry

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

Date	Location	User	Value	Reason
Sep-02-2020 14:02:11 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Tara Beatty (b) (4)	<u>Data Entry:</u> Osteoporosis of back	Initial Entry

1.k Start Date:

Date	Location	User	Value	Reason
Sep-02-2020 14:02:11 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Tara Beatty (b) (4)	<u>Data Entry:</u> Apr/25/2007	Initial Entry

1.k Ongoing:

Date	Location	User	Value	Reason
Sep-02-2020 14:02:11 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Tara Beatty (b) (4)	<u>Data Entry:</u> YES	Initial Entry

1.l

Date	Location	User	Value	Reason
Sep-02-2020 14:02:52 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> Line/MH Numb 12 er:	Initial Entry

090177e196ae3d44\Final\Final On: 01-Apr-2021 04:29 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1130

Subject No: 11301031

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

			Medical History ROSACE	
			Term: A	
			Start Date: Nov/17/2000	
			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, Locked, Frozen, Verified**Site No:** 1130**Site Name:** (1130) Kaiser Permanente Center For Health Research**Subject No:** 11301031**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 11:25**1.1 Line/MH Number:**

Date	Location	User	Value	Reason
Sep-02-2020 14:02:52 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 12	Initial Entry

1.1 Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:

Date	Location	User	Value	Reason
Sep-02-2020 14:02:52 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Tara Beatty (b) (4)	Data Entry: ROSACEA	Initial Entry

1.1 Start Date:

Date	Location	User	Value	Reason
Sep-02-2020 14:02:52 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Tara Beatty (b) (4)	Data Entry: Nov/17/2000	Initial Entry

1.1 Ongoing:

Date	Location	User	Value	Reason
Sep-02-2020 14:02:52 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Tara Beatty (b) (4)	Data Entry: YES	Initial Entry

1.m

Date	Location	User	Value	Reason
Sep-02-2020 14:03:18	ACV0PFEINFP6000	auto calc	Data Entry:	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1130

Subject No: 11301031

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

(UTC-08:00) Pacific Time (US & Canada)		(autocalc)	Line/MH 13 Number: Medical History T SPINAL STENOSIS OF LUMBAR SPINE erm: R SPINE Start Date: Jul/30/2019 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, Locked, Frozen, Verified**Site No:** 1130**Site Name:** (1130) Kaiser Permanente Center For Health Research**Subject No:** 11301031**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 11:25***1.m Line/MH Number:***

Date	Location	User	Value	Reason
Sep-02-2020 14:03:18 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 13	Initial Entry

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

Date	Location	User	Value	Reason
Sep-02-2020 14:03:18 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Tara Beatty (b) (4)	Data Entry: SPINAL STENOSIS OF L UMBAR SPINE	Initial Entry

1.m Start Date:

Date	Location	User	Value	Reason
Sep-02-2020 14:03:18 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Tara Beatty (b) (4)	Data Entry: Jul/30/2019	Initial Entry

1.m Ongoing:

Date	Location	User	Value	Reason
Sep-02-2020 14:03:18 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Tara Beatty (b) (4)	Data Entry: YES	Initial Entry

1.n

Date	Location	User	Value	Reason
Sep-02-2020 14:04:07	ACV0PFEINFP6000	auto calc	Data Entry:	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, Locked, Frozen, Verified

Site No: 1130

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

Subject No: 11301031

Subject Initials: ---

Generated By: (b) (4)

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

(UTC-08:00) Pacific Time (US & Canada)		(autocalc)	Line/M 14 H Num ber: Medica SPONDYLOSIS C I Histor ERVICAL JOINT y Term: Without MYELOP ATHY Start D Nov/26/2003 ate: Ongoin YES g:	
--	--	------------	---	--

090177e196ae3d44\Final\Final On: 01-Apr-2021 04:29 (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, Locked, Frozen, Verified**Site No:** 1130**Site Name:** (1130) Kaiser Permanente Center For Health Research**Subject No:** 11301031**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 11:25***1.n Line/MH Number:***

Date	Location	User	Value	Reason
Sep-02-2020 14:04:07 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 14	Initial Entry

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

Date	Location	User	Value	Reason
Sep-02-2020 14:04:07 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Tara Beatty (b) (4)	Data Entry: SPONDYLOSIS CERVICA L JOINT Without MYELO PATHY	Initial Entry

1.n Start Date:

Date	Location	User	Value	Reason
Sep-02-2020 14:04:07 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Tara Beatty (b) (4)	Data Entry: Nov/26/2003	Initial Entry

1.n Ongoing:

Date	Location	User	Value	Reason
Sep-02-2020 14:04:07 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Tara Beatty (b) (4)	Data Entry: YES	Initial Entry

1.o

Date	Location	User	Value	Reason
Sep-02-2020 14:11:52	ACV0PFEINFP6000	auto calc	Data Entry:	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1130

Subject No: 11301031

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

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

(autocalc)

Line/MH 15

Number:

Medical GASTROESOPH

History AGEAL REFLU

Term: X DISEASE

Start Dat Mar/24/1995

e:

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, Locked, Frozen, Verified

Site No: 1130

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

Subject No: 11301031

Subject Initials: ---

Generated By: (b) (4)

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

1.o Line/MH Number:

Date	Location	User	Value	Reason
Sep-02-2020 14:11:52 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 15	Initial Entry

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

Date	Location	User	Value	Reason
Sep-02-2020 14:11:52 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Tara Beatty (b) (4)	Data Entry: GASTROESOPHAGEAL REFLUX DISEASE	Initial Entry

1.o Start Date:

Date	Location	User	Value	Reason
Sep-02-2020 14:11:52 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Tara Beatty (b) (4)	Data Entry: Mar/24/1995	Initial Entry

1.o Ongoing:

Date	Location	User	Value	Reason
Sep-02-2020 14:11:52 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Tara Beatty (b) (4)	Data Entry: YES	Initial Entry

1.p

Date	Location	User	Value	Reason
Sep-03-2020 10:28:04 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Tara Beatty (b) (4)	Data Entry: Line/ 16 MH Numb	Transcription Error

090177e196ae3d44\Final\Final On: 01-Apr-2021 04:29 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1130

Subject No: 11301031

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

			er: Medic BASAL CELL CA al His RCINOMA, FACE tory T LEFT FOREHEA erm: D ABOVE EYEB ROW Start Feb/5/2002 Date: Ongoi NO ng: End Date: Feb/5/2002	
Sep-02-2020 14:12:58 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/ 16 MH N umbe r: Medic BASAL CELL C al Hist ARCINOMA, FA ory Te CE Left FOREHE rm: AD SUPRABRO W Start Feb/5/2002 Date: Ongoi NO ng: End Date: Feb/5/2002	Initial Entry

090177e196ae3d44\Final\Final On: 01-Apr-2021 04:29 (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, Locked, Frozen, Verified

Site No: 1130

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

Subject No: 11301031

Subject Initials: ---

Generated By: (b) (4)

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

1.p Line/MH Number:

Date	Location	User	Value	Reason
Sep-02-2020 14:12:58 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 16	Initial Entry

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

Date	Location	User	Value	Reason
Sep-03-2020 19:57:49 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	PFETMS Oracle (b) (4)	Query 1: Closed	Discrepancy has been closed.
Sep-03-2020 10:28:04 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Transcription Error
Sep-03-2020 10:28:04 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Tara Beatty (b) (4)	Data Entry: : BAS AL C ELL CAR CINO MA, FACE LEFT FORE HEA D AB	Transcription Error

090177e196ae3d44\Final\Final On: 01-Apr-2021 04:29 (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, Locked, Frozen, Verified

Site No: 1130

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

Subject No: 11301031

Subject Initials: ---

Generated By: (b) (4)

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

			OVE EYE BRO W	
Sep-03-2020 05:53:45 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	PFETMS Oracle (b) (4)	Query 1: Op ened	Clarify BASAL CELL CARCINOMA, FACE LEFT FOREHEAD SUPRABROW as follows...Please clarify SUPRABROW and edit the term. If reporting BASAL CELL CARCINOMA, FACE LEFT FOREHEAD ABOVE EYEBROW, edit as such. Otherwise clarify and edit the term as appropriate. Thank you.
Sep-02-2020 14:12:58 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Tara Beatty (b) (4)	Data Entry : BAS AL C ELL CAR CINO	Initial Entry

090177e196ae3d44\Final\Final On: 01-Apr-2021 04:29 (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, Locked, Frozen, Verified

Site No: 1130

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

Subject No: 11301031

Subject Initials: ---

Generated By: (b) (4)

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

				MA, FACE Left F ORE HEA D SU PRA BRO W
--	--	--	--	--

I.p Start Date:

Date	Location	User	Value	Reason
Sep-02-2020 14:12:58 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Tara Beatty (b) (4)	Data Entry: Feb/5/2002	Initial Entry

I.p Ongoing:

Date	Location	User	Value	Reason
Sep-02-2020 14:12:58 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Tara Beatty (b) (4)	Data Entry: NO End Date: Feb/5/2002	Initial Entry

I.q

Date	Location	User	Value	Reason
Sep-02-2020 14:14:07 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/M 17 H Num ber:	Initial Entry

090177e196ae3d44\Final\Final On: 01-Apr-2021 04:29 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1130

Subject No: 11301031

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

			Medical History Term Mohs micrographic surgery to Left face basal cell carcinoma Start Date: Feb/5/2002 Ongoing: NO End Date: Feb/5/2002	
--	--	--	---	--

090177e196ae3d44\Final\Final On: 01-Apr-2021 04:29 (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, Locked, Frozen, Verified

Site No: 1130

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

Subject No: 11301031

Subject Initials: ---

Generated By: (b) (4)

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

1.q Line/MH Number:

Date	Location	User	Value	Reason
Sep-02-2020 14:14:07 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 17	Initial Entry

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

Date	Location	User	Value	Reason
Sep-02-2020 14:14:07 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Tara Beatty (b) (4)	Data Entry: Mohs micrographic surgery to Left face basal cell carcinoma	Initial Entry

1.q Start Date:

Date	Location	User	Value	Reason
Sep-02-2020 14:14:07 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Tara Beatty (b) (4)	Data Entry: Feb/5/2002	Initial Entry

1.q Ongoing:

Date	Location	User	Value	Reason
Sep-02-2020 14:14:07 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Tara Beatty (b) (4)	Data Entry: NO End Date: Feb/5/2002	Initial Entry

090177e196ae3d44\Final\Final On: 01-Apr-2021 04:29 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 21-Aug-2020 02:51

Site No: 1130

Subject No: 11301031

Generated By: (b) (4)

Form: VITAL SIGNS - BASELINE - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

[Back to Form](#)

1. Date:

Date	Location	User	Value	Reason
Sep-02-2020 14:04:54 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Tara Beatty (b) (4)	Data Entry: Sep/2/2020	Initial Entry

2. Weight:

Date	Location	User	Value	Reason
Sep-02-2020 14:04:54 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Tara Beatty (b) (4)	Data Entry: 50.8	Initial Entry

3. Unit:

Date	Location	User	Value	Reason
Sep-02-2020 14:04:54 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Tara Beatty (b) (4)	Data Entry: kg	Initial Entry

4. Height:

Date	Location	User	Value	Reason
Sep-02-2020 14:04:54 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Tara Beatty (b) (4)	Data Entry: 152.4	Initial Entry

5. Unit:

Date	Location	User	Value	Reason
Sep-02-2020 14:04:54 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Tara Beatty (b) (4)	Data Entry: cm	Initial Entry

090177e196ae3d44\Final\Final On: 01-Apr-2021 04:29 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 21-Aug-2020 02:51

Site No: 1130

Subject No: 11301031

Generated By: (b) (4)

Form: VITAL SIGNS - BASELINE - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

6. Body Mass Index:

Date	Location	User	Value	Reason
Sep-02-2020 14:04:54 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 21.9	Initial Entry

7.a

Date	Location	User	Value	Reason
Sep-02-2020 14:04:54 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Tara Beatty (b) (4)	Data Entry: Record Identifier: Temperature: 98.3 Temperature Unit: Temperature Location: ORAL CAVITY	Initial Entry

7.a Record Identifier:

Date	Location	User	Value	Reason
Sep-02-2020 14:04:54 (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
Sep-02-2020 14:04:54 (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
------	----------	------	-------	--------

090177e196ae3d44\Final\Final On: 01-Apr-2021 04:29 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 21-Aug-2020 02:51

Site No: 1130

Subject No: 11301031

Generated By: (b) (4)

Form: VITAL SIGNS - BASELINE - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

Sep-02-2020 14:04:54 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Tara Beatty (b) (4)	Data Entry: F	Initial Entry
---	-----------------	------------------------	-------------------------	---------------

7.a Temperature Location:

Date	Location	User	Value	Reason
Sep-02-2020 14:04:54 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Tara Beatty (b) (4)	Data Entry: ORAL CAVITY	Initial Entry

090177e196ae3d44\Final\Final On: 01-Apr-2021 04:29 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

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

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1130

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

Subject No: 11301031

Subject Initials: ---

Generated By: (b) (4)

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

[Back to Form](#)

1. Lab Panel:

Date	Location	User	Value	Reason
Sep-02-2020 15:25:31 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: URINALYSIS	Initial Entry

2. Lab Sub-Panel:

Date	Location	User	Value	Reason
Sep-02-2020 15:25:31 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: PREGNANCY	Initial Entry

3. Collection Date:

Date	Location	User	Value	Reason
Sep-02-2020 15:25:31 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Sperry Robinson (b) (4)	Data Entry: Sep/2/2020	Initial Entry

4. Laboratory Name and Address (Derived)

Date	Location	User	Value	Reason
Sep-02-2020 15:25:31 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: STUDY SITE	Initial Entry

5. Specimen Type:

Date	Location	User	Value	Reason
Sep-02-2020 15:25:31	ACV0PFEINFP6000	auto calc	Data Entry:	Initial Entry

090177e196ae3d44\Final\Final On: 01-Apr-2021 04:29 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

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

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1130

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

Subject No: 11301031

Subject Initials: ---

Generated By: (b) (4)

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

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

(autocalc) URINE

6.a

Date	Location	User	Value	Reason
Sep-02-2020 15:25:31 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sponsor-Def 113 ined Identifier: Test:: Choriogonadotropin Beta_PX 113 Result:: Not Done:: NOT DONE	Initial Entry

6.a Sponsor ID:

Date	Location	User	Value	Reason
Sep-02-2020 15:25:31 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 113	Initial Entry

6.a Test:

Date	Location	User	Value	Reason
Sep-02-2020 15:25:31 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Sperry Robinson (b) (4)	Data Entry: Choriogonadotropin Beta_PX113	Initial Entry

6.a Not Done:

Date	Location	User	Value	Reason
Sep-02-2020	ACV0PFEINFP6000	Sperry	Data Entry:	Initial Entry

090177e196ae3d44\Final\Final On: 01-Apr-2021 04:29 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

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

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1130

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

Subject No: 11301031

Subject Initials: ---

Generated By: (b) (4)

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

15:25:31 (UTC-08:00) Pacific Time (US & Canada)		Robinson (b) (4)	NOT DONE	
---	--	---------------------	----------	--

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1130

Subject No: 11301031

Generated By: (b) (4)

Form: RANDOMIZATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

[Back to Form](#)

1. Randomization Date :

Date	Location	User	Value	Reason
Sep-02-2020 15:26:08 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Sperry Robinson (b) (4)	Data Entry: Sep/2/2020	Initial Entry

2. Randomization Number:

Date	Location	User	Value	Reason
Sep-02-2020 15:26:08 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Sperry Robinson (b) (4)	Data Entry: 250094	Initial Entry

090177e196ae3d44\Final\Final On: 01-Apr-2021 04:29 (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, Locked, Frozen, Verified

Site No: 1130

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

Subject No: 11301031

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
Sep-02-2020 15:18:40 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Sep-02-2020 15:18:40 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SERUM	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Sep-02-2020 15:18:50 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Sep-02-2020 15:18:40 (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.
Sep-02-2020 15:18:40 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Kristi Bays (b) (4)	Data Entry: YES Date of Collection: Sep/2/2020	Initial Entry

090177e196ae3d44\Final\Final On: 01-Apr-2021 04:29 (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, Locked, Frozen, Verified

Site No: 1130

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

Subject No: 11301031

Subject Initials: ---

Generated By: (b) (4)

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

5.a

Date	Location	User	Value	Reason
Sep-02-2020 15:18:50 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Kristi Bays (b) (4)	Data Entry: Sample ID: BPOX1D	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Sep-02-2020 15:18:50 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Kristi Bays (b) (4)	Data Entry: BPOX1D	Initial Entry

5.b

Date	Location	User	Value	Reason
Sep-02-2020 15:19:01 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Kristi Bays (b) (4)	Data Entry: Sample ID: BPOX1F	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Sep-02-2020 15:19:01 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Kristi Bays (b) (4)	Data Entry: BPOX1F	Initial Entry

5.c

Date	Location	User	Value	Reason
Sep-02-2020 15:19:22 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Kristi Bays (b) (4)	Data Entry: Sample ID: BPOX1G	Initial Entry

090177e196ae3d44\Final\Final On: 01-Apr-2021 04:29 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1130

Subject No: 11301031

Generated By: (b) (4)

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

Form Status: Data Complete, Locked, Frozen, 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
Sep-02-2020 15:19:22 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Kristi Bays (b) (4)	<u>Data Entry:</u> BP0X1G	Initial Entry

5.d

Date	Location	User	Value	Reason
Sep-02-2020 15:20:29 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Kristi Bays (b) (4)	<u>Data Entry:</u> Sample ID: BPHTTW	Initial Entry

5.d Sample ID

Date	Location	User	Value	Reason
Sep-02-2020 15:20:29 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Kristi Bays (b) (4)	<u>Data Entry:</u> BPHTTW	Initial Entry

5.e

Date	Location	User	Value	Reason
Sep-02-2020 15:20:44 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Kristi Bays (b) (4)	<u>Data Entry:</u> Sample ID: BPHTTV	Initial Entry

5.e Sample ID

Date	Location	User	Value	Reason
Sep-02-2020 15:20:44 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Kristi Bays (b) (4)	<u>Data Entry:</u> BPHTTV	Initial Entry

5.f

090177e196ae3d44\Final\Final On: 01-Apr-2021 04:29 (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, Locked, Frozen, Verified

Site No: 1130

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

Subject No: 11301031

Subject Initials: ---

Generated By: (b) (4)

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

Date	Location	User	Value	Reason
Sep-02-2020 15:20:54 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Kristi Bays (b) (4)	Data Entry: Sample ID: BPHTTT	Initial Entry

5.f Sample ID

Date	Location	User	Value	Reason
Sep-02-2020 15:20:54 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Kristi Bays (b) (4)	Data Entry: BPHTTT	Initial Entry

5.g

Date	Location	User	Value	Reason
Sep-02-2020 15:21:04 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Kristi Bays (b) (4)	Data Entry: Sample ID: BPHTTS	Initial Entry

5.g Sample ID

Date	Location	User	Value	Reason
Sep-02-2020 15:21:04 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Kristi Bays (b) (4)	Data Entry: BPHTTS	Initial Entry

090177e196ae3d44\Final\Final On: 01-Apr-2021 04:29 (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, Locked, Frozen, Verified

Site No: 1130

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

Subject No: 11301031

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
Sep-02-2020 13:59:16 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Sep-02-2020 13:59:16 (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
Sep-02-2020 13:59:27 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Sep-02-2020 13:59:16 (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.
Sep-02-2020 13:59:16 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Kristi Bays (b) (4)	Data Entry: YES Date of Collection: Sep/2/2020	Initial Entry

090177e196ae3d44\Final\Final On: 01-Apr-2021 04:29 (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, Locked, Frozen, Verified
Site No: 1130
Site Name: (1130) Kaiser Permanente Center For Health Research
Subject No: 11301031
Subject Initials: ---
Generated By: (b) (4)
Generated Time (GMT): 29-Mar-2021 11:25

5.a

Date	Location	User	Value	Reason
Sep-02-2020 13:59:27 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Kristi Bays (b) (4)	Data Entry: Sample ID: BPOX1L	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Sep-02-2020 13:59:27 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Kristi Bays (b) (4)	Data Entry: BPOX1L	Initial Entry

090177e196ae3d44\Final\Final On: 01-Apr-2021 04:29 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:04

Site No: 1130

Subject No: 11301031

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

[Back to Form](#)

1. Was there a temporary delay of vaccination?

Date	Location	User	Value	Reason
Sep-02-2020 15:27:05 (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
Sep-02-2020 15:27:05 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocale)	Data Entry: BLINDED THERAPY	Initial Entry

3. Formulation:

Date	Location	User	Value	Reason
Sep-02-2020 15:27:05 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocale)	Data Entry: INJECTION	Initial Entry

4. Dose Date Time:

Date	Location	User	Value	Reason
Sep-02-2020 15:27:05 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Sperry Robinson (b) (4)	Data Entry: Sep/2/2020 14:18	Initial Entry

5. Anatomical Location:

Date	Location	User	Value	Reason
Sep-02-2020 15:27:05	ACV0PFEINFP6000	auto calc	Data Entry:	Initial Entry

090177e196ae3d44\Final\Final On: 01-Apr-2021 04:29 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:04

Site No: 1130

Subject No: 11301031

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

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

(autocalc)

DELTOID MUSCLE

6. Body Side:

Date	Location	User	Value	Reason
Sep-02-2020 15:27:05 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Sperry Robinson (b) (4)	Data Entry: LEFT	Initial Entry

7. Route:

Date	Location	User	Value	Reason
Sep-02-2020 15:27:05 (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
Sep-02-2020 15:27:05 (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
Sep-02-2020 15:27:05 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Sperry Robinson (b) (4)	Data Entry: YES	Initial Entry

090177e196ae3d44\Final\Final On: 01-Apr-2021 04:29 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 06-Jul-2020 21:53

Site No: 1130

Subject No: 11301031

Generated By: (b) (4)

Form: REACTOGENICITY DIARY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

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 - Reactogenicity diary collection

Date	Location	User	Value	Reason
Sep-02-2020 15:26:14 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Sperry Robinson (b) (4)	Data Entry: NO - REACTOGENICIT Y E-DIARY NOT COLLE CTED FOR THIS SUBJE CT	Initial Entry

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 1130

Subject No: 11301031

Generated By: (b) (4)

Form: DATE OF VISIT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

[Back to Form](#)

1. Date of Visit

Date	Location	User	Value	Reason
Sep-30-2020 04:18:18 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Per site confirmation
Sep-29-2020 09:55:44 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Tara Beatty (b) (4)	Query 1: Answered	Symptoms not deemed Covid-19 symptoms during conversation with patient. Related to dramatically reduced air quality d/t extensive fires. Note uploaded to Florence.
Sep-29-2020 08:46:21 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	As per Illness edinary records, subject reported "Yes" for the question "Have you experienced any of the following?" for the COVID-19 symptoms or diagnosis on 18SEP2020. But there is no COVID Illness visit reported in the database. Please clarify.

090177e196ae3d44\Final\Final On: 01-Apr-2021 04:29 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 1130

Subject No: 11301031

Generated By: (b) (4)

Form: DATE OF VISIT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

Sep-21-2020 14:36:54 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Tara Beatty (b) (4)	Data Entry: Sep/21/2020	Initial Entry
--	-----------------	------------------------	-----------------------------------	---------------

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 15-Sep-2020 21:54

Site No: 1130

Subject No: 11301031

Generated By: (b) (4)

Form: VITAL SIGNS - TEMP - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

[Back to Form](#)

1. Date:

Date	Location	User	Value	Reason
Sep-21-2020 14:37:22 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Tara Beatty (b) (4)	Data Entry: Sep/21/2020	Initial Entry

2.a

Date	Location	User	Value	Reason
Sep-21-2020 14:37:22 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Tara Beatty (b) (4)	Data Entry: Record Identifier:: Temperature: 97.8 Temperature Unit: Temperature Location:: ORAL CAVITY	Initial Entry

2.a Record Identifier:

Date	Location	User	Value	Reason
Sep-21-2020 14:37:22 (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
Sep-21-2020 14:37:22 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Tara Beatty (b) (4)	Data Entry: 97.8	Initial Entry

2.a Unit:

090177e196ae3d44\Final\Final On: 01-Apr-2021 04:29 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 15-Sep-2020 21:54

Site No: 1130

Subject No: 11301031

Generated By: (b) (4)

Form: VITAL SIGNS - TEMP - eCRF Audit Trail History

Form Status: Data Complete, Locked, 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
Sep-21-2020 14:37:22 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Tara Beatty (b) (4)	Data Entry: F	Initial Entry

2.a Temperature Location:

Date	Location	User	Value	Reason
Sep-21-2020 14:37:22 (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: LAB URINALYSIS - PREGNANCY TEST - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1130

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

Subject No: 11301031

Subject Initials: ---

Generated By: (b) (4)

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

[Back to Form](#)

1. Lab Panel:

Date	Location	User	Value	Reason
Sep-22-2020 10:50:49 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: URINALYSIS	Initial Entry

2. Lab Sub-Panel:

Date	Location	User	Value	Reason
Sep-22-2020 10:50:49 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: PREGNANCY	Initial Entry

3. Collection Date:

Date	Location	User	Value	Reason
Sep-22-2020 10:51:05 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Sep-22-2020 10:51:05 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Sperry Robinson (b) (4)	Data Entry: Sep/21/2020	Transcription Error
Sep-22-2020 10:50:49 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	Collection Date 22/Sep/2020 is not the same as the Date of Visit 21/Sep/2020. Please correct or confirm.

090177e196ae3d44\Final\Final On: 01-Apr-2021 04:29 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

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

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1130

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

Subject No: 11301031

Subject Initials: ---

Generated By: (b) (4)

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

Sep-22-2020 10:50:49 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Sperry Robinson (b) (4)	Data Entry: Sep/22/2020	Initial Entry
---	-----------------	-------------------------	-----------------------------------	---------------

4. Laboratory Name and Address (Derived)

Date	Location	User	Value	Reason
Sep-22-2020 10:50:49 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: STUDY SITE	Initial Entry

5. Specimen Type:

Date	Location	User	Value	Reason
Sep-22-2020 10:50:49 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: URINE	Initial Entry

6.a

Date	Location	User	Value	Reason
Sep-22-2020 10:50:49 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sponsor-Def 113 ined Identifier: Test:: Choriogonadot ropin Beta_PX 113 Result:: Not Done:: NOT DONE	Initial Entry

6.a Sponsor ID:

Date	Location	User	Value	Reason
------	----------	------	-------	--------

090177e196ae3d44\Final\Final On: 01-Apr-2021 04:29 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

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

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1130

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

Subject No: 11301031

Subject Initials: ---

Generated By: (b) (4)

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

Sep-22-2020 10:50:49 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 113	Initial Entry
--	-----------------	-------------------------	---------------------------	---------------

6.a Test:

Date	Location	User	Value	Reason
Sep-22-2020 10:50:49 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Sperry Robinson (b) (4)	Data Entry: Choriogonadotropin Beta_ PX113	Initial Entry

6.a Not Done:

Date	Location	User	Value	Reason
Sep-22-2020 10:50:49 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Sperry Robinson (b) (4)	Data Entry: NOT DONE	Initial Entry

090177e196ae3d44\Final\Final On: 01-Apr-2021 04:29 (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, Locked, Frozen, Verified

Site No: 1130

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

Subject No: 11301031

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
Sep-21-2020 09:47:34 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Sep-21-2020 09:47:34 (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
Sep-21-2020 09:47:44 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Sep-21-2020 09:47:34 (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.
Sep-21-2020 09:47:34 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Kristi Bays (b) (4)	Data Entry: YES Date of Collection: Sep/21/2020	Initial Entry

090177e196ae3d44\Final\Final On: 01-Apr-2021 04:29 (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, Locked, Frozen, Verified

Site No: 1130

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

Subject No: 11301031

Subject Initials: ---

Generated By: (b) (4)

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

5.a

Date	Location	User	Value	Reason
Sep-21-2020 09:47:44 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Kristi Bays (b) (4)	Data Entry: Sample ID: BP0X7H	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Sep-21-2020 09:47:44 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Kristi Bays (b) (4)	Data Entry: BP0X7H	Initial Entry

090177e196ae3d44\Final\Final On: 01-Apr-2021 04:29 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1130

Subject No: 11301031

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

[Back to Form](#)

1. Was there a temporary delay of vaccination?

Date	Location	User	Value	Reason
Sep-21-2020 10:45:06 (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
Sep-21-2020 10:45:06 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: BLINDED THERAPY	Initial Entry

3. Formulation:

Date	Location	User	Value	Reason
Sep-21-2020 10:45:06 (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
Sep-21-2020 10:45:06 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sep/21/2020 10:24	Initial Entry

5. Anatomical Location:

Date	Location	User	Value	Reason
Sep-21-2020 10:45:06	ACV0PFEINFP6000	auto calc	Data Entry:	Initial Entry

090177e196ae3d44\Final\Final On: 01-Apr-2021 04:29 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1130

Subject No: 11301031

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

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

6. Body Side:

Date	Location	User	Value	Reason
Sep-21-2020 10:45:06 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: LEFT	Initial Entry

7. Route:

Date	Location	User	Value	Reason
Sep-21-2020 10:45:06 (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
Sep-21-2020 10:45:06 (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
Sep-21-2020 10:45:06 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

090177e196ae3d44\Final\Final On: 01-Apr-2021 04:29 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 1130

Subject No: 11301031

Generated By: (b) (4)

Form: DATE OF VISIT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

[Back to Form](#)

1. Date of Visit

Date	Location	User	Value	Reason
Oct-19-2020 09:30:35 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Dorothy Kurdyla (b) (4)	Data Entry: Oct/19/2020	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, Locked, Frozen, Verified

Site No: 1130

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

Subject No: 11301031

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
Oct-19-2020 10:27:56 (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-19-2020 10:27:56 (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-19-2020 10:28:12 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Oct-19-2020 10:27:56 (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-19-2020 10:27:56 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Kristi Bays (b) (4)	Data Entry: YES Date of Collection: Oct/19/2020	Initial Entry

090177e196ae3d44\Final\Final On: 01-Apr-2021 04:29 (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, Locked, Frozen, Verified

Site No: 1130

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

Subject No: 11301031

Subject Initials: ---

Generated By: (b) (4)

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

5.a

Date	Location	User	Value	Reason
Oct-19-2020 10:28:12 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Kristi Bays (b) (4)	Data Entry: Sample ID: BR8MW5	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Oct-19-2020 10:28:12 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Kristi Bays (b) (4)	Data Entry: BR8MW5	Initial Entry

5.b

Date	Location	User	Value	Reason
Oct-19-2020 10:28:27 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Kristi Bays (b) (4)	Data Entry: Sample ID: BR8MW6	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Oct-19-2020 10:28:27 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Kristi Bays (b) (4)	Data Entry: BR8MW6	Initial Entry

5.c

Date	Location	User	Value	Reason
Oct-19-2020 10:28:47 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Kristi Bays (b) (4)	Data Entry: Sample ID: BS6ZSR	Initial Entry

090177e196ae3d44\Final\Final On: 01-Apr-2021 04:29 (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, Locked, Frozen, Verified

Site No: 1130

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

Subject No: 11301031

Subject Initials: ---

Generated By: (b) (4)

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

5.c Sample ID

Date	Location	User	Value	Reason
Oct-19-2020 10:28:47 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Kristi Bays (b) (4)	Data Entry: BS6ZSR	Initial Entry

5.d

Date	Location	User	Value	Reason
Oct-19-2020 10:28:59 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Kristi Bays (b) (4)	Data Entry: Sample ID: BS6ZSS	Initial Entry

5.d Sample ID

Date	Location	User	Value	Reason
Oct-19-2020 10:28:59 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Kristi Bays (b) (4)	Data Entry: BS6ZSS	Initial Entry

5.e

Date	Location	User	Value	Reason
Oct-19-2020 10:29:11 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Kristi Bays (b) (4)	Data Entry: Sample ID: BS6ZST	Initial Entry

5.e Sample ID

Date	Location	User	Value	Reason
Oct-19-2020 10:29:11 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Kristi Bays (b) (4)	Data Entry: BS6ZST	Initial Entry

090177e196ae3d44\Final\Final On: 01-Apr-2021 04:29 (GMT)

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, Locked, Frozen, Verified

Site No: 1130

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

Subject No: 11301031

Subject Initials: ---

Generated By: (b) (4)

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

[Back to Form](#)

1. Date of Completion/Discontinuation/Death :

Date	Location	User	Value	Reason
Oct-19-2020 09:30:46 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Dorothy Kurdyla (b) (4)	Data Entry: Oct/19/2020	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Oct-19-2020 09:30:46 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: VACCINATION	Initial Entry

3. Status:

Date	Location	User	Value	Reason
Oct-19-2020 09:30:46 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Dorothy Kurdyla (b) (4)	Data Entry: COMPLETED	Initial Entry

090177e196ae3d44\Final\Final On: 01-Apr-2021 04:29 (GMT)

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: 11301031

Subject Initials: ---

Generated By: (b) (4)

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

[Back to Form](#)

Date	Location	User	Value	Reason
Feb-16-2021 10:29:42 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1130

Subject No: 11301031

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - Audit Trail

Form Status:

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

Subject Initials: ---

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

[Back to Form](#)

Date	Location	User	Value	Reason
Feb-17-2021 10:43:19 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Dorothy Kurdyla (b) (4)	Form Created	

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1130

Subject No: 11301031

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - Audit Trail

Form Status:

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

Subject Initials: ---

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

[Back to Form](#)

Date	Location	User	Value	Reason
Mar-09-2021 11:29:22 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Tara Beatty (b) (4)	Form Created	

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1130

Subject No: 11301031

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - Audit Trail

Form Status:

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

Subject Initials: ---

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

[Back to Form](#)

Date	Location	User	Value	Reason
Mar-09-2021 11:42:08 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Tara Beatty (b) (4)	Form Created	

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1130

Subject No: 11301031

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Answered Queries

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

Subject Initials: ---

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

[Back to Form](#)

1. Category:

Date	Location	User	Value	Reason
Feb-16-2021 10:29:42 (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-16-2021 10:29:42 (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-17-2021 12:46:04 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	PFETMS Oracle (b) (4)	Query 1: Closed	Discrepancy has been closed.
Feb-17-2021 10:42:17 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Changed Information
Feb-17-2021 10:42:17 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Dorothy Kurdyla (b) (4)	Data Entry: Rash - injection site	Changed Information

090177e196ae3d44\Final\Final On: 01-Apr-2021 04:29 (GMT)

Header Text: c4591001
Visit: Logs - Unscheduled
Form Version: 22-Apr-2020 21:02
Site No: 1130
Subject No: 11301031
Generated By: (b) (4)
Form: ADVERSE EVENT REPORT - eCRF Audit Trail History
Form Status: Data Complete, Answered Queries
Site Name: (1130) Kaiser Permanente Center For Health Research
Subject Initials: ---
Generated Time (GMT): 29-Mar-2021 11:25

Canada)				
Feb-16-2021 14:38:20 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	PFETMS Oracle (b) (4)	Query 1: Open ed	Multiple concepts in the term RASH - INJECTION SITE AND VARIOUS PLACES ON BODY. Split the term into RASH - INJECTION SITE and RASH VARIOUS PLACES ON BODY and report as separate entries. Thank you.
Feb-16-2021 10:29:42 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Rash - i njectio n site a nd vari ous pla ces on body	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason
Feb-16-2021 10:29:42	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Feb/9/2021 19:00	Initial Entry

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1130

Subject No: 11301031

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Answered Queries

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

Subject Initials: ---

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

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

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

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Mar-11-2021 11:24:06 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	New Information
Mar-11-2021 11:24:06 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Tara Beatty (b) (4)	Data Entry: NO End Date Time: Feb/19/2021 UNK:U NK	New Information
Mar-10-2021 06:08:22 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	CLINQUERY - Rash inj site (09 Feb 21) related to Vax 4, is still indicated as ONGOING. Please review and confirm ONGOING, or enter END date if known.
Feb-16-2021 10:29:42 (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
------	----------	------	-------	--------

090177e196ae3d44\Final\Final On: 01-Apr-2021 04:29 (GMT)

Header Text: c4591001**Visit:** Logs - Unscheduled**Form Version:** 22-Apr-2020 21:02**Site No:** 1130**Subject No:** 11301031**Generated By:** (b) (4)**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History**Form Status:** Data Complete, Answered Queries**Site Name:** (1130) Kaiser Permanente Center For Health Research**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 11:25

Feb-17-2021 22:10:36 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED] [REDACTED]	Query 1: Closed	Response satisfies query
Feb-17-2021 10:39:54 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Initial Entry
Feb-17-2021 10:39:54 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Dorothy Kurdyla (b) (4)	Data Entry: 1	Initial Entry
Feb-16-2021 21:40:26 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED] [REDACTED]	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).**

Date	Location	User	Value	Reason
Feb-16-2021 10:29:42 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry: NO	Initial Entry

8. Is this adverse event the result of a study Medication Error?**If Yes, record the type of medication error on the Medication Error Log.**

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Answered Queries

Site No: 1130

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

Subject No: 11301031

Subject Initials: ---

Generated By: (b) (4)

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

Date	Location	User	Value	Reason
Feb-16-2021 10:29:42 (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 22:10:01 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Feb-17-2021 10:40:04 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Initial Entry
Feb-17-2021 10:40:04 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Dorothy Kurdyla (b) (4)	Data Entry: RELATED	Initial Entry
Feb-16-2021 21:40:41 (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-16-2021 10:29:42 (UTC-08:00) Pacific	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NOT APPLICABLE	Initial Entry

090177e196ae3d44\Final\Final On: 01-Apr-2021 04:29 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Answered Queries

Site No: 1130

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

Subject No: 11301031

Subject Initials: ---

Generated By: (b) (4)

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

Time (US & Canada)				
--------------------	--	--	--	--

11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
Feb-16-2021 10:29:42 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Feb-16-2021 10:29:42 (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
Mar-11-2021 11:24:40 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Mar-11-2021 11:24:40 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Tara Beatty (b) (4)	Data Entry: RECOVERED/RESOLVED	New Information
Mar-11-2021 11:24:06 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	For AE Rash - injection site: Response to "What was the outcome of this adverse event?" is

090177e196ae3d44\Final\Final On: 01-Apr-2021 04:29 (GMT)

Header Text: c4591001
Visit: Logs - Unscheduled **Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History
Form Version: 22-Apr-2020 21:02 **Form Status:** Data Complete, Answered Queries
Site No: 1130 **Site Name:** (1130) Kaiser Permanente Center For Health Research
Subject No: 11301031 **Subject Initials:** ---
Generated By: (b) (4) **Generated Time (GMT):** 29-Mar-2021 11:25

				'Not Recovered/Not Resolved' but AE End Date/Time is present.
Feb-16-2021 10:29:42 (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?

Date	Location	User	Value	Reason
Feb-16-2021 10:29:42 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

090177e196ae3d44\Final\Final On: 01-Apr-2021 04:29 (GMT)

Header Text: c4591001**Visit:** Logs - Unscheduled**Form Version:** 22-Apr-2020 21:02**Site No:** 1130**Subject No:** 11301031**Generated By:** (b) (4)**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History**Form Status:** Data Complete, Answered Queries**Site Name:** (1130) Kaiser Permanente Center For Health Research**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 11:25[Back to Form](#)**1. Category:**

Date	Location	User	Value	Reason
Feb-17-2021 10:43:19 (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-17-2021 10:43:19 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 2	Initial Entry

3. Adverse Event:*(If possible specify diagnosis, not individual symptoms)*

Date	Location	User	Value	Reason
Feb-17-2021 10:43:19 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Dorothy Kurdyla (b) (4)	Data Entry: Rash- various places on bo dy	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason
Feb-17-2021 10:43:19 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Dorothy Kurdyla (b) (4)	Data Entry: Feb/9/2021 19:00	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
------	----------	------	-------	--------

Header Text: c4591001**Visit:** Logs - Unscheduled**Form Version:** 22-Apr-2020 21:02**Site No:** 1130**Subject No:** 11301031**Generated By:** (b) (4)**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History**Form Status:** Data Complete, Answered Queries**Site Name:** (1130) Kaiser Permanente Center For Health Research**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 11:25

Mar-11-2021 11:25:20 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	New Information
Mar-11-2021 11:25:20 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Tara Beatty (b) (4)	Data Entry: NO End Date Time: Feb/19/2021 UNK:UN K	New Information
Mar-10-2021 06:08:43 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	CLINQUERY - Rash BODY (09 Feb 21) related to Vax 4, is still indicated as ONGOING. Please review and confirm ONGOING, or enter END date if known.
Feb-17-2021 10:43:19 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Dorothy Kurdyla (b) (4)	Data Entry: YES	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
Feb-17-2021 10:43:19 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Dorothy Kurdyla (b) (4)	Data Entry: 1	Initial Entry

7. Is the adverse event serious?**If Yes, NOTIFY PFIZER IMMEDIATELY.**

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1130

Subject No: 11301031

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Answered Queries

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

Subject Initials: ---

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

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

Date	Location	User	Value	Reason
Feb-17-2021 10:43:19 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Dorothy Kurdyla (b) (4)	<u>Data Entry:</u> NO	Initial Entry

8. Is this adverse event the result of a study Medication Error?
If Yes, record the type of medication error on the Medication Error Log.

Date	Location	User	Value	Reason
Feb-17-2021 10:43:19 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Dorothy Kurdyla (b) (4)	<u>Data Entry:</u> NO	Initial Entry

9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Feb-17-2021 10:43:19 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Dorothy Kurdyla (b) (4)	<u>Data Entry:</u> RELATED	Initial Entry

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Feb-17-2021 10:43:19 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Dorothy Kurdyla (b) (4)	<u>Data Entry:</u> NOT APPLICABLE	Initial Entry

11. Was a Concomitant Medication given?

090177e196ae3d44\Final\Final On: 01-Apr-2021 04:29 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Answered Queries

Site No: 1130

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

Subject No: 11301031

Subject Initials: ---

Generated By: (b) (4)

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

Date	Location	User	Value	Reason
Feb-17-2021 10:43:19 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Dorothy Kurdyla (b) (4)	Data Entry: NO	Initial Entry

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Feb-17-2021 10:43:19 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Dorothy Kurdyla (b) (4)	Data Entry: NO	Initial Entry

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

Date	Location	User	Value	Reason
Mar-11-2021 11:25:41 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Mar-11-2021 11:25:41 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Tara Beatty (b) (4)	Data Entry: RECOVERED/RESOLV ED	New Information
Mar-11-2021 11:25:20 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	For AE Rash- various places on body: Response to "What was the outcome of this adverse event?" is 'Not Recovered/Not Resolved' but AE End Date/Time is present.

090177e196ae3d44\Final\Final On: 01-Apr-2021 04:29 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1130

Subject No: 11301031

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Answered Queries

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

Subject Initials: ---

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

Feb-17-2021 10:43:19 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Dorothy Kurdyla (b) (4)	Data Entry: NOT RECOVERED/NO T RESOLVED	Initial Entry
--	-----------------	-------------------------------	--	---------------

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

Date	Location	User	Value	Reason
Feb-17-2021 10:43:19 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Dorothy Kurdyla (b) (4)	Data Entry: NO	Initial Entry

090177e196ae3d44\Final\Final On: 01-Apr-2021 04:29 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1130

Subject No: 11301031

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - 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

[Back to Form](#)

1. Category:

Date	Location	User	Value	Reason
Mar-09-2021 11:29:22 (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
Mar-09-2021 11:29:22 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 3	Initial Entry

3. Adverse Event:

(If possible specify diagnosis, not individual symptoms)

Date	Location	User	Value	Reason
Mar-09-2021 11:29:22 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Tara Beatty (b) (4)	Data Entry: Transient Ischemic Attack	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason
Mar-09-2021 11:29:22 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Tara Beatty (b) (4)	Data Entry: Mar/7/2021 08:00	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
------	----------	------	-------	--------

090177e196ae3d44\Final\Final On: 01-Apr-2021 04:29 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete

Site No: 1130

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

Subject No: 11301031

Subject Initials: ---

Generated By: (b) (4)

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

Mar-09-2021 11:29:22 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Tara Beatty (b) (4)	Data Entry: NO End Date Time: Mar/7/2021 10:07	Initial Entry
---	-----------------	------------------------	--	---------------

6. Toxicity Grade:

Date	Location	User	Value	Reason
Mar-11-2021 10:21:46 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	data updated
Mar-11-2021 07:04:14 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Initial Entry
Mar-11-2021 07:04:14 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Tara Beatty (b) (4)	Data Entry: 2	Initial Entry
Mar-09-2021 22:12:16 (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).

090177e196ae3d44\Final\Final On: 01-Apr-2021 04:29 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1130

Subject No: 11301031

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - 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

Date	Location	User	Value	Reason
Mar-12-2021 06:39:10 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Mar-09-2021 17:56:54 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	For AE Transient Ischemic Attack: Response to "Is the adverse event serious?" is 'Yes' but "Serious Adverse Event Number" is blank.
Mar-09-2021 17:56:54 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Tara Beatty (b) (4)	<p>Data Entry:</p> <p>YES</p> <p>Is this serious event associated with congenital anomaly or birth defect?</p> <p>NO</p> <p>Did this serious event result in death?</p> <p>NO</p> <p>Did this serious event require or prolong hospitalization?</p> <p>YES</p> <p>Did this serious event result in persistent or significant disability/incapacity?</p> <p>NO</p>	Initial Entry

090177e196ae3d44\Final\Final On: 01-Apr-2021 04:29 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1130

Subject No: 11301031

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - 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

			Is this serious event life threatening? NO Other medically important serious event YES	
--	--	--	---	--

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
Mar-09-2021 11:29:22 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Tara Beatty (b) (4)	Data Entry: NO	Initial Entry

9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Mar-11-2021 10:21:56 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	data updated
Mar-11-2021 07:04:46 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Tara Beatty (b) (4)	Data Entry: NOT RELATED If Not Related to study treatment(s), this event is due to: OTHER <i>If Other, specify:</i> Related to hypercho	Transcription Error

090177e196ae3d44\Final\Final On: 01-Apr-2021 04:29 (GMT)

Header Text: c4591001**Visit:** Logs - Unscheduled**Form Version:** 22-Apr-2020 21:02**Site No:** 1130**Subject No:** 11301031**Generated By:** (b) (4)**Form:** ADVERSE EVENT REPORT - 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

			lesterolemia	
Mar-11-2021 07:04:14 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Initial Entry
Mar-11-2021 07:04:14 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Tara Beatty (b) (4)	Data Entry: NOT RELATED If Not Related to study tr eatment(s), this event is due to: OTHER	Initial Entry
Mar-09-2021 22:12:34 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED] [REDACTED]	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
Mar-09-2021 11:29:22 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Tara Beatty (b) (4)	Data Entry: NOT APPLICABLE	Initial Entry

11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
Mar-09-2021 11:29:22 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Tara Beatty (b) (4)	Data Entry: YES	Initial Entry

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete

Site No: 1130

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

Subject No: 11301031

Subject Initials: ---

Generated By: (b) (4)

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

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Mar-09-2021 11:29:22 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Tara Beatty (b) (4)	Data Entry: NO	Initial Entry

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

Date	Location	User	Value	Reason
Mar-09-2021 11:29:22 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Tara Beatty (b) (4)	Data Entry: RECOVERED/RESOLVED	Initial Entry

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

Date	Location	User	Value	Reason
Mar-09-2021 11:29:22 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Tara Beatty (b) (4)	Data Entry: NO	Initial Entry

15. Serious Adverse Event Number: For Pfizer Use Only

Date	Location	User	Value	Reason
Mar-12-2021 06:39:10 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [Redacted] [Redacted]	Data Entry: 2021264920	Initial Entry

090177e196ae3d44\Final\Final On: 01-Apr-2021 04:29 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1130

Subject No: 11301031

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - 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

[Back to Form](#)

1. Category:

Date	Location	User	Value	Reason
Mar-09-2021 11:42:08 (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
Mar-09-2021 11:42:08 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 4	Initial Entry

3. Adverse Event:

(If possible specify diagnosis, not individual symptoms)

Date	Location	User	Value	Reason
Mar-09-2021 11:42:08 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Tara Beatty (b) (4)	Data Entry: Urinary Tract Infection	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason
Mar-09-2021 11:42:08 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Tara Beatty (b) (4)	Data Entry: Mar/7/2021 09:48	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
------	----------	------	-------	--------

090177e196ae3d44\Final\Final On: 01-Apr-2021 04:29 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete

Site No: 1130

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

Subject No: 11301031

Subject Initials: ---

Generated By: (b) (4)

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

Mar-09-2021 11:42:08 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Tara Beatty (b) (4)	Data Entry: YES	Initial Entry
--	-----------------	------------------------	---------------------------	---------------

6. Toxicity Grade:

Date	Location	User	Value	Reason
Mar-11-2021 10:22:17 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	data updated
Mar-11-2021 07:05:21 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Initial Entry
Mar-11-2021 07:05:21 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Tara Beatty (b) (4)	Data Entry: 1	Initial Entry
Mar-09-2021 22:13:11 (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).

Date	Location	User	Value	Reason
------	----------	------	-------	--------

090177e196ae3d44\Final\Final On: 01-Apr-2021 04:29 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete

Site No: 1130

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

Subject No: 11301031

Subject Initials: ---

Generated By: (b) (4)

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

Mar-09-2021 11:42:08 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Tara Beatty (b) (4)	Data Entry: NO	Initial Entry
--	-----------------	------------------------	--------------------------	---------------

8. Is this adverse event the result of a study Medication Error?
If Yes, record the type of medication error on the Medication Error Log.

Date	Location	User	Value	Reason
Mar-09-2021 11:42:08 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Tara Beatty (b) (4)	Data Entry: NO	Initial Entry

9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Mar-12-2021 12:49:32 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Mar-12-2021 08:08:05 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Transcription Error
Mar-12-2021 08:08:05 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Tara Beatty (b) (4)	Data Entry: NOT RELATED If Not Related to study tr eatment(s), this event is due to: OTHER <i>If Other, specify:</i> Bacteria in the Urin ary Tract	Transcription Error

090177e196ae3d44\Final\Final On: 01-Apr-2021 04:29 (GMT)

Header Text: c4591001**Visit:** Logs - Unscheduled**Form Version:** 22-Apr-2020 21:02**Site No:** 1130**Subject No:** 11301031**Generated By:** (b) (4)**Form:** ADVERSE EVENT REPORT - 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

Mar-11-2021 20:24:54 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Query 1: Reissued:Opened	DM: Please clarify other, unknown is not valid response. Thank you.
Mar-11-2021 11:16:40 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Transcription Error
Mar-11-2021 11:16:40 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Tara Beatty (b) (4)	Data Entry: NOT RELATED If Not Related to study treatment(s), this event is due to: OTHER <i>If Other, specify:</i> Unknown	Transcription Error
Mar-11-2021 10:23:02 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Query 1: Reissued:Opened	Response to 'If other, specify' is NOT RELATED, please consider updating this field to what is causing this AE.
Mar-11-2021 07:06:02 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Tara Beatty (b) (4)	Data Entry: NOT RELATED If Not Related to study treatment(s), this event is due to: OTHER <i>If Other, specify:</i>	Transcription Error

Header Text: c4591001**Visit:** Logs - Unscheduled**Form Version:** 22-Apr-2020 21:02**Site No:** 1130**Subject No:** 11301031**Generated By:** (b) (4)**Form:** ADVERSE EVENT REPORT - 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

			Not related	
Mar-11-2021 07:05:21 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Initial Entry
Mar-11-2021 07:05:21 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Tara Beatty (b) (4)	Data Entry: NOT RELATED	Initial Entry
Mar-09-2021 22:13:36 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	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
Mar-09-2021 11:42:08 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Tara Beatty (b) (4)	Data Entry: NOT APPLICABLE	Initial Entry

11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
Mar-09-2021 11:42:08 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Tara Beatty (b) (4)	Data Entry: YES	Initial Entry

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
------	----------	------	-------	--------

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1130

Subject No: 11301031

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - 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

Mar-09-2021 11:42:08 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Tara Beatty (b) (4)	Data Entry: NO	Initial Entry
--	-----------------	------------------------	--------------------------	---------------

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

Date	Location	User	Value	Reason
Mar-09-2021 11:42:08 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Tara Beatty (b) (4)	Data Entry: RECOVERING/RESOLVI NG	Initial Entry

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

Date	Location	User	Value	Reason
Mar-09-2021 11:42:08 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Tara Beatty (b) (4)	Data Entry: NO	Initial Entry

090177e196ae3d44\Final\Final On: 01-Apr-2021 04:29 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - NON STUDY
VACCINATIONS - Audit Trail

Form Version: 22-Apr-2020 21:03

Form Status:

Site No: 1130

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

Subject No: 11301031

Subject Initials: ---

Generated By: (b) (4)

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

[Back to Form](#)

Date	Location	User	Value	Reason
Nov-13-2020 17:11:31 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Tara Beatty (b) (4)	Form Created	

Header Text: c4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - NON STUDY VACCINATIONS - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1130

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

Subject No: 11301031

Subject Initials: ---

Generated By: (b) (4)

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

[Back to Form](#)

1. What is the medication identifier?

Date	Location	User	Value	Reason
Nov-13-2020 17:11:31 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 1	Initial Entry

2. Category:

Date	Location	User	Value	Reason
Nov-13-2020 17:11:31 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: VACCINATIONS	Initial Entry

3. Concomitant Medications Pre-specified:

Date	Location	User	Value	Reason
Nov-13-2020 17:11:31 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: NO	Initial Entry

4. Medication:

Provide the complete generic drug name (including salt form, where applicable). Where generic name is unknown, enter the full trade or proprietary name. Include clarifying information in the Medication text (e.g., Ingredient(s), route, use, formulation).

Date	Location	User	Value	Reason
Nov-13-2020 17:11:31 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Tara Beatty (b) (4)	Data Entry: INFs Pres Free High Dose (FLUZONE) (influenza)	Initial Entry

5. Date:

090177e196ae3d44\Final\Final On: 01-Apr-2021 04:29 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1130

Subject No: 11301031

Generated By: (b) (4)

Form: CONCOMITANT MEDICATIONS - NON STUDY VACCINATIONS - eCRF Audit Trail History

Form Status: Data Complete, Locked, 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
Nov-13-2020 17:11:31 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Tara Beatty (b) (4)	Data Entry: Oct/15/2020	Initial Entry

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: 11301031

Subject Initials: ---

Generated By: (b) (4)

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

[Back to Form](#)

1. Date of Visit

Date	Location	User	Value	Reason
Jan-15-2021 09:24:29 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Sperry Robinson (b) (4)	Data Entry: Jan/15/2021	Initial Entry

Header Text: c4591001

Visit: Potential ReVax Initial Contact -
Unscheduled

Form: FURTHER VACCINATION CONFIRMATION - eCRF
Audit Trail History

Form Version: 10-Dec-2020 02:25

Form Status: Data Complete, Frozen, Verified

Site No: 1130

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

Subject No: 11301031

Subject Initials: ---

Generated By: (b) (4)

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-15-2021 09:24:52 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Jan-15-2021 09:24:41 (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-15-2021 09:24:41 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Sperry Robinson (b) (4)	Data Entry: Participant is willing to r eturn for Vaccination 3 Participant is: eligible per other prot ocol allowance(s) and confirmed to have rec eived only placebo at Vaccination 1/2	Initial Entry

090177e196ae3d44\Final\Final On: 01-Apr-2021 04:29 (GMT)

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: 11301031

Subject Initials: ---

Generated By: (b) (4)

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

[Back to Form](#)

1. Date Treatment Unblinded :

Date	Location	User	Value	Reason
Jan-15-2021 09:24:52 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Sperry Robinson (b) (4)	Data Entry: Jan/15/2021	Initial Entry

2. Primary Reason for Unblinding:

Date	Location	User	Value	Reason
Jan-15-2021 09:24:52 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Sperry Robinson (b) (4)	Data Entry: ASSESS ELIGIBILITY F OR ADDITIONAL VACC INATION	Initial Entry

090177e196ae3d44\Final\Final On: 01-Apr-2021 04:29 (GMT)

Header Text: c4591001

Visit: V101_VAX3

Form Version: 22-Apr-2020 21:02

Site No: 1130

Subject No: 11301031

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

[Back to Form](#)

1. Date of Visit

Date	Location	User	Value	Reason
Jan-20-2021 10:17:20 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Dorothy Kurdyla (b) (4)	Data Entry: Jan/20/2021	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: 11301031

Subject Initials: ---

Generated By: (b) (4)

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

[Back to Form](#)

1. Consent Was:

Date	Location	User	Value	Reason
Jan-20-2021 10:17:32 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Dorothy Kurdyla (b) (4)	Data Entry: OBTAINED Date Written Consent Obtained Jan/20/2021	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: 11301031

Subject Initials: ---

Generated By: (b) (4)

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

[Back to Form](#)

1. Date of Completion/Discontinuation/Death :

Date	Location	User	Value	Reason
Jan-20-2021 10:17:56 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Dorothy Kurdyla (b) (4)	Data Entry: Jan/20/2021	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Jan-20-2021 10:17:56 (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-20-2021 10:17:56 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Dorothy Kurdyla (b) (4)	Data Entry: COMPLETED	Initial Entry

090177e196ae3d44\Final\Final On: 01-Apr-2021 04:29 (GMT)

Header Text: c4591001**Visit:** V101_VAX3**Form:** LAB URINALYSIS - PREGNANCY TEST - eCRF Audit Trail History**Form Version:** 14-Jan-2021 02:21**Form Status:** Data Complete, Frozen, Verified**Site No:** 1130**Site Name:** (1130) Kaiser Permanente Center For Health Research**Subject No:** 11301031**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 11:25[Back to Form](#)**1. Lab Panel:**

Date	Location	User	Value	Reason
Jan-20-2021 11:23:58 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: URINALYSIS	Initial Entry

2. Lab Sub-Panel:

Date	Location	User	Value	Reason
Jan-20-2021 11:23:58 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: PREGNANCY	Initial Entry

3. Collection Date:

Date	Location	User	Value	Reason
Jan-20-2021 11:23:58 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Jan/20/2021	Initial Entry

4. Laboratory Name and Address (Derived)

Date	Location	User	Value	Reason
Jan-20-2021 11:23:58 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: STUDY SITE	Initial Entry

5. Specimen Type:

Date	Location	User	Value	Reason
Jan-20-2021 11:23:58	ACV0PFEINFP6000	auto calc	Data Entry:	Initial Entry

Header Text: c4591001
Visit: V101_VAX3 **Form:** LAB URINALYSIS - PREGNANCY TEST - eCRF Audit Trail History
Form Version: 14-Jan-2021 02:21 **Form Status:** Data Complete, Frozen, Verified
Site No: 1130 **Site Name:** (1130) Kaiser Permanente Center For Health Research
Subject No: 11301031 **Subject Initials:** ---
Generated By: (b) (4) **Generated Time (GMT):** 29-Mar-2021 11:25

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

6.a

Date	Location	User	Value	Reason
Jan-20-2021 11:23:45 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sponsor-Def 113 ined Identifier: Test:: Choriogonadotropin Beta_PX 113 Result:: Not Done:: NOT DONE	Initial Entry

6.a Sponsor ID:

Date	Location	User	Value	Reason
Jan-20-2021 11:23:45 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 113	Initial Entry

6.a Test:

Date	Location	User	Value	Reason
Jan-20-2021 11:23:45 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Choriogonadotropin Beta_PX113	Initial Entry

6.a Not Done:

Date	Location	User	Value	Reason
Jan-20-2021	ACV0PFEINFP6000	(b) (6)	Data Entry:	Initial Entry

090177e196ae3d44\Final\Final On: 01-Apr-2021 04:29 (GMT)

Header Text: c4591001

Visit: V101_VAX3

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

Form Version: 14-Jan-2021 02:21

Form Status: Data Complete, Frozen, Verified

Site No: 1130

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

Subject No: 11301031

Subject Initials: ---

Generated By: (b) (4)

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

11:23:45
(UTC-08:00) Pacific
Time (US & Canada)

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

NOT DONE

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: 11301031

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
Jan-20-2021 11:18:20 (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-20-2021 11:18:20 (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-20-2021 11:18:30 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Jan-20-2021 11:18:20 (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-20-2021 11:18:20 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Kristi Bays (b) (4)	Data Entry: YES Date of Collection: Jan/20/2021	Initial Entry

090177e196ae3d44\Final\Final On: 01-Apr-2021 04:29 (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: 11301031

Subject Initials: ---

Generated By: (b) (4)

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

5.a

Date	Location	User	Value	Reason
Jan-20-2021 11:18:30 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Kristi Bays (b) (4)	Data Entry: Sample ID: BPOXDS	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Jan-20-2021 11:18:30 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Kristi Bays (b) (4)	Data Entry: BPOXDS	Initial Entry

5.b

Date	Location	User	Value	Reason
Jan-20-2021 11:18:48 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Kristi Bays (b) (4)	Data Entry: Sample ID: BPOXF7	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Jan-20-2021 11:18:48 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Kristi Bays (b) (4)	Data Entry: BPOXF7	Initial Entry

5.c

Date	Location	User	Value	Reason
Jan-20-2021 11:19:01 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Kristi Bays (b) (4)	Data Entry: Sample ID: BPHV4J	Initial Entry

090177e196ae3d44\Final\Final On: 01-Apr-2021 04:29 (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: 11301031

Subject Initials: ---

Generated By: (b) (4)

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

5.c Sample ID

Date	Location	User	Value	Reason
Jan-20-2021 11:19:01 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Kristi Bays (b) (4)	<u>Data Entry:</u> BPHV4J	Initial Entry

5.d

Date	Location	User	Value	Reason
Jan-20-2021 11:19:09 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Kristi Bays (b) (4)	<u>Data Entry:</u> Sample ID: BPHV4K	Initial Entry

5.d Sample ID

Date	Location	User	Value	Reason
Jan-20-2021 11:19:09 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Kristi Bays (b) (4)	<u>Data Entry:</u> BPHV4K	Initial Entry

5.e

Date	Location	User	Value	Reason
Jan-20-2021 11:19:18 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Kristi Bays (b) (4)	<u>Data Entry:</u> Sample ID: BPHV4L	Initial Entry

5.e Sample ID

Date	Location	User	Value	Reason
Jan-20-2021 11:19:18 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Kristi Bays (b) (4)	<u>Data Entry:</u> BPHV4L	Initial Entry

090177e196ae3d44\Final\Final On: 01-Apr-2021 04:29 (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: 11301031

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
Jan-20-2021 10:24:17 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Jan-20-2021 10:24:17 (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
Jan-20-2021 10:24:29 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Jan-20-2021 10:24:17 (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.
Jan-20-2021 10:24:17 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Kristi Bays (b) (4)	Data Entry: YES Date of Collection: Jan/20/2021	Initial Entry

090177e196ae3d44\Final\Final On: 01-Apr-2021 04:29 (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: 11301031

Subject Initials: ---

Generated By: (b) (4)

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

5.a

Date	Location	User	Value	Reason
Jan-20-2021 10:24:29 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Kristi Bays (b) (4)	Data Entry: Sample ID: BP0XDZ	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Jan-20-2021 10:24:29 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Kristi Bays (b) (4)	Data Entry: BP0XDZ	Initial Entry

090177e196ae3d44\Final\Final On: 01-Apr-2021 04:29 (GMT)

Header Text: c4591001

Visit: V101_VAX3

Form Version: 10-Dec-2020 02:26

Site No: 1130

Subject No: 11301031

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

[Back to Form](#)

1. Was there a temporary delay of vaccination?

Date	Location	User	Value	Reason
Jan-20-2021 11:24:40 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2. Treatment Name

Date	Location	User	Value	Reason
Jan-20-2021 11:24:40 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: BNT162b2	Initial Entry

3. Formulation:

Date	Location	User	Value	Reason
Jan-20-2021 11:24:40 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INJECTION	Initial Entry

4. Dose Date Time:

Date	Location	User	Value	Reason
Jan-20-2021 11:24:40 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Jan/20/2021 10:29	Initial Entry

5. Anatomical Location:

Date	Location	User	Value	Reason
Jan-20-2021 11:24:40	ACV0PFEINFP6000	auto calc	Data Entry:	Initial Entry

090177e196ae3d44\Final\Final On: 01-Apr-2021 04:29 (GMT)

Header Text: c4591001

Visit: V101_VAX3

Form Version: 10-Dec-2020 02:26

Site No: 1130

Subject No: 11301031

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

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

(autocalc)

DELTOID MUSCLE

6. Body Side:

Date	Location	User	Value	Reason
Jan-20-2021 11:24:40 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> LEFT	Initial Entry

7. Route:

Date	Location	User	Value	Reason
Jan-20-2021 11:24:40 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> INTRAMUSCULAR	Initial Entry

8. Actual Dose:

Date	Location	User	Value	Reason
Jan-20-2021 11:24:40 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> 30.0	Initial Entry

9. Unit:

Date	Location	User	Value	Reason
Jan-20-2021 11:24:40 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> ug	Initial Entry

10. Timeframe Subject Was Observed

Date	Location	User	Value	Reason
Jan-20-2021 11:24:40 (UTC-08:00) Pacific	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> 30 MINUTES	Initial Entry

090177e196ae3d44\Final\Final On: 01-Apr-2021 04:29 (GMT)

Header Text: c4591001

Visit: V101_VAX3

Form Version: 10-Dec-2020 02:26

Site No: 1130

Subject No: 11301031

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

Time (US & Canada)				
--------------------	--	--	--	--

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

Date	Location	User	Value	Reason
Jan-20-2021 11:24:40 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [Redacted]	<u>Data Entry:</u> YES	Initial Entry

Header Text: c4591001

Visit: V102_VAX4

Form Version: 22-Apr-2020 21:02

Site No: 1130

Subject No: 11301031

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

[Back to Form](#)

1. Date of Visit

Date	Location	User	Value	Reason
Feb-09-2021 10:28:49 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Kristi Bays (b) (4)	Data Entry: Feb/9/2021	Initial Entry

090177e196ae3d44\Final\Final On: 01-Apr-2021 04:29 (GMT)

Header Text: c4591001**Visit:** V102_VAX4**Form:** LAB URINALYSIS - PREGNANCY TEST - eCRF Audit Trail History**Form Version:** 14-Jan-2021 02:21**Form Status:** Data Complete, Frozen, Verified**Site No:** 1130**Site Name:** (1130) Kaiser Permanente Center For Health Research**Subject No:** 11301031**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 11:25[Back to Form](#)**1. Lab Panel:**

Date	Location	User	Value	Reason
Feb-09-2021 11:58:26 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: URINALYSIS	Initial Entry

2. Lab Sub-Panel:

Date	Location	User	Value	Reason
Feb-09-2021 11:58:26 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: PREGNANCY	Initial Entry

3. Collection Date:

Date	Location	User	Value	Reason
Feb-09-2021 11:58:26 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Sperry Robinson (b) (4)	Data Entry: Feb/9/2021	Initial Entry

4. Laboratory Name and Address (Derived)

Date	Location	User	Value	Reason
Feb-09-2021 11:58:26 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: STUDY SITE	Initial Entry

5. Specimen Type:

Date	Location	User	Value	Reason
Feb-09-2021 11:58:26	ACV0PFEINFP6000	auto calc	Data Entry:	Initial Entry

Header Text: c4591001

Visit: V102_VAX4

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

Form Version: 14-Jan-2021 02:21

Form Status: Data Complete, Frozen, Verified

Site No: 1130

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

Subject No: 11301031

Subject Initials: ---

Generated By: (b) (4)

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

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

6.a

Date	Location	User	Value	Reason
Feb-09-2021 11:58:26 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sponsor-Def 113 ined Identifier: Test:: Choriogonadotropin Beta_PX 113 Result:: Not Done:: NOT DONE	Initial Entry

6.a Sponsor ID:

Date	Location	User	Value	Reason
Feb-09-2021 11:58:26 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 113	Initial Entry

6.a Test:

Date	Location	User	Value	Reason
Feb-09-2021 11:58:26 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Sperry Robinson (b) (4)	Data Entry: Choriogonadotropin Beta_PX113	Initial Entry

6.a Not Done:

Date	Location	User	Value	Reason
Feb-09-2021	ACV0PFEINFP6000	Sperry	Data Entry:	Initial Entry

090177e196ae3d44\Final\Final On: 01-Apr-2021 04:29 (GMT)

Header Text: c4591001

Visit: V102_VAX4

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

Form Version: 14-Jan-2021 02:21

Form Status: Data Complete, Frozen, Verified

Site No: 1130

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

Subject No: 11301031

Subject Initials: ---

Generated By: (b) (4)

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

11:58:26 (UTC-08:00) Pacific Time (US & Canada)		Robinson (b) (4)	NOT DONE	
---	--	---------------------	----------	--

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: 11301031

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-09-2021 10:28:25 (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-09-2021 10:28:25 (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-09-2021 10:28:39 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Feb-09-2021 10:28:25 (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-09-2021 10:28:25 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Kristi Bays (b) (4)	Data Entry: YES Date of Collection: Feb/9/2021	Initial Entry

090177e196ae3d44\Final\Final On: 01-Apr-2021 04:29 (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: 11301031

Subject Initials: ---

Generated By: (b) (4)

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

5.a

Date	Location	User	Value	Reason
Feb-09-2021 10:28:39 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Kristi Bays (b) (4)	Data Entry: Sample ID: BPOXJD	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Feb-09-2021 10:28:39 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Kristi Bays (b) (4)	Data Entry: BPOXJD	Initial Entry

Header Text: c4591001

Visit: V102_VAX4

Form Version: 10-Dec-2020 02:26

Site No: 1130

Subject No: 11301031

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

[Back to Form](#)

1. Was there a temporary delay of vaccination?

Date	Location	User	Value	Reason
Feb-09-2021 12:00:36 (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-09-2021 12:00:36 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: BNT162b2	Initial Entry

3. Formulation:

Date	Location	User	Value	Reason
Feb-09-2021 12:00:36 (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-09-2021 12:00:36 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Sperry Robinson (b) (4)	Data Entry: Feb/9/2021 10:26	Initial Entry

5. Anatomical Location:

Date	Location	User	Value	Reason
Feb-09-2021 12:00:36	ACV0PFEINFP6000	auto calc	Data Entry:	Initial Entry

090177e196ae3d44\Final\Final On: 01-Apr-2021 04:29 (GMT)

Header Text: c4591001

Visit: V102_VAX4

Form Version: 10-Dec-2020 02:26

Site No: 1130

Subject No: 11301031

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

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

6. Body Side:

Date	Location	User	Value	Reason
Feb-09-2021 12:00:36 (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-09-2021 12:00:36 (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-09-2021 12:00:36 (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-09-2021 12:00:36 (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-09-2021 12:00:36 (UTC-08:00) Pacific	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 30 MINUTES	Initial Entry

090177e196ae3d44\Final\Final On: 01-Apr-2021 04:29 (GMT)

Header Text: c4591001

Visit: V102_VAX4

Form: VACCINATION - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:26

Form Status: Data Complete, Frozen, Verified

Site No: 1130

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

Subject No: 11301031

Subject Initials: ---

Generated By: (b) (4)

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

Time (US & Canada)				
--------------------	--	--	--	--

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

Date	Location	User	Value	Reason
Feb-09-2021 12:00:36 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Sperry Robinson (b) (4)	<u>Data Entry:</u> YES	Initial Entry

Header Text: c4591001

Visit: V103_MONTH1

Form Version: 22-Apr-2020 21:02

Site No: 1130

Subject No: 11301031

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

[Back to Form](#)

1. Date of Visit

Date	Location	User	Value	Reason
Mar-09-2021 11:27:13 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Tara Beatty (b) (4)	Data Entry: Mar/9/2021	Initial Entry

Header Text: c4591001

Visit: V103_MONTH1

Form Version: 22-Apr-2020 21:04

Site No: 1130

Subject No: 11301031

Generated By: (b) (4)

Form: CONTACT OUTCOME - 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

[Back to Form](#)

1. Contact Type:

Date	Location	User	Value	Reason
Mar-09-2021 11:27:51 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: TELEPHONE VISIT	Initial Entry

2. Was contact made?

Date	Location	User	Value	Reason
Mar-09-2021 11:27:51 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Tara Beatty (b) (4)	Data Entry: YES Date of Contact: Mar/9/2021	Initial Entry

090177e196ae3d44\Final\Final On: 01-Apr-2021 04:29 (GMT)

Header Text: c4591001

Visit: FURTHER_VACCINATION_EOT - **Form:** DISPOSITION - TREATMENT - eCRF Audit Trail
Unscheduled History

Form Version: 20-Feb-2021 02:26

Form Status: Data Complete, Frozen, Verified

Site No: 1130

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

Subject No: 11301031

Subject Initials: ---

Generated By: (b) (4)

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

[Back to Form](#)

1. Date of Completion/Discontinuation/Death :

Date	Location	User	Value	Reason
Mar-09-2021 11:28:04 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Tara Beatty (b) (4)	Data Entry: Mar/9/2021	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Mar-09-2021 11:28:04 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: OPEN LABEL TREATMEN T	Initial Entry

3. Status:

Date	Location	User	Value	Reason
Mar-09-2021 11:28:04 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Tara Beatty (b) (4)	Data Entry: COMPLETED	Initial Entry

090177e196ae3d44\Final\Final On: 01-Apr-2021 04:29 (GMT)

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: 11301031

Subject Initials: ---

Generated By: (b) (4)

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

[Back to Form](#)

1. Subject Status

Date	Location	User	Value	Reason
Oct-19-2020 09:30:46 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: FOLLOW-UP	Initial Entry
Sep-02-2020 15:26:08 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: ENROLLED/RANDOMIZED	Initial Entry
Sep-02-2020 13:46:20 (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
Oct-19-2020 09:30:46 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Oct/19/2020	Initial Entry
Sep-02-2020 15:26:08 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sep/2/2020	Initial Entry
Sep-02-2020 13:46:20 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sep/2/2020	Initial Entry

090177e196ae3d44\Final\Final On: 01-Apr-2021 04:29 (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: 11301031

Subject Initials: ---

Generated By: (b) (4)

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

[Back to Form](#)

1. Casebook Signature

Date	Location	User	Value	Reason
Oct-27-2020 08:38:22 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Sperry Robinson (b) (4)	Data Entry: Click Here to Enable	Initial Entry