

**Header Text:** C4591001

**Visit:** COHORT\_SELECTION

**Form Version:** 30-Jul-2020 21:29

**Site No:** 1177

**Subject No:** 11771317

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

**Form:** COHORT\_SELECTION

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

**Site Name:** (1177) East-West Medical Research Institute

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 12:55

[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

090177e196ae2fd9\Final\Final On: 01-Apr-2021 03:53 (GMT)

**Header Text:** C4591001

**Visit:** COHORT\_SELECTION

**Form:** MAIN INFORMED CONSENT

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

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

**Site No:** 1177

**Site Name:** (1177) East-West Medical Research Institute

**Subject No:** 11771317

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 12:55

[eCRF Audit Trail History](#)

**Informed Consent**

1.	Consent Was:	OBTAINED Date Written Consent Obtained Sep/9/2020
----	--------------	---

**Header Text:** C4591001

**Visit:** COHORT\_SELECTION

**Form:** DEMOGRAPHY

**Form Version:** 06-Jul-2020 21:55

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

**Site No:** 1177

**Site Name:** (1177) East-West Medical Research Institute

**Subject No:** 11771317

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 12:55

[eCRF Audit Trail History](#)

**Demography**

1.	Subject ID	[11771317]
2.	Birth Date:	(b) (6)/1958
3.	Sex:	FEMALE
4.	Ethnicity:	NOT HISPANIC OR LATINO(A) OR OF SPANISH ORIGIN
5.	Race: (Check X all that apply):	ASIAN
6.	Racial Designation:	JAPANESE

090177e196ae2fd9\Final\Final On: 01-Apr-2021 03:53 (GMT)

**Header Text:** C4591001

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

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

**Site No:** 1177

**Subject No:** 11771317

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

**Form:** DATE OF VISIT

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

**Site Name:** (1177) East-West Medical Research Institute

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 12:55

[eCRF Audit Trail History](#)

**Date of Visit**

1.	Date of Visit	Sep/9/2020
2.	Erroneous Visit	

**Header Text:** C4591001

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

**Form Version:** 30-Jul-2020 21:29

**Site No:** 1177

**Subject No:** 11771317

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

**Form:** INCLUSION/EXCLUSION CRITERIA

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

**Site Name:** (1177) East-West Medical Research Institute

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 12:55

[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:** DISPOSITION - SCREENING

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

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

**Site No:** 1177

**Site Name:** (1177) East-West Medical Research Institute

**Subject No:** 11771317

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 12:55

[eCRF Audit Trail History](#)

**Disposition - Screening**

1.	Date of Completion/Discontinuation /Death	Sep/9/2020
2.	Phase of Disposition:	SCREENING
3.	Status:	COMPLETED
4.	Specify Status:	[ ]

**Header Text:** C4591001

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

**Form:** GENERAL MEDICAL HISTORY

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

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

**Site No:** 1177

**Site Name:** (1177) East-West Medical Research Institute

**Subject No:** 11771317

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 12:55

[eCRF Audit Trail History](#)

**Medical History Details**

1.a	Line/MH Number:	[1]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Allergic to latex]
	Start Date:	UNK/UNK/1990
	Ongoing:	YES
1.b	Line/MH Number:	[2]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Allergic to bee venom]
	Start Date:	UNK/UNK/1970
	Ongoing:	YES
1.c	Line/MH Number:	[3]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Allergic to tomatoes]
	Start Date:	UNK/UNK/1970
	Ongoing:	YES
1.d	Line/MH Number:	[4]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Hypertension]
	Start Date:	UNK/UNK/2018
	Ongoing:	YES

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**Header Text:** C4591001

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

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

**Site No:** 1177

**Subject No:** 11771317

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

**Form:** GENERAL MEDICAL HISTORY

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

**Site Name:** (1177) East-West Medical Research Institute

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 12:55

1.e	Line/MH Number:	[5]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Transient ischemic attack ("mini stroke")]
	Start Date:	UNK/UNK/1990
	Ongoing:	NO End Date: UNK/UNK/1990
1.f	Line/MH Number:	[6]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Diabetes, Type II]
	Start Date:	UNK/UNK/2010
	Ongoing:	YES
1.g	Line/MH Number:	[7]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Dyslipidemia]
	Start Date:	UNK/UNK/2019
	Ongoing:	YES
1.h	Line/MH Number:	[8]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Hypothyroidism]
	Start Date:	UNK/UNK/1990
	Ongoing:	YES

090177e196ae2fd9\Final\Final On: 01-Apr-2021 03:53 (GMT)



**Header Text:** C4591001

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

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

**Site No:** 1177

**Subject No:** 11771317

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

**Form:** GENERAL MEDICAL HISTORY

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

**Site Name:** (1177) East-West Medical Research Institute

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 12:55

1.i	Line/MH Number:	[9]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Depression]
	Start Date:	UNK/UNK/1990
	Ongoing:	YES
1.j	Line/MH Number:	[10]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Barrett's esophagus]
	Start Date:	UNK/UNK/2010
	Ongoing:	YES
1.k	Line/MH Number:	[11]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Sleep apnea]
	Start Date:	UNK/UNK/1990
	Ongoing:	YES
1.l	Line/MH Number:	[12]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Gastroesophageal reflux disease]
	Start Date:	UNK/UNK/2010
	Ongoing:	YES

090177e196ae2fd9\Final\Final On: 01-Apr-2021 03:53 (GMT)

**Header Text:** C4591001

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

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

**Site No:** 1177

**Subject No:** 11771317

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

**Form:** GENERAL MEDICAL HISTORY

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

**Site Name:** (1177) East-West Medical Research Institute

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 12:55

1.m	Line/MH Number:	[13]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Septoplasty]
	Start Date:	UNK/UNK/1986
	Ongoing:	NO End Date: UNK/UNK/1986
1.n	Line/MH Number:	[14]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Deviated septum]
	Start Date:	UNK/UNK/1986
	Ongoing:	NO End Date: UNK/UNK/1986
1.o	Line/MH Number:	[15]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Removal of vocal cord polyp]
	Start Date:	UNK/UNK/1997
	Ongoing:	NO End Date: UNK/UNK/1997

090177e196ae2fd9\Final\Final On: 01-Apr-2021 03:53 (GMT)

**Header Text:** C4591001

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

**Form:** GENERAL MEDICAL HISTORY

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

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

**Site No:** 1177

**Site Name:** (1177) East-West Medical Research Institute

**Subject No:** 11771317

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 12:55

1.p	Line/MH Number:	[16]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Vocal cord polyp]
	Start Date:	UNK/UNK/1997
	Ongoing:	NO End Date: UNK/UNK/1997
1.q	Line/MH Number:	[17]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Carpal tunnel syndrome, bilateral]
	Start Date:	UNK/UNK/2001
	Ongoing:	NO End Date: UNK/UNK/2001
1.r	Line/MH Number:	[18]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Carpal tunnel release, bilateral]
	Start Date:	UNK/UNK/2001
	Ongoing:	NO End Date: UNK/UNK/2001

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**Header Text:** C4591001

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

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

**Site No:** 1177

**Subject No:** 11771317

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

**Form:** GENERAL MEDICAL HISTORY

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

**Site Name:** (1177) East-West Medical Research Institute

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 12:55

1.s	Line/MH Number:	[19]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Broken wrist, left]
	Start Date:	Jul/27/2020
	Ongoing:	NO End Date: Jul/27/2020
1.t	Line/MH Number:	[20]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Broken wrist repair, left]
	Start Date:	Jul/27/2020
	Ongoing:	NO End Date: Jul/27/2020

090177e196ae2fd9\Final\Final On: 01-Apr-2021 03:53 (GMT)

**Header Text:** C4591001

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

**Form:** VITAL SIGNS - BASELINE

**Form Version:** 21-Aug-2020 02:51

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

**Site No:** 1177

**Site Name:** (1177) East-West Medical Research Institute

**Subject No:** 11771317

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 12:55

[eCRF Audit Trail History](#)

**Vital Signs**

1.	Date:	Sep/9/2020
2.	Weight:	[79.4]
3.	Unit:	kg
4.	Height:	[158.5]
5.	Unit:	cm
6.	Body Mass Index:	[31.6]

**Vital Signs Details**

7.a	Record Identifier:	1
	Temperature:	[97.1]
	Unit:	F
	Temperature Location:	FOREHEAD

090177e196ae2fd9\Final\Final On: 01-Apr-2021 03:53 (GMT)

**Header Text:** C4591001

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

**Form:** LAB URINALYSIS - PREGNANCY TEST

**Form Version:** 21-Aug-2020 02:49

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

**Site No:** 1177

**Site Name:** (1177) East-West Medical Research Institute

**Subject No:** 11771317

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 12:55

[Form Comments](#)

[eCRF Audit Trail History](#)

**Lab Urinalysis**

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

**Lab Result**

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

090177e196ae2fd9\Final\Final On: 01-Apr-2021 03:53 (GMT)

**Header Text:** C4591001

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

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

**Site No:** 1177

**Subject No:** 11771317

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

**Form:** RANDOMIZATION

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

**Site Name:** (1177) East-West Medical Research Institute

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 12:55

[eCRF Audit Trail History](#)

**Disposition**

1.	Randomization Date :	Sep/9/2020
2.	Randomization Number:	[255088]
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:** 1177

**Site Name:** (1177) East-West Medical Research Institute

**Subject No:** 11771317

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 12:55

[eCRF Audit Trail History](#)

**Electronic Sample Tracking**

1.	Data Origin	SITE
2.	Sample Type	SERUM
3.	Sample Collected?	YES Date of Collection: Sep/9/2020
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	[BP0TFX]
5.b	Sample ID	[BLCGFX]
5.c	Sample ID	[BLCGFY]



**Header Text:** C4591001

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

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

**Site No:** 1177

**Subject No:** 11771317

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

**Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB

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

**Site Name:** (1177) East-West Medical Research Institute

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 12:55

[eCRF Audit Trail History](#)

**Electronic Sample Tracking**

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Sep/9/2020
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	[BP8J8N]
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090177e196ae2fd9\Final\Final On: 01-Apr-2021 03:53 (GMT)

**Header Text:** C4591001

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

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

**Site No:** 1177

**Subject No:** 11771317

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

**Form:** VACCINATION

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

**Site Name:** (1177) East-West Medical Research Institute

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 12:55

**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/9/2020 08:48
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

090177e196ae2fd9\Final\Final On: 01-Apr-2021 03:53 (GMT)

**Header Text:** C4591001

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

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

**Site No:** 1177

**Subject No:** 11771317

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

**Form:** REACTOGENICITY DIARY

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

**Site Name:** (1177) East-West Medical Research Institute

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 12:55

[eCRF Audit Trail History](#)

**Reactogenicity Diary**

1.	Select appropriate response - Reactogenicity diary collection	NO - REACTOGENICITY E-DIARY NOT COLLECTED FOR THIS SUBJECT
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090177e196ae2fd9\Final\Final On: 01-Apr-2021 03:53 (GMT)

**Header Text:** C4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1177

**Subject No:** 11771317

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

**Form:** DATE OF VISIT

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

**Site Name:** (1177) East-West Medical Research Institute

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 12:55

[eCRF Audit Trail History](#)

**Date of Visit**

1.	Date of Visit	Sep/30/2020
2.	Erroneous Visit	

**Header Text:** C4591001

**Visit:** V2\_VAX2\_L

**Form:** VITAL SIGNS - TEMP

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

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

**Site No:** 1177

**Site Name:** (1177) East-West Medical Research Institute

**Subject No:** 11771317

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 12:55

[eCRF Audit Trail History](#)

**Vital Signs**

1.	Date:	Sep/30/2020
----	-------	-------------

**Vital Signs Details**

2.a	Record Identifier:	1
	Temperature:	[97.3]
	Unit:	F
	Temperature Location:	FOREHEAD

**Header Text:** C4591001

**Visit:** V2\_VAX2\_L

**Form Version:** 21-Aug-2020 02:49

**Site No:** 1177

**Subject No:** 11771317

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

**Form:** LAB URINALYSIS - PREGNANCY TEST

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

**Site Name:** (1177) East-West Medical Research Institute

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 12:55

[Form Comments](#)

[eCRF Audit Trail History](#)

**Lab Urinalysis**

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

**Lab Result**

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

090177e196ae2fd9\Final\Final On: 01-Apr-2021 03:53 (GMT)

**Header Text:** C4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1177

**Subject No:** 11771317

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

**Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB

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

**Site Name:** (1177) East-West Medical Research Institute

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 12:55

[eCRF Audit Trail History](#)

**Electronic Sample Tracking**

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Sep/30/2020
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	[BR92VG]
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090177e196ae2fd9\Final\Final On: 01-Apr-2021 03:53 (GMT)

**Header Text:** C4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1177

**Subject No:** 11771317

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

**Form:** VACCINATION

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

**Site Name:** (1177) East-West Medical Research Institute

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 12:55

[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/30/2020 08:12
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

090177e196ae2fd9\Final\Final On: 01-Apr-2021 03:53 (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:** 1177

**Site Name:** (1177) East-West Medical Research Institute

**Subject No:** 11771317

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 12:55

[eCRF Audit Trail History](#)

**Date of Visit**

1.	Date of Visit	Oct/28/2020
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:** 1177**Site Name:** (1177) East-West Medical Research Institute**Subject No:** 11771317**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 12:55[eCRF Audit Trail History](#)**Electronic Sample Tracking**

1.	Data Origin	SITE
2.	Sample Type	SERUM
3.	Sample Collected?	YES Date of Collection: Oct/28/2020
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	[BRJ5CJ]
5.b	Sample ID	[BSMJ5M]
5.c	Sample ID	[BSMJ5N]

**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:** 1177

**Site Name:** (1177) East-West Medical Research Institute

**Subject No:** 11771317

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 12:55

**Date of Visit**

1.	Date of Visit	//
2.	Erroneous Visit	

**COVID-19 Illness Visit**

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

090177e196ae2fd9\Final\Final On: 01-Apr-2021 03:53 (GMT)

**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:** 1177

**Site Name:** (1177) East-West Medical Research Institute

**Subject No:** 11771317

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 12:55

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

090177e196ae2fd9\Final\Final On: 01-Apr-2021 03:53 (GMT)

**Header Text:** C4591001

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

**Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB  
SELF

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

**Form Status:** Not Started

**Site No:** 1177

**Site Name:** (1177) East-West Medical Research Institute

**Subject No:** 11771317

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 12:55

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

090177e196ae2fd9\Final\Final On: 01-Apr-2021 03:53 (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:** 1177

**Site Name:** (1177) East-West Medical Research Institute

**Subject No:** 11771317

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 12:55

**Electronic Sample Tracking**

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

**Aliquot**

Please enter barcode for each aliquot.

5.	Sample ID	[ ]
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**Header Text:** C4591001

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

**Form:** HEALTH CARE UTILIZATION

**Form Version:** 20-Feb-2021 02:19

**Form Status:** Not Started

**Site No:** 1177

**Site Name:** (1177) East-West Medical Research Institute

**Subject No:** 11771317

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 12:55

**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?	
----	--	--

090177e196ae2fd9\Final\Final On: 01-Apr-2021 03:53 (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:** 1177

**Site Name:** (1177) East-West Medical Research Institute

**Subject No:** 11771317

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 12:55

**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:** 1177

**Site Name:** (1177) East-West Medical Research Institute

**Subject No:** 11771317

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 12:55

**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:** ELECTRONIC SAMPLE TRACKING -  
IMMUNOGENICITY

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

**Form Status:** Not Started

**Site No:** 1177

**Site Name:** (1177) East-West Medical Research Institute

**Subject No:** 11771317

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 12:55

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

090177e196ae2fd9\Final\Final On: 01-Apr-2021 03:53 (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:** 1177

**Site Name:** (1177) East-West Medical Research Institute

**Subject No:** 11771317

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 12:55

**Date of Visit**

1.	Date of Visit	//
2.	Erroneous Visit	

090177e196ae2fd9\Final\Final On: 01-Apr-2021 03:53 (GMT)

**Header Text:** C4591001

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

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

**Form Status:** Not Started

**Site No:** 1177

**Site Name:** (1177) East-West Medical Research Institute

**Subject No:** 11771317

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 12:55

**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:** 1177

**Site Name:** (1177) East-West Medical Research Institute

**Subject No:** 11771317

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 12:55

[eCRF Audit Trail History](#)

**Disposition - Treatment**

1.	Date of Completion/Discontinuation /Death :	Oct/28/2020
2.	Phase of Disposition:	VACCINATION
3.	Status:	COMPLETED
4.	Specify Status:	[ ]

090177e196ae2fd9\Final\Final On: 01-Apr-2021 03:53 (GMT)

**Header Text:** C4591001

**Visit:** Follow-Up - Unscheduled

**Form:** DISPOSITION - FOLLOW-UP

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

**Form Status:** Not Started

**Site No:** 1177

**Site Name:** (1177) East-West Medical Research Institute

**Subject No:** 11771317

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 12:55

**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:** 1177

**Site Name:** (1177) East-West Medical Research Institute

**Subject No:** 11771317

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 12:55

**Date of Visit**

1.	Date of Visit	//
2.	Erroneous Visit	

**COVID-19 Repeat Swab**

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

090177e196ae2fd9\Final\Final On: 01-Apr-2021 03:53 (GMT)

**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:** 1177

**Site Name:** (1177) East-West Medical Research Institute

**Subject No:** 11771317

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 12:55

**Electronic Sample Tracking**

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

**Aliquot**

Please enter barcode for each aliquot.

5.	Sample ID	[ ]
----	-----------	-----



**Header Text:** C4591001

**Visit:** Logs

**Form:** ADVERSE EVENT REPORT

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

**Site No:** 1177

**Site Name:** (1177) East-West Medical Research Institute

**Subject No:** 11771317

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 12:55

#	Category	AE Identifier	Adverse Event	Start Date	Is the Adverse Event Still Ongoing	Form Instance
1.	ADVERSE EVENT	1	Breast Cancer, Stage 1	Nov/30/2020 14:00	YES	<a href="#">Repeating Pages</a>

090177e196ae2fd9\Final\Final On: 01-Apr-2021 03:53 (GMT)

Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1177

Subject No: 11771317

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Verified

Site Name: (1177) East-West Medical Research Institute

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:55

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**Adverse Event Report**

1.	Category:	ADVERSE EVENT
2.	AE ID:	[1]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[Breast Cancer, Stage 1]
4.	Start Date Time:	Nov/30/2020 14:00
5.	Is the adverse event still ongoing?	YES
6.	Toxicity Grade:	2
7.	Is the adverse event serious?  If Yes, NOTIFY PFIZER IMMEDIATELY.  Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).	<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? NO</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>

090177e196ae2fd9\Final\Final On: 01-Apr-2021 03:53 (GMT)

**Header Text:** C4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1177

**Subject No:** 11771317

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

**Form:** ADVERSE EVENT REPORT

**Form Status:** Data Complete, Verified

**Site Name:** (1177) East-West Medical Research Institute

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 12:55

8.	Is this adverse event the result of a study Medication Error? If Yes, record the type of medication error on the Medication Error Log.	NO
9.	Is this event related to study treatment:	NOT RELATED If Not Related to study treatment(s), this event is due to: OTHER If Other, specify: [Neoplasia]
10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE
11.	Was a Concomitant Medication given?	NO
12.	Was a Non-Drug Treatment given?	YES
13.	What was the outcome of this adverse event?:	RECOVERING/RESOLVING
14.	Did the adverse event cause the subject to be discontinued from the study?	NO
15.	Serious Adverse Event Number: For Pfizer Use Only	[2020511355]

090177e196ae2fd9\Final\Final On: 01-Apr-2021 03:53 (GMT)

**Header Text:** C4591001

**Visit:** Logs

**Form:** MEDICATION ERROR

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

**Site No:** 1177

**Site Name:** (1177) East-West Medical Research Institute

**Subject No:** 11771317

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 12:55

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

**Header Text:** C4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1177

**Subject No:** 11771317

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

**Form:** MEDICATION ERROR

**Form Status:** Not Started

**Site Name:** (1177) East-West Medical Research Institute

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 12:55

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**Medication Error**

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

090177e196ae2fd9\Final\Final On: 01-Apr-2021 03:53 (GMT)

**Header Text:** C4591001

**Visit:** Logs

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

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

**Site No:** 1177

**Site Name:** (1177) East-West Medical Research Institute

**Subject No:** 11771317

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 12:55

#	Sponsor-Defined Identifier	Category for Medication	Concomitant Medications Pre-specified	Name of Medication	Start Date	Form Instance
1.	1	VACCINATIONS	NO	Flu vaccine	Oct/15/2020	<a href="#">Repeating Pages</a>

**Header Text:** C4591001

**Visit:** Logs - Unscheduled

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

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

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

**Site No:** 1177

**Site Name:** (1177) East-West Medical Research Institute

**Subject No:** 11771317

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 12:55

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[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).	[Flu vaccine]
5.	Date:	Oct/15/2020

090177e196ae2fd9\Final\Final On: 01-Apr-2021 03:53 (GMT)

**Header Text:** C4591001

**Visit:** Logs

**Form:** CONCOMITANT MEDICATIONS - PROHIBITED

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

**Site No:** 1177

**Site Name:** (1177) East-West Medical Research Institute

**Subject No:** 11771317

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 12:55

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



**Header Text:** C4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1177

**Subject No:** 11771317

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

**Form:** CONCOMITANT MEDICATIONS - PROHIBITED

**Form Status:** Not Started

**Site Name:** (1177) East-West Medical Research Institute

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 12:55

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**Concomitant Medications**

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

090177e196ae2fd9\Final\Final On: 01-Apr-2021 03:53 (GMT)

**Header Text:** C4591001

**Visit:** Logs

**Form:** RADIATION TREATMENT

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

**Site No:** 1177

**Site Name:** (1177) East-West Medical Research Institute

**Subject No:** 11771317

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 12:55

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

**Header Text:** C4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1177

**Subject No:** 11771317

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

**Form:** RADIATION TREATMENT

**Form Status:** Not Started

**Site Name:** (1177) East-West Medical Research Institute

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 12:55

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**Radiation Treatment**

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

090177e196ae2fd9\Final\Final On: 01-Apr-2021 03:53 (GMT)

**Header Text:** C4591001

**Visit:** Logs

**Form:** TRANSFUSIONS

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

**Site No:** 1177

**Site Name:** (1177) East-West Medical Research Institute

**Subject No:** 11771317

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 12:55

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

**Header Text:** C4591001

**Visit:** Logs - Unscheduled

**Form:** TRANSFUSIONS

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

**Form Status:** Not Started

**Site No:** 1177

**Site Name:** (1177) East-West Medical Research Institute

**Subject No:** 11771317

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 12:55

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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:** 1177

**Site Name:** (1177) East-West Medical Research Institute

**Subject No:** 11771317

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 12:55

**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:** 1177

**Site Name:** (1177) East-West Medical Research Institute

**Subject No:** 11771317

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 12:55

**Vital Signs**

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

**Vital Signs Details**

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

**Header Text:** C4591001

**Visit:** Unplanned Vaccination -  
Unscheduled

**Form:** LAB URINALYSIS - PREGNANCY TEST

**Form Version:** 20-Feb-2021 02:14

**Form Status:** Not Started

**Site No:** 1177

**Site Name:** (1177) East-West Medical Research Institute

**Subject No:** 11771317

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 12:55

**Lab Urinalysis**

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

**Lab Result**

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



**Header Text:** C4591001

**Visit:** Unplanned Vaccination -  
Unscheduled

**Form:** VACCINATION

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

**Form Status:** Not Started

**Site No:** 1177

**Site Name:** (1177) East-West Medical Research Institute

**Subject No:** 11771317

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 12:55

**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?	

090177e196ae2fd9\Final\Final On: 01-Apr-2021 03:53 (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:** 1177

**Site Name:** (1177) East-West Medical Research Institute

**Subject No:** 11771317

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 12:55

**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:** 1177

**Site Name:** (1177) East-West Medical Research Institute

**Subject No:** 11771317

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 12:55

**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:** 1177

**Site Name:** (1177) East-West Medical Research Institute

**Subject No:** 11771317

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 12:55

[eCRF Audit Trail History](#)

**Date of Visit**

1.	Date of Visit	Jan/14/2021
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:** 1177

**Site Name:** (1177) East-West Medical Research Institute

**Subject No:** 11771317

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 12:55

[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 local/national recommendations and confirmed to have received only placebo at Vaccination 1/2
----	---	---

**Header Text:** C4591001

**Visit:** Disposition - Unscheduled

**Form:** TREATMENT UNBLINDED

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

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

**Site No:** 1177

**Site Name:** (1177) East-West Medical Research Institute

**Subject No:** 11771317

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 12:55

[eCRF Audit Trail History](#)

**Treatment Unblinded**

1.	Date Treatment Unblinded :	Jan/14/2021
2.	Primary Reason for Unblinding:	ASSESS ELIGIBILITY FOR ADDITIONAL VACCINATION

**Header Text:** C4591001

**Visit:** Disposition - Unscheduled

**Form:** WITHDRAWAL OF CONSENT

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

**Form Status:** Not Started

**Site No:** 1177

**Site Name:** (1177) East-West Medical Research Institute

**Subject No:** 11771317

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 12:55

**Withdrawal Of Consent**

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

**Header Text:** C4591001

**Visit:** Disposition - Unscheduled

**Form:** DEATH DETAILS CODED

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

**Form Status:** Not Started

**Site No:** 1177

**Site Name:** (1177) East-West Medical Research Institute

**Subject No:** 11771317

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 12:55

**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:** DATE OF VISIT

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

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

**Site No:** 1177

**Site Name:** (1177) East-West Medical Research Institute

**Subject No:** 11771317

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 12:55

[eCRF Audit Trail History](#)

**Date of Visit**

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

090177e196ae2fd9\Final\Final On: 01-Apr-2021 03:53 (GMT)

**Header Text:** C4591001

**Visit:** V101\_VAX3

**Form:** INFORMED CONSENT - FURTHER VACCINATION

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

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

**Site No:** 1177

**Site Name:** (1177) East-West Medical Research Institute

**Subject No:** 11771317

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 12:55

[eCRF Audit Trail History](#)

**Informed Consent - Further Vaccination**

1.	Consent Was:	OBTAINED Date Written Consent Obtained Jan/18/2021
----	--------------	--

**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:** 1177

**Site Name:** (1177) East-West Medical Research Institute

**Subject No:** 11771317

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 12:55

[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:** 1177

**Site Name:** (1177) East-West Medical Research Institute

**Subject No:** 11771317

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 12:55

[eCRF Audit Trail History](#)

**Disposition - Screening for Further Vaccination**

1.	Date of Completion/Discontinuation /Death :	Jan/18/2021
2.	Phase of Disposition:	REPEAT SCREENING 1
3.	Status:	COMPLETED
4.	Specify Status:	[ ]

**Header Text:** C4591001

**Visit:** V101\_VAX3

**Form:** LAB URINALYSIS - PREGNANCY TEST

**Form Version:** 14-Jan-2021 02:21

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

**Site No:** 1177

**Site Name:** (1177) East-West Medical Research Institute

**Subject No:** 11771317

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 12:55

[Form Comments](#)

[eCRF Audit Trail History](#)

**Lab Urinalysis**

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

**Lab Result**

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

090177e196ae2fd9\Final\Final On: 01-Apr-2021 03:53 (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:** 1177

**Site Name:** (1177) East-West Medical Research Institute

**Subject No:** 11771317

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 12:55

[eCRF Audit Trail History](#)

**Electronic Sample Tracking**

1.	Data Origin	SITE
2.	Sample Type	SERUM
3.	Sample Collected?	YES Date of Collection: Jan/18/2021
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[ ]

**Aliquot**

Please enter barcode for each aliquot.

5.a	Sample ID	[BR8VJK]
5.b	Sample ID	[BSH97C]
5.c	Sample ID	[BSH97D]

090177e196ae2fd9\Final\Final On: 01-Apr-2021 03:53 (GMT)

**Header Text:** C4591001

**Visit:** V101\_VAX3

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

**Site No:** 1177

**Subject No:** 11771317

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

**Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB

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

**Site Name:** (1177) East-West Medical Research Institute

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 12:55

[eCRF Audit Trail History](#)

**Electronic Sample Tracking**

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Jan/18/2021
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[ ]

**Aliquot**

Please enter barcode for each aliquot.

5.a	Sample ID	[BR92C9]
-----	-----------	----------

090177e196ae2fd9\Final\Final On: 01-Apr-2021 03:53 (GMT)

**Header Text:** C4591001

**Visit:** V101\_VAX3

**Form:** VACCINATION

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

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

**Site No:** 1177

**Site Name:** (1177) East-West Medical Research Institute

**Subject No:** 11771317

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 12:55

[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/18/2021 07:56
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

090177e196ae2fd9\Final\Final On: 01-Apr-2021 03:53 (GMT)



**Header Text:** C4591001

**Visit:** V102\_VAX4

**Form:** DATE OF VISIT

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

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

**Site No:** 1177

**Site Name:** (1177) East-West Medical Research Institute

**Subject No:** 11771317

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 12:55

[eCRF Audit Trail History](#)

**Date of Visit**

1.	Date of Visit	Feb/8/2021
2.	Erroneous Visit	

**Header Text:** C4591001**Visit:** V102\_VAX4**Form:** LAB URINALYSIS - PREGNANCY TEST**Form Version:** 14-Jan-2021 02:21**Form Status:** Data Complete, Frozen, Verified**Site No:** 1177**Site Name:** (1177) East-West Medical Research Institute**Subject No:** 11771317**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 12:55[Form Comments](#)[eCRF Audit Trail History](#)**Lab Urinalysis**

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

**Lab Result**

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

**Header Text:** C4591001

**Visit:** V102\_VAX4

**Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB

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

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

**Site No:** 1177

**Site Name:** (1177) East-West Medical Research Institute

**Subject No:** 11771317

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 12:55

[eCRF Audit Trail History](#)

**Electronic Sample Tracking**

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Feb/8/2021
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	[BR92JH]
-----	-----------	----------

090177e196ae2fd9\Final\Final On: 01-Apr-2021 03:53 (GMT)

**Header Text:** C4591001

**Visit:** V102\_VAX4

**Form:** VACCINATION

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

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

**Site No:** 1177

**Site Name:** (1177) East-West Medical Research Institute

**Subject No:** 11771317

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 12:55

[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/8/2021 07:22
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

090177e196ae2fd9\Final\Final On: 01-Apr-2021 03:53 (GMT)

**Header Text:** C4591001

**Visit:** V103\_MONTH1

**Form:** DATE OF VISIT

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

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

**Site No:** 1177

**Site Name:** (1177) East-West Medical Research Institute

**Subject No:** 11771317

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 12:55

[eCRF Audit Trail History](#)

**Date of Visit**

1.	Date of Visit	Mar/8/2021
2.	Erroneous Visit	

**Header Text:** C4591001

**Visit:** V103\_MONTH1

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

**Site No:** 1177

**Subject No:** 11771317

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

**Form:** CONTACT OUTCOME

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

**Site Name:** (1177) East-West Medical Research Institute

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 12:55

[eCRF Audit Trail History](#)

**Contact Outcome**

1.	Contact Type:	TELEPHONE VISIT
2.	Was contact made?	YES Date of Contact: Mar/8/2021
3.	Comments:	[ ]

**Header Text:** C4591001

**Visit:** V104\_MONTH6

**Form:** DATE OF VISIT

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

**Form Status:** Not Started

**Site No:** 1177

**Site Name:** (1177) East-West Medical Research Institute

**Subject No:** 11771317

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 12:55

**Date of Visit**

1.	Date of Visit	//
2.	Erroneous Visit	

**Header Text:** C4591001

**Visit:** V104\_MONTH6

**Form:** CONTACT OUTCOME

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

**Form Status:** Not Started

**Site No:** 1177

**Site Name:** (1177) East-West Medical Research Institute

**Subject No:** 11771317

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 12:55

**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:** 1177

**Subject No:** 11771317

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

**Form:** DATE OF VISIT

**Form Status:** Not Started

**Site Name:** (1177) East-West Medical Research Institute

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 12:55

**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:** 1177

**Subject No:** 11771317

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

**Form:** CONTACT OUTCOME

**Form Status:** Not Started

**Site Name:** (1177) East-West Medical Research Institute

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 12:55

**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:** 1177

**Site Name:** (1177) East-West Medical Research Institute

**Subject No:** 11771317

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 12:55

[eCRF Audit Trail History](#)

**Disposition - Treatment**

1.	Date of Completion/Discontinuation/Death :	Mar/8/2021
2.	Phase of Disposition:	OPEN LABEL TREATMENT
3.	Status:	COMPLETED
4.	Specify Status:	[ ]

090177e196ae2fd9\Final\Final On: 01-Apr-2021 03:53 (GMT)

**Header Text:** C4591001

**Visit:** Subject Status - Unscheduled

**Form:** SUBJECT STATUS

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

**Form Status:** Data Complete, Verified

**Site No:** 1177

**Site Name:** (1177) East-West Medical Research Institute

**Subject No:** 11771317

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 12:55

[eCRF Audit Trail History](#)

**Subject Status**

1.	Subject Status	FOLLOW-UP
2.	Subject Status Date	Oct/28/2020

**Header Text:** C4591001

**Visit:** Investigator Signature -  
Unscheduled

**Form:** CASEBOOK SIGNATURE FORM

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

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

**Site No:** 1177

**Site Name:** (1177) East-West Medical Research Institute

**Subject No:** 11771317

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 12:55

[eCRF Audit Trail History](#)

**Casebook Signature Form**

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

**Header Text:** C4591001

**Visit:** Investigator Signature -  
Unscheduled

**Form:** CASEBOOK SIGNATURE FORM

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

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

**Site No:** 1177

**Site Name:** (1177) East-West Medical Research Institute

**Subject No:** 11771317

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 12:55

[Audit Trail](#)

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

- CRF\_Sign

Name	Signature Meaning	Date	Type	Action
David Fitz-Patrick	Approved	Mar-08-2021 16:40:35 (UTC-10:00) Aleutian Islands	BOOK	Signed

**Affidavit:**

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

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

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

**Header Text:** C4591001

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

**Form Version:** 30-Jul-2020 21:29

**Site No:** 1177

**Subject No:** 11771317

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

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

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

**Site Name:** (1177) East-West Medical Research Institute

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 12:55

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Item	Date	User	Comment
Form	Sep-09-2020 12:23:29 (UTC-10:00) Aleutian Islands	(b) (4), (b) (6) [Redacted]	Not Applicable

**Header Text:** C4591001

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

**Form Version:** 21-Aug-2020 02:49

**Site No:** 1177

**Subject No:** 11771317

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

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

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

**Site Name:** (1177) East-West Medical Research Institute

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 12:55

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Item	Date	User	Comment
Form	Sep-09-2020 12:24:55 (UTC-10:00) Aleutian Islands	(b) (4), (b) (6) [Redacted]	Not Applicable



**Header Text:** C4591001

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

**Form Version:** 21-Aug-2020 02:49

**Site No:** 1177

**Subject No:** 11771317

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

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

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

**Site Name:** (1177) East-West Medical Research Institute

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 12:55

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Item	Date	User	Comment
1	Sep-09-2020 12:24:55 (UTC-10:00) Aleutian Islands	(b) (4), (b) (6) [Redacted]	Not Applicable

**Header Text:** C4591001

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

**Form Version:** 21-Aug-2020 02:49

**Site No:** 1177

**Subject No:** 11771317

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

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

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

**Site Name:** (1177) East-West Medical Research Institute

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 12:55

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Item	Date	User	Comment
2	Sep-09-2020 12:24:55 (UTC-10:00) Aleutian Islands	(b) (4), (b) (6) [Redacted]	Not Applicable

**Header Text:** C4591001

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

**Form Version:** 21-Aug-2020 02:49

**Site No:** 1177

**Subject No:** 11771317

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

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

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

**Site Name:** (1177) East-West Medical Research Institute

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 12:55

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Item	Date	User	Comment
3	Sep-09-2020 12:24:55 (UTC-10:00) Aleutian Islands	(b) (4), (b) (6) [Redacted]	Not Applicable

**Header Text:** C4591001

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

**Form Version:** 21-Aug-2020 02:49

**Site No:** 1177

**Subject No:** 11771317

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

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

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

**Site Name:** (1177) East-West Medical Research Institute

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 12:55

[Back to Form](#)

Item	Date	User	Comment
4	Sep-09-2020 12:24:55 (UTC-10:00) Aleutian Islands	(b) (4), (b) (6)	Not Applicable

**Header Text:** C4591001

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

**Form Version:** 21-Aug-2020 02:49

**Site No:** 1177

**Subject No:** 11771317

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

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

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

**Site Name:** (1177) East-West Medical Research Institute

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 12:55

[Back to Form](#)

Item	Date	User	Comment
5	Sep-09-2020 12:24:55 (UTC-10:00) Aleutian Islands	(b) (4), (b) (6) [Redacted]	Not Applicable

**Header Text:** C4591001

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

**Form Version:** 21-Aug-2020 02:49

**Site No:** 1177

**Subject No:** 11771317

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

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

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

**Site Name:** (1177) East-West Medical Research Institute

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 12:55

[Back to Form](#)

Item	Date	User	Comment
6.a	Sep-09-2020 12:24:55 (UTC-10:00) Aleutian Islands	(b) (4), (b) (6) [Redacted]	Not Applicable

**Header Text:** C4591001

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

**Form Version:** 21-Aug-2020 02:49

**Site No:** 1177

**Subject No:** 11771317

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

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

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

**Site Name:** (1177) East-West Medical Research Institute

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 12:55

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Item	Date	User	Comment
6.a	Sep-09-2020 12:24:55 (UTC-10:00) Aleutian Islands	(b) (4), (b) (6) [Redacted]	Not Applicable

**Header Text:** C4591001

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

**Form Version:** 21-Aug-2020 02:49

**Site No:** 1177

**Subject No:** 11771317

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

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

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

**Site Name:** (1177) East-West Medical Research Institute

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 12:55

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Item	Date	User	Comment
6.a	Sep-09-2020 12:24:55 (UTC-10:00) Aleutian Islands	(b) (4), (b) (6) [Redacted]	Not Applicable



**Header Text:** C4591001

**Visit:** V2\_VAX2\_L

**Form Version:** 21-Aug-2020 02:49

**Site No:** 1177

**Subject No:** 11771317

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

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

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

**Site Name:** (1177) East-West Medical Research Institute

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 12:55

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Item	Date	User	Comment
Form	Sep-30-2020 09:34:46 (UTC-10:00) Aleutian Islands	(b) (4), (b) (6) [Redacted]	Not Applicable

**Header Text:** C4591001

**Visit:** V2\_VAX2\_L

**Form Version:** 21-Aug-2020 02:49

**Site No:** 1177

**Subject No:** 11771317

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

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

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

**Site Name:** (1177) East-West Medical Research Institute

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 12:55

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Item	Date	User	Comment
1	Sep-30-2020 09:34:46 (UTC-10:00) Aleutian Islands	(b) (4), (b) (6) [Redacted]	Not Applicable

**Header Text:** C4591001

**Visit:** V2\_VAX2\_L

**Form Version:** 21-Aug-2020 02:49

**Site No:** 1177

**Subject No:** 11771317

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

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

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

**Site Name:** (1177) East-West Medical Research Institute

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 12:55

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Item	Date	User	Comment
2	Sep-30-2020 09:34:46 (UTC-10:00) Aleutian Islands	(b) (4), (b) (6) [REDACTED]	Not Applicable

**Header Text:** C4591001

**Visit:** V2\_VAX2\_L

**Form Version:** 21-Aug-2020 02:49

**Site No:** 1177

**Subject No:** 11771317

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

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

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

**Site Name:** (1177) East-West Medical Research Institute

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 12:55

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Item	Date	User	Comment
3	Sep-30-2020 09:34:46 (UTC-10:00) Aleutian Islands	(b) (4), (b) (6) [REDACTED]	Not Applicable

**Header Text:** C4591001

**Visit:** V2\_VAX2\_L

**Form Version:** 21-Aug-2020 02:49

**Site No:** 1177

**Subject No:** 11771317

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

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

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

**Site Name:** (1177) East-West Medical Research Institute

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 12:55

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Item	Date	User	Comment
4	Sep-30-2020 09:34:46 (UTC-10:00) Aleutian Islands	(b) (4), (b) (6) [REDACTED]	Not Applicable

**Header Text:** C4591001

**Visit:** V2\_VAX2\_L

**Form Version:** 21-Aug-2020 02:49

**Site No:** 1177

**Subject No:** 11771317

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

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**Site Name:** (1177) East-West Medical Research Institute

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 12:55

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Item	Date	User	Comment
5	Sep-30-2020 09:34:46 (UTC-10:00) Aleutian Islands	(b) (4), (b) (6) [Redacted]	Not Applicable

**Header Text:** C4591001

**Visit:** V2\_VAX2\_L

**Form Version:** 21-Aug-2020 02:49

**Site No:** 1177

**Subject No:** 11771317

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

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

**Site Name:** (1177) East-West Medical Research Institute

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 12:55

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Item	Date	User	Comment
6.a	Sep-30-2020 09:34:46 (UTC-10:00) Aleutian Islands	(b) (4), (b) (6) [Redacted]	Not Applicable

**Header Text:** C4591001

**Visit:** V2\_VAX2\_L

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**Site No:** 1177

**Subject No:** 11771317

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

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

**Site Name:** (1177) East-West Medical Research Institute

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 12:55

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Item	Date	User	Comment
6.a	Sep-30-2020 09:34:46 (UTC-10:00) Aleutian Islands	(b) (4), (b) (6) [Redacted]	Not Applicable



**Header Text:** C4591001

**Visit:** V2\_VAX2\_L

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**Site No:** 1177

**Subject No:** 11771317

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

**Site Name:** (1177) East-West Medical Research Institute

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 12:55

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Item	Date	User	Comment
6.a	Sep-30-2020 09:34:46 (UTC-10:00) Aleutian Islands	(b) (4), (b) (6) [Redacted]	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:** 1177

**Site Name:** (1177) East-West Medical Research Institute

**Subject No:** 11771317

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 12:55

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Item	Date	User	Comment
Form	Jan-18-2021 08:01:34 (UTC-10:00) Aleutian Islands	(b) (4), (b) (6) [Redacted]	Not Applicable

**Header Text:** C4591001

**Visit:** V101\_VAX3

**Form Version:** 14-Jan-2021 02:21

**Site No:** 1177

**Subject No:** 11771317

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

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

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

**Site Name:** (1177) East-West Medical Research Institute

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 12:55

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Item	Date	User	Comment
Form	Jan-18-2021 08:02:06 (UTC-10:00) Aleutian Islands	(b) (4), (b) (6) [REDACTED]	Not Applicable

**Header Text:** C4591001

**Visit:** V101\_VAX3

**Form Version:** 14-Jan-2021 02:21

**Site No:** 1177

**Subject No:** 11771317

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

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

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

**Site Name:** (1177) East-West Medical Research Institute

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 12:55

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Item	Date	User	Comment
1	Jan-18-2021 08:02:06 (UTC-10:00) Aleutian Islands	(b) (4), (b) (6)	Not Applicable

**Header Text:** C4591001

**Visit:** V101\_VAX3

**Form Version:** 14-Jan-2021 02:21

**Site No:** 1177

**Subject No:** 11771317

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

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

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

**Site Name:** (1177) East-West Medical Research Institute

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 12:55

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Item	Date	User	Comment
2	Jan-18-2021 08:02:06 (UTC-10:00) Aleutian Islands	(b) (4), (b) (6)	Not Applicable

**Header Text:** C4591001

**Visit:** V101\_VAX3

**Form Version:** 14-Jan-2021 02:21

**Site No:** 1177

**Subject No:** 11771317

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

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

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

**Site Name:** (1177) East-West Medical Research Institute

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 12:55

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Item	Date	User	Comment
3	Jan-18-2021 08:02:06 (UTC-10:00) Aleutian Islands	(b) (4), (b) (6)	Not Applicable

**Header Text:** C4591001

**Visit:** V101\_VAX3

**Form Version:** 14-Jan-2021 02:21

**Site No:** 1177

**Subject No:** 11771317

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

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**Site Name:** (1177) East-West Medical Research Institute

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**Generated Time (GMT):** 29-Mar-2021 12:55

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Item	Date	User	Comment
4	Jan-18-2021 08:02:06 (UTC-10:00) Aleutian Islands	(b) (4), (b) (6)	Not Applicable

**Header Text:** C4591001

**Visit:** V101\_VAX3

**Form Version:** 14-Jan-2021 02:21

**Site No:** 1177

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

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

**Site Name:** (1177) East-West Medical Research Institute

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 12:55

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Item	Date	User	Comment
5	Jan-18-2021 08:02:06 (UTC-10:00) Aleutian Islands	(b) (4), (b) (6)	Not Applicable



**Header Text:** C4591001

**Visit:** V101\_VAX3

**Form Version:** 14-Jan-2021 02:21

**Site No:** 1177

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**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 12:55

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Item	Date	User	Comment
6.a	Jan-18-2021 08:02:06 (UTC-10:00) Aleutian Islands	(b) (4), (b) (6)	Not Applicable

**Header Text:** C4591001

**Visit:** V101\_VAX3

**Form Version:** 14-Jan-2021 02:21

**Site No:** 1177

**Subject No:** 11771317

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

**Site Name:** (1177) East-West Medical Research Institute

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 12:55

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Item	Date	User	Comment
6.a	Jan-18-2021 08:02:06 (UTC-10:00) Aleutian Islands	(b) (4), (b) (6) [Redacted]	Not Applicable

**Header Text:** C4591001

**Visit:** V101\_VAX3

**Form Version:** 14-Jan-2021 02:21

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

**Site Name:** (1177) East-West Medical Research Institute

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 12:55

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Item	Date	User	Comment
6.a	Jan-18-2021 08:02:06 (UTC-10:00) Aleutian Islands	(b) (4), (b) (6) [Redacted]	Not Applicable

**Header Text:** C4591001

**Visit:** V102\_VAX4

**Form Version:** 14-Jan-2021 02:21

**Site No:** 1177

**Subject No:** 11771317

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

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

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

**Site Name:** (1177) East-West Medical Research Institute

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 12:55

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Item	Date	User	Comment
Form	Feb-08-2021 07:27:16 (UTC-10:00) Aleutian Islands	Sarah Thompson (b) (4)	Not Applicable

**Header Text:** C4591001

**Visit:** V102\_VAX4

**Form Version:** 14-Jan-2021 02:21

**Site No:** 1177

**Subject No:** 11771317

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

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

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

**Site Name:** (1177) East-West Medical Research Institute

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 12:55

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Item	Date	User	Comment
1	Feb-08-2021 07:27:16 (UTC-10:00) Aleutian Islands	Sarah Thompson (b) (4)	Not Applicable

**Header Text:** C4591001

**Visit:** V102\_VAX4

**Form Version:** 14-Jan-2021 02:21

**Site No:** 1177

**Subject No:** 11771317

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

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

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

**Site Name:** (1177) East-West Medical Research Institute

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 12:55

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Item	Date	User	Comment
2	Feb-08-2021 07:27:16 (UTC-10:00) Aleutian Islands	Sarah Thompson (b) (4)	Not Applicable

**Header Text:** C4591001

**Visit:** V102\_VAX4

**Form Version:** 14-Jan-2021 02:21

**Site No:** 1177

**Subject No:** 11771317

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

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

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**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 12:55

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Item	Date	User	Comment
3	Feb-08-2021 07:27:16 (UTC-10:00) Aleutian Islands	Sarah Thompson (b) (4)	Not Applicable

**Header Text:** C4591001

**Visit:** V102\_VAX4

**Form Version:** 14-Jan-2021 02:21

**Site No:** 1177

**Subject No:** 11771317

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

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

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

**Site Name:** (1177) East-West Medical Research Institute

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 12:55

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Item	Date	User	Comment
4	Feb-08-2021 07:27:16 (UTC-10:00) Aleutian Islands	Sarah Thompson (b) (4)	Not Applicable



**Header Text:** C4591001

**Visit:** V102\_VAX4

**Form Version:** 14-Jan-2021 02:21

**Site No:** 1177

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

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

**Site Name:** (1177) East-West Medical Research Institute

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**Generated Time (GMT):** 29-Mar-2021 12:55

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Item	Date	User	Comment
5	Feb-08-2021 07:27:16 (UTC-10:00) Aleutian Islands	Sarah Thompson (b) (4)	Not Applicable

**Header Text:** C4591001

**Visit:** V102\_VAX4

**Form Version:** 14-Jan-2021 02:21

**Site No:** 1177

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Item	Date	User	Comment
6.a	Feb-08-2021 07:27:16 (UTC-10:00) Aleutian Islands	Sarah Thompson (b) (4)	Not Applicable

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Item	Date	User	Comment
6.a	Feb-08-2021 07:27:16 (UTC-10:00) Aleutian Islands	Sarah Thompson (b) (4)	Not Applicable

**Header Text:** C4591001

**Visit:** V102\_VAX4

**Form Version:** 14-Jan-2021 02:21

**Site No:** 1177

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**Site Name:** (1177) East-West Medical Research Institute

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**Generated Time (GMT):** 29-Mar-2021 12:55

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Item	Date	User	Comment
6.a	Feb-08-2021 07:27:16 (UTC-10:00) Aleutian Islands	Sarah Thompson (b) (4)	Not Applicable

**Header Text:** C4591001

**Visit:** Investigator Signature -  
Unscheduled

**Form:** CASEBOOK SIGNATURE FORM - Signature History

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

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

**Site No:** 1177

**Site Name:** (1177) East-West Medical Research Institute

**Subject No:** 11771317

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 12:55

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

- CRF\_Sign

Name	Signature Meaning	Date	Type	Action
David Fitz-Patrick	Approved	Mar-08-2021 16:40:35 (UTC-10:00) Aleutian Islands	BOOK	Signed

**Affidavit:**

By my dated signature below, I, DavidFitz-Patrick, 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.

Sarah Thompson	N/A	Feb-08-2021 07:27:08 (UTC-10:00) Aleutian Islands		Edit - All signatures invalidated
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**Affidavit:**

N/A

David Fitz-Patrick	Approved	Jan-20-2021 11:38:00 (UTC-10:00) Aleutian Islands	BOOK	Signed
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**Affidavit:**

By my dated signature below, I, DavidFitz-Patrick, 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.

090177e196ae2fd9\Final\Final On: 01-Apr-2021 03:53 (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, Signed, Verified

**Site No:** 1177

**Site Name:** (1177) East-West Medical Research Institute

**Subject No:** 11771317

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 12:55

(b) (6)	N/A	Dec-28-2020 10:29:31 (UTC-10:00) Aleutian Islands		Edit - All signatures invalidated
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**Affidavit:**

N/A

David Fitz-Patrick	Approved	Dec-10-2020 15:11:43 (UTC-10:00) Aleutian Islands	BOOK	Signed
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**Affidavit:**

By my dated signature below, I, DavidFitz-Patrick, 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	Dec-10-2020 13:40:22 (UTC-10:00) Aleutian Islands		Edit - All signatures invalidated
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**Affidavit:**

N/A

David Fitz-Patrick	Approved	Nov-03-2020 10:49:00 (UTC-10:00) Aleutian Islands	BOOK	Signed
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**Affidavit:**

By my dated signature below, I, DavidFitz-Patrick, 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.

090177e196ae2fd9\Final\Final On: 01-Apr-2021 03:53 (GMT)

**Header Text:** C4591001

**Visit:** COHORT\_SELECTION

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

**Form Version:** 30-Jul-2020 21:29

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

**Site No:** 1177

**Site Name:** (1177) East-West Medical Research Institute

**Subject No:** 11771317

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 12:55

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

Date	Location	User	Value	Reason
Sep-09-2020 12:22:43 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 24 JUL 2020	Initial Entry

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

Date	Location	User	Value	Reason
Sep-09-2020 12:22:43 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> STAGE 3 COHORTS	Initial Entry

090177e196ae2fd9\Final\Final On: 01-Apr-2021 03:53 (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:** 1177

**Site Name:** (1177) East-West Medical Research Institute

**Subject No:** 11771317

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 12:55

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**I. Consent Was:**

Date	Location	User	Value	Reason
Sep-09-2020 12:22:50 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> OBTAINED Date Written Consent Obtained  Sep/9/2020	Initial Entry



**Header Text:** C4591001

**Visit:** COHORT\_SELECTION

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

**Form Version:** 06-Jul-2020 21:55

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

**Site No:** 1177

**Site Name:** (1177) East-West Medical Research Institute

**Subject No:** 11771317

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 12:55

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**1. Subject ID**

Date	Location	User	Value	Reason
Sep-09-2020 12:22:35 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 11771317	Item copied from previous form

**2. Birth Date:**

Date	Location	User	Value	Reason
Sep-09-2020 12:22:30 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> (b) (6)/1958	Enrollment Entry

**3. Sex:**

Date	Location	User	Value	Reason
Sep-09-2020 12:23:07 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> FEMALE	Initial Entry

**4. Ethnicity:**

Date	Location	User	Value	Reason
Sep-09-2020 12:23:07 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NOT HISPANIC OR LATIN O(A) OR OF SPANISH ORI GIN	Initial Entry

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

Date	Location	User	Value	Reason
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090177e196ae2fd9\Final\Final On: 01-Apr-2021 03:53 (GMT)

**Header Text:** C4591001**Visit:** COHORT\_SELECTION**Form:** DEMOGRAPHY - eCRF Audit Trail History**Form Version:** 06-Jul-2020 21:55**Form Status:** Data Complete, Frozen, Verified**Site No:** 1177**Site Name:** (1177) East-West Medical Research Institute**Subject No:** 11771317**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 12:55

Dec-04-2020 10:58:40 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Dec-04-2020 07:13:43 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Japanese
Dec-03-2020 11:36:19 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	Subject is indicated on Demography CRF as Asian, please specify further racial designation as Japanese (i.e. defined as all four grandparents born in Japan, of Japanese ancestry), or Other
Sep-09-2020 12:23:07 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> ASIAN	Initial Entry

**6. Racial Designation:**

Date	Location	User	Value	Reason
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**Header Text:** C4591001

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

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

**Site No:** 1177

**Subject No:** 11771317

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

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

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

**Site Name:** (1177) East-West Medical Research Institute

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 12:55

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*I. Date of Visit*

Date	Location	User	Value	Reason
Sep-09-2020 12:23:20 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sep/9/2020	Initial Entry

**Header Text:** C4591001

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

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

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

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

**Site No:** 1177

**Site Name:** (1177) East-West Medical Research Institute

**Subject No:** 11771317

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 12:55

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

Date	Location	User	Value	Reason
Sep-09-2020 12:23:47 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sep/9/2020	Initial Entry

**2. Phase of Disposition:**

Date	Location	User	Value	Reason
Sep-09-2020 12:23:47 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SCREENING	Initial Entry

**3. Status:**

Date	Location	User	Value	Reason
Sep-09-2020 12:23:47 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> COMPLETED	Initial Entry

090177e196ae2fd9\Final\Final On: 01-Apr-2021 03:53 (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:** 1177

**Site Name:** (1177) East-West Medical Research Institute

**Subject No:** 11771317

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 12:55

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*I.a*

Date	Location	User	Value	Reason
Sep-09-2020 16:36:24 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Line/MH Number:</b> 1 <b>Medical History Term:</b> Allergic to latex <b>Start Date:</b> UNK/UNK/1990 <b>Ongoing:</b> YES	Transcription Error
Sep-09-2020 16:35:24 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Line/MH Number:</b> 1 <b>Medical History Term:</b> Allergic to latex <b>Start Date:</b> UNK/UNK/1990 <b>Ongoing:</b> NO End Date:  UNK/UNK/1990	Initial Entry

*I.a Line/MH Number:*

Date	Location	User	Value	Reason
Sep-09-2020 16:35:24 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 1	Initial Entry

090177e196ae2fd9\Final\Final On: 01-Apr-2021 03:53 (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: 1177

Site Name: (1177) East-West Medical Research Institute

Subject No: 11771317

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:55

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

Date	Location	User	Value	Reason
Sep-09-2020 16:35:24 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Allergic to latex	Initial Entry

***1.a Start Date:***

Date	Location	User	Value	Reason
Sep-09-2020 16:35:24 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> UNK/UNK/1990	Initial Entry

***1.a Ongoing:***

Date	Location	User	Value	Reason
Sep-09-2020 16:36:24 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Transcription Error
Sep-09-2020 16:35:24 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO End Date:  UNK/UNK/1990	Initial Entry

***1.b***

Date	Location	User	Value	Reason
Sep-09-2020 16:36:02 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Line/MH Number:</b> 2 <b>Medical History Term:</b> Allergic to bee venom	Initial Entry

090177e196ae2fd9\Final\Final On: 01-Apr-2021 03:53 (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:** 1177**Site Name:** (1177) East-West Medical Research Institute**Subject No:** 11771317**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 12:55

			<b>Start Date:</b> UNK/UNK/ 1970	
			<b>Ongoing:</b> YES	

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

Date	Location	User	Value	Reason
Sep-09-2020 16:36:02 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 2	Initial Entry

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

Date	Location	User	Value	Reason
Sep-09-2020 16:36:02 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Allergic to bee venom	Initial Entry

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

Date	Location	User	Value	Reason
Sep-09-2020 16:36:02 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> UNK/UNK/1970	Initial Entry

***1.b Ongoing:***

Date	Location	User	Value	Reason
Sep-09-2020 16:36:02 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

***1.c***

Date	Location	User	Value	Reason
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**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:** 1177

**Site Name:** (1177) East-West Medical Research Institute

**Subject No:** 11771317

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 12:55

Sep-09-2020 16:37:00 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Line/MH Nu</b> 3 <b>mber:</b> <b>Medical Hist</b> Allergic to t <b>ory Term:</b> omatoes <b>Start Date:</b> UNK/UNK/ 1970 <b>Ongoing:</b> YES	Initial Entry
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**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:** 1177**Site Name:** (1177) East-West Medical Research Institute**Subject No:** 11771317**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 12:55***I.c Line/MH Number:***

Date	Location	User	Value	Reason
Sep-09-2020 16:37:00 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 3	Initial Entry

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

Date	Location	User	Value	Reason
Sep-09-2020 16:37:00 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Allergic to tomatoes	Initial Entry

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

Date	Location	User	Value	Reason
Sep-09-2020 16:37:00 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> UNK/UNK/1970	Initial Entry

***I.c Ongoing:***

Date	Location	User	Value	Reason
Sep-09-2020 16:37:00 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

***I.d***

Date	Location	User	Value	Reason
Sep-09-2020 16:38:42 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Line/MH Num 4 ber:</b>	Initial Entry

Header Text: C4591001

Visit: V1\_DAY1\_VAX1\_L

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

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Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1177

Site Name: (1177) East-West Medical Research Institute

Subject No: 11771317

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:55

			<b>Medical History Term:</b> Hypertension <b>Start Date:</b> UNK/UNK/2018 <b>Ongoing:</b> YES
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**1.d Line/MH Number:**

Date	Location	User	Value	Reason
Sep-09-2020 16:38:42 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 4	Initial Entry

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

Date	Location	User	Value	Reason
Sep-09-2020 16:38:42 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Hypertension	Initial Entry

**1.d Start Date:**

Date	Location	User	Value	Reason
Sep-09-2020 16:38:42 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> UNK/UNK/2018	Initial Entry

**1.d Ongoing:**

Date	Location	User	Value	Reason
Sep-09-2020 16:38:42 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

090177e196ae2fd9\Final\Final On: 01-Apr-2021 03:53 (GMT)

**Header Text:** C4591001

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

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

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

**Site No:** 1177

**Site Name:** (1177) East-West Medical Research Institute

**Subject No:** 11771317

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 12:55

*I.e*

Date	Location	User	Value	Reason
Sep-09-2020 16:39:57 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Line/MH 5</b> <b>Number:</b> <b>Medical History Term:</b> Transient ischemic attack ("mini stroke") <b>Start Date:</b> UNK/UNK/1990 <b>Ongoing:</b> NO End Date: UNK/UNK/1990	Initial Entry

090177e196ae2fd9\Final\Final On: 01-Apr-2021 03:53 (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:** 1177**Site Name:** (1177) East-West Medical Research Institute**Subject No:** 11771317**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 12:55***I.e Line/MH Number:***

Date	Location	User	Value	Reason
Sep-09-2020 16:39:57 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 5	Initial Entry

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

Date	Location	User	Value	Reason
Sep-09-2020 16:39:57 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Transient ischemic attack ("mini stroke")	Initial Entry

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

Date	Location	User	Value	Reason
Sep-09-2020 16:39:57 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> UNK/UNK/1990	Initial Entry

***I.e Ongoing:***

Date	Location	User	Value	Reason
Sep-09-2020 16:39:57 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO End Date: UNK/UNK/1990	Initial Entry

***I.f***

Date	Location	User	Value	Reason
Sep-09-2020 16:40:41	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b>	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:** 1177

**Site Name:** (1177) East-West Medical Research Institute

**Subject No:** 11771317

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 12:55

(UTC-10:00)  
Aleutian Islands

**Line/MH Num** 6

**ber:**

**Medical History Term:** Diabetes, Type II

**Start Date:** UNK/UNK/2010

**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:** 1177**Site Name:** (1177) East-West Medical Research Institute**Subject No:** 11771317**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 12:55***1.f Line/MH Number:***

Date	Location	User	Value	Reason
Sep-09-2020 16:40:41 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 6	Initial Entry

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

Date	Location	User	Value	Reason
Sep-09-2020 16:40:41 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Diabetes, Type II	Initial Entry

***1.f Start Date:***

Date	Location	User	Value	Reason
Sep-09-2020 16:40:41 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> UNK/UNK/2010	Initial Entry

***1.f Ongoing:***

Date	Location	User	Value	Reason
Sep-09-2020 16:40:41 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

***1.g***

Date	Location	User	Value	Reason
Sep-09-2020 16:41:09 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Line/MH Num 7 ber:</b>	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: 1177

Site Name: (1177) East-West Medical Research Institute

Subject No: 11771317

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:55

			<b>Medical History Term:</b> Dyslipidemia <b>Start Date:</b> UNK/UNK/2019 <b>Ongoing:</b> YES
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*1.g Line/MH Number:*

Date	Location	User	Value	Reason
Sep-09-2020 16:41:09 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 7	Initial Entry

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

Date	Location	User	Value	Reason
Sep-09-2020 16:41:09 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Dyslipidemia	Initial Entry

*1.g Start Date:*

Date	Location	User	Value	Reason
Sep-09-2020 16:41:09 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> UNK/UNK/2019	Initial Entry

*1.g Ongoing:*

Date	Location	User	Value	Reason
Sep-09-2020 16:41:09 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

090177e196ae2fd9\Final\Final On: 01-Apr-2021 03:53 (GMT)

**Header Text:** C4591001

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

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

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

**Site No:** 1177

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

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*1.h*

Date	Location	User	Value	Reason
Sep-09-2020 16:43:02 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Line/MH Num 8</b> <b>ber:</b> <b>Medical History Term:</b> Hypothyroidism <b>Start Date:</b> UNK/UNK/1990 <b>Ongoing:</b> 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: 1177

Site Name: (1177) East-West Medical Research Institute

Subject No: 11771317

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:55

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

Date	Location	User	Value	Reason
Sep-09-2020 16:43:02 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 8	Initial Entry

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

Date	Location	User	Value	Reason
Sep-09-2020 16:43:02 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Hypothyroidism	Initial Entry

**1.h Start Date:**

Date	Location	User	Value	Reason
Sep-09-2020 16:43:02 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> UNK/UNK/1990	Initial Entry

**1.h Ongoing:**

Date	Location	User	Value	Reason
Sep-09-2020 16:43:02 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

**1.i**

Date	Location	User	Value	Reason
Sep-09-2020 16:43:30 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> Line/MH Num 9 ber:	Initial Entry

090177e196ae2fd9\Final\Final On: 01-Apr-2021 03:53 (GMT)

Header Text: C4591001

Visit: V1\_DAY1\_VAX1\_L

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

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Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1177

Site Name: (1177) East-West Medical Research Institute

Subject No: 11771317

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:55

			<b>Medical History Term:</b> Depression <b>Start Date:</b> UNK/UNK/1990 <b>Ongoing:</b> YES
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*1.i Line/MH Number:*

Date	Location	User	Value	Reason
Sep-09-2020 16:43:30 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 9	Initial Entry

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

Date	Location	User	Value	Reason
Sep-09-2020 16:43:30 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Depression	Initial Entry

*1.i Start Date:*

Date	Location	User	Value	Reason
Sep-09-2020 16:43:30 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> UNK/UNK/1990	Initial Entry

*1.i Ongoing:*

Date	Location	User	Value	Reason
Sep-09-2020 16:43:30 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

090177e196ae2fd9\Final\Final On: 01-Apr-2021 03:53 (GMT)

Header Text: C4591001

Visit: V1\_DAY1\_VAX1\_L

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Site No: 1177

Site Name: (1177) East-West Medical Research Institute

Subject No: 11771317

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:55

*1.j*

Date	Location	User	Value	Reason
Sep-09-2020 16:44:21 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Line/MH Number:</b> 10 <b>Medical History Term:</b> Barrett's esophagus <b>Start Date:</b> UNK/UNK/2010 <b>Ongoing:</b> YES	Initial Entry

*1.j Line/MH Number:*

Date	Location	User	Value	Reason
Sep-09-2020 16:44:21 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 10	Initial Entry

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

Date	Location	User	Value	Reason
Sep-09-2020 16:44:21 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Barrett's esophagus	Initial Entry

090177e196ae2fd9\Final\Final On: 01-Apr-2021 03:53 (GMT)

Header Text: C4591001

Visit: V1\_DAY1\_VAX1\_L

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Site No: 1177

Site Name: (1177) East-West Medical Research Institute

Subject No: 11771317

Subject Initials: ---

Generated By: (b) (4)

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***1.j Start Date:***

Date	Location	User	Value	Reason
Sep-09-2020 16:44:21 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> UNK/UNK/2010	Initial Entry

***1.j Ongoing:***

Date	Location	User	Value	Reason
Sep-09-2020 16:44:21 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

***1.k***

Date	Location	User	Value	Reason
Sep-09-2020 16:44:45 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> Line/MH Num 11 ber: Medical Histo Sleep apnea ry Term: a Start Date: UNK/UNK/1990 Ongoing: YES	Initial Entry

090177e196ae2fd9\Final\Final On: 01-Apr-2021 03:53 (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:** 1177**Site Name:** (1177) East-West Medical Research Institute**Subject No:** 11771317**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 12:55***1.k Line/MH Number:***

Date	Location	User	Value	Reason
Sep-09-2020 16:44:45 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 11	Initial Entry

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

Date	Location	User	Value	Reason
Sep-09-2020 16:44:45 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sleep apnea	Initial Entry

***1.k Start Date:***

Date	Location	User	Value	Reason
Sep-09-2020 16:44:45 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> UNK/UNK/1990	Initial Entry

***1.k Ongoing:***

Date	Location	User	Value	Reason
Sep-09-2020 16:44:45 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

***1.l***

Date	Location	User	Value	Reason
Sep-09-2020 16:45:23 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Line/MH</b> 12 <b>Number:</b>	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: 1177

Site Name: (1177) East-West Medical Research Institute

Subject No: 11771317

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:55

			<b>Medical History Term</b> : Gastroesophageal reflux disease <b>Start Date</b> : UNK/UNK/2010 <b>Ongoing</b> : YES
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**1.1 Line/MH Number:**

Date	Location	User	Value	Reason
Sep-09-2020 16:45:23 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 12	Initial Entry

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

Date	Location	User	Value	Reason
Sep-09-2020 16:45:23 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Gastroesophageal reflux disease	Initial Entry

**1.1 Start Date:**

Date	Location	User	Value	Reason
Sep-09-2020 16:45:23 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> UNK/UNK/2010	Initial Entry

**1.1 Ongoing:**

Date	Location	User	Value	Reason
Sep-09-2020 16:45:23 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

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**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:** 1177

**Site Name:** (1177) East-West Medical Research Institute

**Subject No:** 11771317

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 12:55

*I.m*

Date	Location	User	Value	Reason
Sep-09-2020 16:47:06 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Line/MH Nu</b> 13 <b>mber:</b> <b>Medical Hist</b> Septoplasty <b>ory Term:</b> <b>Start Date:</b> UNK/UNK/ 1986 <b>Ongoing:</b> NO End Date: UNK/UN K/1986	Initial Entry

090177e196ae2fd9\Final\Final On: 01-Apr-2021 03:53 (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:** 1177**Site Name:** (1177) East-West Medical Research Institute**Subject No:** 11771317**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 12:55***I.m Line/MH Number:***

Date	Location	User	Value	Reason
Sep-09-2020 16:47:06 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 13	Initial Entry

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

Date	Location	User	Value	Reason
Sep-09-2020 16:47:06 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Septoplasty	Initial Entry

***I.m Start Date:***

Date	Location	User	Value	Reason
Sep-09-2020 16:47:06 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> UNK/UNK/1986	Initial Entry

***I.m Ongoing:***

Date	Location	User	Value	Reason
Sep-09-2020 16:47:06 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO End Date:  UNK/UNK/1986	Initial Entry

***I.n***

Date	Location	User	Value	Reason
Sep-09-2020 16:48:15	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b>	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:** 1177

**Site Name:** (1177) East-West Medical Research Institute

**Subject No:** 11771317

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 12:55

(UTC-10:00) Aleutian Islands			<b>Line/MH Number:</b> 14 <b>Medical History Term:</b> Deviated septum <b>Start Date:</b> UNK/UNK/1986 <b>Ongoing:</b> NO End Date: UNK/UNK/1986	
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090177e196ae2fd9\Final\Final On: 01-Apr-2021 03:53 (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:** 1177**Site Name:** (1177) East-West Medical Research Institute**Subject No:** 11771317**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 12:55***I.n Line/MH Number:***

Date	Location	User	Value	Reason
Sep-09-2020 16:48:15 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 14	Initial Entry

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

Date	Location	User	Value	Reason
Sep-09-2020 16:48:15 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Deviated septum	Initial Entry

***I.n Start Date:***

Date	Location	User	Value	Reason
Sep-09-2020 16:48:15 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> UNK/UNK/1986	Initial Entry

***I.n Ongoing:***

Date	Location	User	Value	Reason
Sep-09-2020 16:48:15 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO End Date: UNK/UNK/1986	Initial Entry

***I.o***

Date	Location	User	Value	Reason
Sep-09-2020 16:50:52	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	Transcription Error

**Header Text:** C4591001

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

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

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

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

**Site No:** 1177

**Site Name:** (1177) East-West Medical Research Institute

**Subject No:** 11771317

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 12:55

(UTC-10:00) Aleutian Islands		(b) (4), (b) (6)	<b>Line/MH Number:</b> 15 <b>Medical History Term:</b> Removal of vocal cord polyp <b>Start Date:</b> UNK/UNK/1997 <b>Ongoing:</b> NO End Date: UNK/UNK/1997	
Sep-09-2020 16:49:09 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Line/MH Number:</b> 15 <b>Medical History Term:</b> Removal of vocal chord polyps <b>Start Date:</b> UNK/UNK/1997 <b>Ongoing:</b> NO End Date: UNK/UNK/1997	Initial Entry

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**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:** 1177**Site Name:** (1177) East-West Medical Research Institute**Subject No:** 11771317**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 12:55***I.o Line/MH Number:***

Date	Location	User	Value	Reason
Sep-09-2020 16:49:09 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 15	Initial Entry

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

Date	Location	User	Value	Reason
Sep-09-2020 16:50:52 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Removal of vocal cord poly p	Transcription Error
Sep-09-2020 16:49:09 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Removal of vocal chord pol yps	Initial Entry

***I.o Start Date:***

Date	Location	User	Value	Reason
Sep-09-2020 16:49:09 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> UNK/UNK/1997	Initial Entry

***I.o Ongoing:***

Date	Location	User	Value	Reason
Sep-09-2020 16:49:09 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO End Date:  UNK/UNK/1997	Initial Entry

**Header Text:** C4591001

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

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

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

**Site No:** 1177

**Site Name:** (1177) East-West Medical Research Institute

**Subject No:** 11771317

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 12:55

*l.p*

Date	Location	User	Value	Reason
Sep-09-2020 16:50:32 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Line/MH Number:</b> 16 <b>Medical History Term:</b> Vocal cord polyp <b>Start Date:</b> UNK/UNK/1997 <b>Ongoing:</b> NO End Date:  UNK/UNK/1997	Initial Entry

090177e196ae2fd9\Final\Final On: 01-Apr-2021 03:53 (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:** 1177**Site Name:** (1177) East-West Medical Research Institute**Subject No:** 11771317**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 12:55***1.p Line/MH Number:***

Date	Location	User	Value	Reason
Sep-09-2020 16:50:32 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 16	Initial Entry

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

Date	Location	User	Value	Reason
Sep-09-2020 16:50:32 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Vocal cord polyp	Initial Entry

***1.p Start Date:***

Date	Location	User	Value	Reason
Sep-09-2020 16:50:32 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> UNK/UNK/1997	Initial Entry

***1.p Ongoing:***

Date	Location	User	Value	Reason
Sep-09-2020 16:50:32 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO End Date:  UNK/UNK/1997	Initial Entry

***1.q***

Date	Location	User	Value	Reason
Sep-10-2020 08:12:32	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	New Information

**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:** 1177

**Site Name:** (1177) East-West Medical Research Institute

**Subject No:** 11771317

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 12:55

(UTC-10:00) Aleutian Islands		(b) (4), (b) (6)	<b>Line/MH Number:</b> 17 <b>Medical History Term:</b> Carpal tunnel syndrome, bilateral <b>Start Date:</b> UNK/UNK/2001 <b>Ongoing:</b> NO End Date: UNK/UNK/2001	
Sep-09-2020 16:51:46 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Line/MH Number:</b> 17 <b>Medical History Term:</b> Carpal tunnel syndrome, bilateral <b>Start Date:</b> UNK/UNK/2001 <b>Ongoing:</b> NO End Date: UNK/UNK/2001	Initial Entry

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Header Text: C4591001

Visit: V1\_DAY1\_VAX1\_L

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

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Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1177

Site Name: (1177) East-West Medical Research Institute

Subject No: 11771317

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:55

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

Date	Location	User	Value	Reason
Sep-09-2020 16:51:46 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 17	Initial Entry

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

Date	Location	User	Value	Reason
Sep-10-2020 21:41:41 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000.InFormAdapter.Discrepancy	PFETMS Oracle (b) (4)	Query 1: Closed	Discrepancy has been closed.
Sep-10-2020 08:12:32 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	New Information
Sep-10-2020 08:12:32 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> ; Carpal tunnel syndrome, bilateral	New Information
Sep-10-2020 04:03:07 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000.InFormAdapter.Discrepancy	PFETMS Oracle (b) (4)	Query 1: Opened	Clarify the term CARPAL TUNNEL, BILATERAL

090177e196ae2fd9\Final\Final On: 01-Apr-2021 03:53 (GMT)



**Header Text:** C4591001

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

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

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

**Site No:** 1177

**Site Name:** (1177) East-West Medical Research Institute

**Subject No:** 11771317

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 12:55

				as follows. The term appears incomplete, please clarify the condition or procedure being reported. Are you reporting CARPAL TUNNEL SYNDROME BILATERAL ? Or CARPAL TUNNEL REPAIR BILATERAL ? Or Other? if so then edit as such. Otherwise please clarify the term further. Thank you.
Sep-09-2020 16:51:46 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry</b> : Carpa l tunn el, bil ateral	Initial Entry

<b><i>1.q Start Date:</i></b>				
<b>Date</b>	<b>Location</b>	<b>User</b>	<b>Value</b>	<b>Reason</b>

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: 1177

Site Name: (1177) East-West Medical Research Institute

Subject No: 11771317

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:55

Sep-09-2020 16:51:46 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> UNK/UNK/2001	Initial Entry
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***1.q Ongoing:***

Date	Location	User	Value	Reason
Sep-09-2020 16:51:46 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO End Date:  UNK/UNK/2001	Initial Entry

***1.r***

Date	Location	User	Value	Reason
Sep-09-2020 16:53:28 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Line/MH</b> 18 <b>Number:</b> <b>Medical History Term:</b> Carpal tunnel release, bilateral <b>Start Date:</b> UNK/UNK/2001 <b>Ongoing:</b> NO End Date:  UNK/UNK/2001	Initial Entry

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**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:** 1177**Site Name:** (1177) East-West Medical Research Institute**Subject No:** 11771317**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 12:55***I.r Line/MH Number:***

Date	Location	User	Value	Reason
Sep-09-2020 16:53:28 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 18	Initial Entry

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

Date	Location	User	Value	Reason
Sep-09-2020 16:53:28 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Carpal tunnel release, bilater al	Initial Entry

***I.r Start Date:***

Date	Location	User	Value	Reason
Sep-09-2020 16:53:28 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> UNK/UNK/2001	Initial Entry

***I.r Ongoing:***

Date	Location	User	Value	Reason
Sep-09-2020 16:53:28 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO End Date:  UNK/UNK/2001	Initial Entry

***I.s***

Date	Location	User	Value	Reason
Sep-09-2020 16:55:29	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b>	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:** 1177

**Site Name:** (1177) East-West Medical Research Institute

**Subject No:** 11771317

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 12:55

(UTC-10:00)  
Aleutian Islands

<b>Line/MH Number:</b> 19
<b>Medical History Term:</b> Broken wrist, left
<b>Start Date:</b> Jul/27/2020
<b>Ongoing:</b> NO
<b>End Date:</b> Jul/27/2020

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: 1177

Site Name: (1177) East-West Medical Research Institute

Subject No: 11771317

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:55

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*I.s Line/MH Number:*

Date	Location	User	Value	Reason
Sep-09-2020 16:55:29 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 19	Initial Entry

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

Date	Location	User	Value	Reason
Sep-09-2020 16:55:29 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Broken wrist, left	Initial Entry

*I.s Start Date:*

Date	Location	User	Value	Reason
Sep-09-2020 16:55:29 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Jul/27/2020	Initial Entry

*I.s Ongoing:*

Date	Location	User	Value	Reason
Sep-09-2020 16:55:29 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO End Date:  Jul/27/2020	Initial Entry

*I.t*

Date	Location	User	Value	Reason
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**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:** 1177

**Site Name:** (1177) East-West Medical Research Institute

**Subject No:** 11771317

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 12:55

Sep-09-2020 16:56:42 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Line/MH N</b> 20 <b>umber:</b> <b>Medical His</b> Broken wrist <b>tory Term:</b> repair, left <b>Start Date:</b> Jul/27/2020 <b>Ongoing:</b> NO End Date:  Jul/27/2020	Initial Entry
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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: 1177

Site Name: (1177) East-West Medical Research Institute

Subject No: 11771317

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:55

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

Date	Location	User	Value	Reason
Sep-09-2020 16:56:42 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 20	Initial Entry

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

Date	Location	User	Value	Reason
Sep-09-2020 16:56:42 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Broken wrist repair, left	Initial Entry

***1.t Start Date:***

Date	Location	User	Value	Reason
Sep-09-2020 16:56:42 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Jul/27/2020	Initial Entry

***1.t Ongoing:***

Date	Location	User	Value	Reason
Sep-09-2020 16:56:42 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO End Date: Jul/27/2020	Initial Entry

090177e196ae2fd9\Final\Final On: 01-Apr-2021 03:53 (GMT)

**Header Text:** C4591001

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

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

**Form Version:** 21-Aug-2020 02:51

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

**Site No:** 1177

**Site Name:** (1177) East-West Medical Research Institute

**Subject No:** 11771317

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 12:55

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**1. Date:**

Date	Location	User	Value	Reason
Sep-09-2020 12:24:43 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sep/9/2020	Initial Entry

**2. Weight:**

Date	Location	User	Value	Reason
Sep-09-2020 12:24:43 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 79.4	Initial Entry

**3. Unit:**

Date	Location	User	Value	Reason
Sep-09-2020 12:24:43 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> kg	Initial Entry

**4. Height:**

Date	Location	User	Value	Reason
Sep-09-2020 12:24:43 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 158.5	Initial Entry

**5. Unit:**

Date	Location	User	Value	Reason
Sep-09-2020 12:24:43 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> cm	Initial Entry

090177e196ae2fd9\Final\Final On: 01-Apr-2021 03:53 (GMT)



Header Text: C4591001

Visit: V1\_DAY1\_VAX1\_L

Form: VITAL SIGNS - BASELINE - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1177

Site Name: (1177) East-West Medical Research Institute

Subject No: 11771317

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:55

6. Body Mass Index:

Date	Location	User	Value	Reason
Sep-09-2020 12:24:43 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 31.6	Initial Entry

7.a

Date	Location	User	Value	Reason
Sep-09-2020 12:24:43 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Record Identifier:</b> 1 <b>Temperature:</b> 97.1 <b>Temperature Unit:</b> F <b>Temperature Location:</b> FOREHEAD	Initial Entry

7.a Record Identifier:

Date	Location	User	Value	Reason
Sep-09-2020 12:24:43 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 1	Initial Entry

7.a Temperature:

Date	Location	User	Value	Reason
Sep-09-2020 12:24:43 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 97.1	Initial Entry

7.a Unit:

090177e196ae2fd9\Final\Final On: 01-Apr-2021 03:53 (GMT)

**Header Text:** C4591001

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

**Form Version:** 21-Aug-2020 02:51

**Site No:** 1177

**Subject No:** 11771317

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

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

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

**Site Name:** (1177) East-West Medical Research Institute

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 12:55

Date	Location	User	Value	Reason
Sep-09-2020 12:24:43 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> F	Initial Entry

**7.a Temperature Location:**

Date	Location	User	Value	Reason
Sep-09-2020 12:24:43 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> FOREHEAD	Initial Entry

**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:** 1177

**Site Name:** (1177) East-West Medical Research Institute

**Subject No:** 11771317

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 12:55

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**1. Lab Panel:**

Date	Location	User	Value	Reason
Sep-09-2020 12:24:55 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**2. Lab Sub-Panel:**

Date	Location	User	Value	Reason
Sep-09-2020 12:24:55 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**3. Collection Date:**

Date	Location	User	Value	Reason
Sep-09-2020 12:24:55 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

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

Date	Location	User	Value	Reason
Sep-09-2020 12:24:55 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**5. Specimen Type:**

Date	Location	User	Value	Reason
Sep-09-2020 12:24:55 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

090177e196ae2fd9\Final\Final On: 01-Apr-2021 03:53 (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: 1177

Site Name: (1177) East-West Medical Research Institute

Subject No: 11771317

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:55

Islands	(b) (4), (b) (6)
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6.a

Date	Location	User	Value	Reason
Sep-09-2020 12:24:55 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sponsor-Defined Identifier:</b> Not Applicable <b>Test::</b> Not Applicable <b>Result::</b> Not Applicable <b>Not Done::</b> Not Applicable	Initial Entry

6.a Sponsor ID:

Date	Location	User	Value	Reason
Sep-09-2020 12:24:55 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

6.a Test:

Date	Location	User	Value	Reason
Sep-09-2020 12:24:55 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

6.a Result:

Date	Location	User	Value	Reason
Sep-09-2020 12:24:55 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

090177e196ae2fd9\Final\Final On: 01-Apr-2021 03:53 (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:** 1177

**Site Name:** (1177) East-West Medical Research Institute

**Subject No:** 11771317

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 12:55

**6.a Not Done:**

Date	Location	User	Value	Reason
Sep-09-2020 12:24:55 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**Header Text:** C4591001

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

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

**Site No:** 1177

**Subject No:** 11771317

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

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

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

**Site Name:** (1177) East-West Medical Research Institute

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 12:55

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**1. Randomization Date :**

Date	Location	User	Value	Reason
Sep-09-2020 12:25:23 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sep/9/2020	Initial Entry

**2. Randomization Number:**

Date	Location	User	Value	Reason
Sep-09-2020 12:25:23 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 255088	Initial Entry

090177e196ae2fd9\Final\Final On: 01-Apr-2021 03:53 (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:** 1177

**Site Name:** (1177) East-West Medical Research Institute

**Subject No:** 11771317

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 12:55

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**1. Data Origin**

Date	Location	User	Value	Reason
Sep-09-2020 14:11:51 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SITE	Initial Entry

**2. Sample Type**

Date	Location	User	Value	Reason
Sep-09-2020 14:11:51 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SERUM	Initial Entry

**3. Sample Collected?**

Date	Location	User	Value	Reason
Sep-09-2020 14:12:30 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Sep-09-2020 14:11:51 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Sep-09-2020 14:11:51 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES Date of Collection:	Initial Entry

090177e196ae2fd9\Final\Final On: 01-Apr-2021 03:53 (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: 1177

Site Name: (1177) East-West Medical Research Institute

Subject No: 11771317

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:55

Sep/9/2020

5.a

Date	Location	User	Value	Reason
Sep-09-2020 14:12:30 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample ID: BP0TFX</b>	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Sep-09-2020 14:12:30 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BP0TFX	Initial Entry

5.b

Date	Location	User	Value	Reason
Sep-09-2020 14:12:47 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample ID: BLCGFX</b>	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Sep-09-2020 14:12:47 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BLCGFX	Initial Entry

5.c

Date	Location	User	Value	Reason
Sep-09-2020 14:12:59 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample ID: BLCGFY</b>	Initial Entry

090177e196ae2fd9\Final\Final On: 01-Apr-2021 03:53 (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:** 1177

**Site Name:** (1177) East-West Medical Research Institute

**Subject No:** 11771317

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 12:55

Islands	(b) (4), (b) (6)
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**5.c Sample ID**

<b>Date</b>	<b>Location</b>	<b>User</b>	<b>Value</b>	<b>Reason</b>
Sep-09-2020 14:12:59 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BLCGFY	Initial Entry

**Header Text:** C4591001**Visit:** V1\_DAY1\_VAX1\_L**Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB  
- eCRF Audit Trail History**Form Version:** 22-Apr-2020 21:03**Form Status:** Data Complete, Locked, Frozen, Verified**Site No:** 1177**Site Name:** (1177) East-West Medical Research Institute**Subject No:** 11771317**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 12:55[Back to Form](#)**1. Data Origin**

Date	Location	User	Value	Reason
Sep-09-2020 14:13:36 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SITE	Initial Entry

**2. Sample Type**

Date	Location	User	Value	Reason
Sep-09-2020 14:13:36 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> NASAL_SWAB	Initial Entry

**3. Sample Collected?**

Date	Location	User	Value	Reason
Sep-09-2020 14:13:36 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES Date of Collection:  Sep/9/2020	Initial Entry

**5.a**

Date	Location	User	Value	Reason
Sep-09-2020 14:13:27 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample ID:</b> BP8J8N	Initial Entry

**5.a Sample ID**

**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:** 1177

**Site Name:** (1177) East-West Medical Research Institute

**Subject No:** 11771317

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 12:55

Date	Location	User	Value	Reason
Sep-09-2020 14:13:27 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BP8J8N	Initial Entry

**Header Text:** C4591001

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

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

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

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

**Site No:** 1177

**Site Name:** (1177) East-West Medical Research Institute

**Subject No:** 11771317

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 12:55

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

Date	Location	User	Value	Reason
Sep-09-2020 12:25:51 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**2. Treatment Name**

Date	Location	User	Value	Reason
Sep-09-2020 12:25:51 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> BLINDED THERAPY	Initial Entry

**3. Formulation:**

Date	Location	User	Value	Reason
Sep-09-2020 12:25:51 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> INJECTION	Initial Entry

**4. Dose Date Time:**

Date	Location	User	Value	Reason
Sep-09-2020 12:25:51 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sep/9/2020 08:48	Initial Entry

**5. Anatomical Location:**

Date	Location	User	Value	Reason
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090177e196ae2fd9\Final\Final On: 01-Apr-2021 03:53 (GMT)

Header Text: C4591001

Visit: V1\_DAY1\_VAX1\_L

Form: VACCINATION - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1177

Site Name: (1177) East-West Medical Research Institute

Subject No: 11771317

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:55

Sep-09-2020 12:25:51 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> DELTOID MUSCLE	Initial Entry
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**6. Body Side:**

Date	Location	User	Value	Reason
Sep-09-2020 12:25:51 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> LEFT	Initial Entry

**7. Route:**

Date	Location	User	Value	Reason
Sep-09-2020 12:25:51 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> INTRAMUSCULAR	Initial Entry

**10. Timeframe Subject Was Observed**

Date	Location	User	Value	Reason
Sep-09-2020 12:25:51 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> THE PROTOCOL SPECIFI ED OBSERVATION PERIO D	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-09-2020 12:25:51 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

090177e196ae2fd9\Final\Final On: 01-Apr-2021 03:53 (GMT)

**Header Text:** C4591001

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

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

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

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

**Site No:** 1177

**Site Name:** (1177) East-West Medical Research Institute

**Subject No:** 11771317

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 12:55

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*1. Select appropriate response - Reactogenicity diary collection*

Date	Location	User	Value	Reason
Sep-09-2020 12:26:00 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO - REACTOGENICITY E-DIARY NOT COLLECTED FOR THIS SUBJECT	Initial Entry

**Header Text:** C4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1177

**Subject No:** 11771317

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

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

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

**Site Name:** (1177) East-West Medical Research Institute

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 12:55

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*1. Date of Visit*

Date	Location	User	Value	Reason
Sep-30-2020 09:34:16 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sep/30/2020	Initial Entry

Header Text: C4591001

Visit: V2\_VAX2\_L

Form: VITAL SIGNS - TEMP - eCRF Audit Trail History

Form Version: 15-Sep-2020 21:54

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1177

Site Name: (1177) East-West Medical Research Institute

Subject No: 11771317

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:55

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**1. Date:**

Date	Location	User	Value	Reason
Sep-30-2020 09:34:38 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sep/30/2020	Initial Entry

**2.a**

Date	Location	User	Value	Reason
Sep-30-2020 09:34:38 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Record Identifier:</b> 1 <b>Temperature:</b> 97.3 <b>Temperature Unit:</b> F <b>Temperature Location:</b> FOREHEAD	Initial Entry

**2.a Record Identifier:**

Date	Location	User	Value	Reason
Sep-30-2020 09:34:38 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 1	Initial Entry

**2.a Temperature:**

Date	Location	User	Value	Reason
Sep-30-2020 09:34:38 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 97.3	Initial Entry

090177e196ae2fd9\Final\Final On: 01-Apr-2021 03:53 (GMT)



**Header Text:** C4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1177

**Subject No:** 11771317

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

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

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

**Site Name:** (1177) East-West Medical Research Institute

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 12:55

**2.a Unit:**

Date	Location	User	Value	Reason
Sep-30-2020 09:34:38 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> F	Initial Entry

**2.a Temperature Location:**

Date	Location	User	Value	Reason
Sep-30-2020 09:34:38 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> FOREHEAD	Initial Entry

090177e196ae2fd9\Final\Final On: 01-Apr-2021 03:53 (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: 1177

Site Name: (1177) East-West Medical Research Institute

Subject No: 11771317

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:55

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**1. Lab Panel:**

Date	Location	User	Value	Reason
Sep-30-2020 09:34:46 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**2. Lab Sub-Panel:**

Date	Location	User	Value	Reason
Sep-30-2020 09:34:46 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**3. Collection Date:**

Date	Location	User	Value	Reason
Sep-30-2020 09:34:46 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

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

Date	Location	User	Value	Reason
Sep-30-2020 09:34:46 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**5. Specimen Type:**

Date	Location	User	Value	Reason
Sep-30-2020 09:34:46 (UTC-10:00) Aleutian	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

090177e196ae2fd9\Final\Final On: 01-Apr-2021 03:53 (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: 1177

Site Name: (1177) East-West Medical Research Institute

Subject No: 11771317

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:55

Islands	(b) (4), (b) (6)
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6.a

Date	Location	User	Value	Reason
Sep-30-2020 09:34:46 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sponsor-Defined Identifier:</b> Not Applicable <b>Test::</b> Not Applicable <b>Result::</b> Not Applicable <b>Not Done::</b> Not Applicable	Initial Entry

6.a Sponsor ID:

Date	Location	User	Value	Reason
Sep-30-2020 09:34:46 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

6.a Test:

Date	Location	User	Value	Reason
Sep-30-2020 09:34:46 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

6.a Result:

Date	Location	User	Value	Reason
Sep-30-2020 09:34:46 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

090177e196ae2fd9\Final\Final On: 01-Apr-2021 03:53 (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:** 1177

**Site Name:** (1177) East-West Medical Research Institute

**Subject No:** 11771317

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 12:55

**6.a Not Done:**

Date	Location	User	Value	Reason
Sep-30-2020 09:34:46 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**Header Text:** C4591001

**Visit:** V2\_VAX2\_L

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

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

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

**Site No:** 1177

**Site Name:** (1177) East-West Medical Research Institute

**Subject No:** 11771317

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 12:55

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**1. Data Origin**

Date	Location	User	Value	Reason
Sep-30-2020 09:47:47 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SITE	Initial Entry

**2. Sample Type**

Date	Location	User	Value	Reason
Sep-30-2020 09:47:47 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> NASAL_SWAB	Initial Entry

**3. Sample Collected?**

Date	Location	User	Value	Reason
Sep-30-2020 09:48:02 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Sep-30-2020 09:47:47 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Sep-30-2020 09:47:47	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

090177e196ae2fd9\Final\Final On: 01-Apr-2021 03:53 (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:** 1177

**Site Name:** (1177) East-West Medical Research Institute

**Subject No:** 11771317

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 12:55

(UTC-10:00) Aleutian Islands	(b) (4), (b) (6)	Date of Collection:  Sep/30/2020
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**5.a**

Date	Location	User	Value	Reason
Sep-30-2020 09:48:02 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample ID:</b> BR92VG	Initial Entry

**5.a Sample ID**

Date	Location	User	Value	Reason
Sep-30-2020 09:48:02 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BR92VG	Initial Entry

090177e196ae2fd9\Final\Final On: 01-Apr-2021 03:53 (GMT)

Header Text: C4591001

Visit: V2\_VAX2\_L

Form: VACCINATION - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1177

Site Name: (1177) East-West Medical Research Institute

Subject No: 11771317

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:55

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

Date	Location	User	Value	Reason
Sep-30-2020 09:35:21 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**2. Treatment Name**

Date	Location	User	Value	Reason
Sep-30-2020 09:35:21 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> BLINDED THERAPY	Initial Entry

**3. Formulation:**

Date	Location	User	Value	Reason
Sep-30-2020 09:35:21 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> INJECTION	Initial Entry

**4. Dose Date Time:**

Date	Location	User	Value	Reason
Sep-30-2020 09:35:21 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sep/30/2020 08:12	Initial Entry

**5. Anatomical Location:**

Date	Location	User	Value	Reason
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090177e196ae2fd9\Final\Final On: 01-Apr-2021 03:53 (GMT)

Header Text: C4591001

Visit: V2\_VAX2\_L

Form: VACCINATION - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1177

Site Name: (1177) East-West Medical Research Institute

Subject No: 11771317

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:55

Sep-30-2020 09:35:21 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> DELTOID MUSCLE	Initial Entry
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**6. Body Side:**

Date	Location	User	Value	Reason
Sep-30-2020 09:35:21 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> LEFT	Initial Entry

**7. Route:**

Date	Location	User	Value	Reason
Sep-30-2020 09:35:21 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> INTRAMUSCULAR	Initial Entry

**10. Timeframe Subject Was Observed**

Date	Location	User	Value	Reason
Sep-30-2020 09:35:21 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> THE PROTOCOL SPECIFI ED OBSERVATION PERIO D	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-30-2020 09:35:21 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

090177e196ae2fd9\Final\Final On: 01-Apr-2021 03:53 (GMT)



**Header Text:** C4591001

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

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

**Site No:** 1177

**Subject No:** 11771317

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

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

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

**Site Name:** (1177) East-West Medical Research Institute

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 12:55

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*1. Date of Visit*

Date	Location	User	Value	Reason
Oct-28-2020 08:28:57 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Oct/28/2020	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:** 1177

**Site Name:** (1177) East-West Medical Research Institute

**Subject No:** 11771317

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 12:55

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**1. Data Origin**

Date	Location	User	Value	Reason
Oct-28-2020 09:46:39 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SITE	Initial Entry

**2. Sample Type**

Date	Location	User	Value	Reason
Oct-28-2020 09:46:39 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SERUM	Initial Entry

**3. Sample Collected?**

Date	Location	User	Value	Reason
Oct-28-2020 09:46:50 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Oct-28-2020 09:46:39 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Oct-28-2020 09:46:39 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES Date of Collection:	Initial Entry

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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: 1177

Site Name: (1177) East-West Medical Research Institute

Subject No: 11771317

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:55

Oct/28/2020

5.a

Date	Location	User	Value	Reason
Oct-28-2020 09:46:50 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sample ID: BRJ5CJ	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Oct-28-2020 09:46:50 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BRJ5CJ	Initial Entry

5.b

Date	Location	User	Value	Reason
Oct-28-2020 09:47:01 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sample ID: BSMJ5M	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Oct-28-2020 09:47:01 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BSMJ5M	Initial Entry

5.c

Date	Location	User	Value	Reason
Oct-28-2020 09:47:16 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sample ID: BSMJ5N	Initial Entry

090177e196ae2fd9\Final\Final On: 01-Apr-2021 03:53 (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:** 1177

**Site Name:** (1177) East-West Medical Research Institute

**Subject No:** 11771317

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 12:55

Islands	(b) (4), (b) (6)
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**5.c Sample ID**

Date	Location	User	Value	Reason
Oct-28-2020 09:47:16 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BSMJ5N	Initial Entry

**Header Text:** C4591001

**Visit:** End of Treatment - Unscheduled

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

**Form Version:** 15-Sep-2020 21:55

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

**Site No:** 1177

**Site Name:** (1177) East-West Medical Research Institute

**Subject No:** 11771317

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 12:55

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

Date	Location	User	Value	Reason
Oct-28-2020 08:29:07 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Oct/28/2020	Initial Entry

**2. Phase of Disposition:**

Date	Location	User	Value	Reason
Oct-28-2020 08:29:07 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> VACCINATION	Initial Entry

**3. Status:**

Date	Location	User	Value	Reason
Oct-28-2020 08:29:07 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> COMPLETED	Initial Entry

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**Header Text:** C4591001

**Visit:** Logs - Unscheduled

**Form:** ADVERSE EVENT REPORT - Audit Trail

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

**Form Status:**

**Site No:** 1177

**Site Name:** (1177) East-West Medical Research Institute

**Subject No:** 11771317

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 12:55

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Date	Location	User	Value	Reason
Dec-28-2020 10:29:31 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

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, Verified

Site No: 1177

Site Name: (1177) East-West Medical Research Institute

Subject No: 11771317

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:55

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1. Category:

Date	Location	User	Value	Reason
Dec-28-2020 10:29:31 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> ADVERSE EVENT	Initial Entry

2. AE ID:

Date	Location	User	Value	Reason
Dec-28-2020 10:29:31 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 1	Initial Entry

3. Adverse Event:

(If possible specify diagnosis, not individual symptoms)

Date	Location	User	Value	Reason
Jan-22-2021 11:42:02 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	Giselle Castillo (b) (4)	Query 1: Closed	Thanks
Jan-15-2021 15:41:08 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Per CRA, we should not leave queries open for a prolonged period of time.
Jan-14-2021 13:26:34 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	Giselle Castillo (b) (4)	Query 1: Reissued:Open ed	Thanks for confirming. Please make every effort possible to

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**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, Verified

**Site No:** 1177

**Site Name:** (1177) East-West Medical Research Institute

**Subject No:** 11771317

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 12:55

				obtain further information and respond to the query once additional information is available.
Jan-06-2021 16:44:44 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Information is unknown at this time. Information will be provided once site knows more
Jan-06-2021 13:53:16 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	Giselle Castillo (b) (4)	Query 1: Opened	Clinical_ Per report, the subject was diagnosed with Breast Cancer. However, information on clinical presentation, clinical setting of diagnosis, and workup (including imaging) are not described. Kindly provide information in a FU report. Thank you.
Dec-28-2020 10:29:31 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Breast Cancer, Stage 1	Initial Entry

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Header Text: C4591001

Visit: Logs - Unscheduled

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Site Name: (1177) East-West Medical Research Institute

Subject No: 11771317

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:55

4. Start Date Time:

Date	Location	User	Value	Reason
Dec-28-2020 10:29:31 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Nov/30/2020 14:00	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Jan-07-2021 09:28:49 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Jan-06-2021 17:00:02 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	AE was still ongoing at last contact
Jan-06-2021 12:19:45 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	ClinQuery: Please verify if Breast Cancer, Stage 1 is ongoing, then update the END DATE and OUTCOME as appropriate
Dec-28-2020 10:29:31 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
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**Header Text:** C4591001

**Visit:** Logs - Unscheduled

**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History

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**Form Status:** Data Complete, Verified

**Site No:** 1177

**Site Name:** (1177) East-West Medical Research Institute

**Subject No:** 11771317

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 12:55

Dec-28-2020 10:29:31 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 2	Initial Entry
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**7. Is the adverse event serious?**

**If Yes, NOTIFY PFIZER IMMEDIATELY.**

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

Date	Location	User	Value	Reason
Jan-01-2021 20:21:30 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Dec-28-2020 10:29:31 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	For AE Breast Cancer, Stage 1: Response to "Is the adverse event serious?" is 'Yes' but "Serious Adverse Event Number" is blank.
Dec-28-2020 10:29:31 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES Is this serious event associated with congenital anomaly or birth defect?  NO  Did this serious event res	Initial Entry

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**Header Text:** C4591001

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**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History

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**Form Status:** Data Complete, Verified

**Site No:** 1177

**Site Name:** (1177) East-West Medical Research Institute

**Subject No:** 11771317

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 12:55

			ult in death?  NO  Did this serious event require or prolong hospitalization?  NO  Did this serious event result in persistent or significant disability/incapacity?  NO  Is this serious event life threatening?  NO  Other medically important serious event  YES	
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**8. Is this adverse event the result of a study Medication Error?**  
 If Yes, record the type of medication error on the Medication Error Log.

Date	Location	User	Value	Reason
Dec-28-2020 10:29:31 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**9. Is this event related to study treatment:**

Header Text: C4591001

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Form Version: 22-Apr-2020 21:02

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Site No: 1177

Site Name: (1177) East-West Medical Research Institute

Subject No: 11771317

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:55

Date	Location	User	Value	Reason
Dec-28-2020 10:29:31 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NOT RELATED If Not Related to study treatment(s), this event is due to:  OTHER  <i>If Other, specify:</i>  Neoplasia	Initial Entry

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Dec-28-2020 10:29:31 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NOT APPLICABLE	Initial Entry

11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
Dec-28-2020 10:29:31 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Dec-28-2020 10:29:31 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

090177e196ae2fd9\Final\Final On: 01-Apr-2021 03:53 (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, Verified

Site No: 1177

Site Name: (1177) East-West Medical Research Institute

Subject No: 11771317

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:55

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

Date	Location	User	Value	Reason
Jan-18-2021 21:24:04 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Closed	Response satisfies query
Jan-18-2021 07:47:19 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Answered	Answer Auto Query
Jan-18-2021 07:47:19 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> RECOVERING/RESOLVING	Data updated and SAE follow up report submitted
Jan-18-2021 02:20:52 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Reissued: Opened	DM 1: Thank you for the response, however the response to "What was the outcome of this adverse event?" is still 'Unknown' and "Is the adverse event still ongoing?" is marked "Yes", kindly review and update the outcome of the AE.
Jan-07-2021 21:34:20 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Reissued: Candidate	Query will be followed up regarding the outcome of the AE
Jan-06-2021 16:44:01 (UTC-10:00) Aleutian	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Answered	Per CRA, queries cannot remain open for a prolonged period of time.

090177e196ae2fd9\Final\Final On: 01-Apr-2021 03:53 (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, Verified

Site No: 1177

Site Name: (1177) East-West Medical Research Institute

Subject No: 11771317

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:55

Islands				
Jan-05-2021 22:23:31 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Reissued: Opened	DM: Thank you for response. Please review once data is available and update response to "What was the outcome of this adverse event?" on this page as needed. Once CRF is updated, respond to the query.
Jan-05-2021 03:28:41 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Jan-04-2021 16:32:31 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Answered	Site will follow up regarding the outcome of the AE
Jan-04-2021 16:30:26 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Opened	For AE Breast Cancer, Stage 1: Response to "What was the outcome of this adverse event?" is 'Unknown' but End Date/Time is provided or "Is the adverse event still ongoing?" is marked "Yes".
Jan-04-2021 16:30:26 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Transcription Error
Jan-04-2021 16:30:26 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> UNKNO WN	Transcription Error

090177e196ae2fd9\Final\Final On: 01-Apr-2021 03:53 (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, Verified

**Site No:** 1177

**Site Name:** (1177) East-West Medical Research Institute

**Subject No:** 11771317

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 12:55

Jan-01-2021 20:25:24 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	SAE RECON:AER#2020511355,outcome was reported as UNKNOWN to Safety DB however, recorded as NOT RECOVERED/NOT RESOLVED on AE CRF. Please confirm correct outcome. If safety update is required, please submit a follow-up form.
Dec-28-2020 10:29:31 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NOT RE COVERE D/NOT R ESOLVE D	Initial Entry

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

Date	Location	User	Value	Reason
Dec-28-2020 10:29:31 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**15. Serious Adverse Event Number: For Pfizer Use Only**

Date	Location	User	Value	Reason
Jan-01-2021 20:21:30 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 2020511355	Initial Entry

**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:** 1177

**Site Name:** (1177) East-West Medical Research Institute

**Subject No:** 11771317

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 12:55

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Date	Location	User	Value	Reason
Oct-28-2020 08:55:26 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	(b) (4), (b) (6)	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: 1177

Site Name: (1177) East-West Medical Research Institute

Subject No: 11771317

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:55

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

Date	Location	User	Value	Reason
Oct-28-2020 08:55:26 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 1	Initial Entry

**2. Category:**

Date	Location	User	Value	Reason
Oct-28-2020 08:55:26 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> VACCINATIONS	Initial Entry

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

Date	Location	User	Value	Reason
Oct-28-2020 08:55:26 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> NO	Initial Entry

**4. Medication:**

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

Date	Location	User	Value	Reason
Oct-28-2020 08:55:26 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Flu vaccine	Initial Entry

**5. Date:**

Date	Location	User	Value	Reason
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090177e196ae2fd9\Final\Final On: 01-Apr-2021 03:53 (GMT)

**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:** 1177

**Site Name:** (1177) East-West Medical Research Institute

**Subject No:** 11771317

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 12:55

Oct-28-2020 08:55:26 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Oct/15/2020	Initial Entry
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**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:** 1177

**Site Name:** (1177) East-West Medical Research Institute

**Subject No:** 11771317

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 12:55

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**I. Date of Visit**

<b>Date</b>	<b>Location</b>	<b>User</b>	<b>Value</b>	<b>Reason</b>
Jan-14-2021 17:40:52 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Jan/14/2021	Initial Entry

090177e196ae2fd9\Final\Final On: 01-Apr-2021 03:53 (GMT)

**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:** 1177

**Site Name:** (1177) East-West Medical Research Institute

**Subject No:** 11771317

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 12:55

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

Date	Location	User	Value	Reason
Jan-14-2021 17:41:03 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Participant is willing to re- turn for Vaccination 3 Participant is:  eligible per local/natio- nal recommendations and confirmed to have received only placebo at Vaccination 1/2	Initial Entry

**Header Text:** C4591001

**Visit:** Disposition - Unscheduled

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

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

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

**Site No:** 1177

**Site Name:** (1177) East-West Medical Research Institute

**Subject No:** 11771317

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 12:55

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**1. Date Treatment Unblinded :**

Date	Location	User	Value	Reason
Jan-14-2021 17:40:44 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Jan/14/2021	Initial Entry

**2. Primary Reason for Unblinding:**

Date	Location	User	Value	Reason
Jan-14-2021 17:40:44 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> ASSESS ELIGIBILITY FOR ADDITIONAL VA CCINATION	Initial Entry

090177e196ae2fd9\Final\Final On: 01-Apr-2021 03:53 (GMT)

**Header Text:** C4591001

**Visit:** V101\_VAX3

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

**Site No:** 1177

**Subject No:** 11771317

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

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

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

**Site Name:** (1177) East-West Medical Research Institute

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 12:55

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*1. Date of Visit*

Date	Location	User	Value	Reason
Jan-18-2021 08:01:06 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Jan/18/2021	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:** 1177

**Site Name:** (1177) East-West Medical Research Institute

**Subject No:** 11771317

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 12:55

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**I. Consent Was:**

Date	Location	User	Value	Reason
Jan-18-2021 08:01:12 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> OBTAINED Date Written Consent Ob tained  Jan/18/2021	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:** 1177

**Site Name:** (1177) East-West Medical Research Institute

**Subject No:** 11771317

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 12:55

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

Date	Location	User	Value	Reason
Jan-18-2021 08:01:47 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Jan/18/2021	Initial Entry

**2. Phase of Disposition:**

Date	Location	User	Value	Reason
Jan-18-2021 08:01:47 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> REPEAT SCREENING 1	Initial Entry

**3. Status:**

Date	Location	User	Value	Reason
Jan-18-2021 08:01:47 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> COMPLETED	Initial Entry

090177e196ae2fd9\Final\Final On: 01-Apr-2021 03:53 (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:** 1177

**Site Name:** (1177) East-West Medical Research Institute

**Subject No:** 11771317

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 12:55

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**1. Lab Panel:**

Date	Location	User	Value	Reason
Jan-18-2021 08:02:06 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**2. Lab Sub-Panel:**

Date	Location	User	Value	Reason
Jan-18-2021 08:02:06 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**3. Collection Date:**

Date	Location	User	Value	Reason
Jan-18-2021 08:02:06 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

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

Date	Location	User	Value	Reason
Jan-18-2021 08:02:06 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**5. Specimen Type:**

090177e196ae2fd9\Final\Final On: 01-Apr-2021 03:53 (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: 1177

Site Name: (1177) East-West Medical Research Institute

Subject No: 11771317

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:55

Date	Location	User	Value	Reason
Jan-18-2021 08:02:06 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

6.a

Date	Location	User	Value	Reason
Jan-18-2021 08:02:06 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sponsor-Defined Identifier:</b> Not Applicable <b>Test::</b> Not Applicable <b>Result::</b> Not Applicable <b>Not Done::</b> Not Applicable	Initial Entry

6.a Sponsor ID:

Date	Location	User	Value	Reason
Jan-18-2021 08:02:06 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

6.a Test:

Date	Location	User	Value	Reason
Jan-18-2021 08:02:06 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

090177e196ae2fd9\Final\Final On: 01-Apr-2021 03:53 (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:** 1177

**Site Name:** (1177) East-West Medical Research Institute

**Subject No:** 11771317

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 12:55

**6.a Result:**

Date	Location	User	Value	Reason
Jan-18-2021 08:02:06 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**6.a Not Done:**

Date	Location	User	Value	Reason
Jan-18-2021 08:02:06 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

090177e196ae2fd9\Final\Final On: 01-Apr-2021 03:53 (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:** 1177

**Site Name:** (1177) East-West Medical Research Institute

**Subject No:** 11771317

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 12:55

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**1. Data Origin**

Date	Location	User	Value	Reason
Jan-18-2021 08:03:55 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SITE	Initial Entry

**2. Sample Type**

Date	Location	User	Value	Reason
Jan-18-2021 08:03:55 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SERUM	Initial Entry

**3. Sample Collected?**

Date	Location	User	Value	Reason
Jan-18-2021 08:04:12 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Jan-18-2021 08:03:55 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Jan-18-2021 08:03:55 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES Date of Collection:	Initial Entry

090177e196ae2fd9\Final\Final On: 01-Apr-2021 03:53 (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: 1177

Site Name: (1177) East-West Medical Research Institute

Subject No: 11771317

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:55

			Jan/18/2021	
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5.a

Date	Location	User	Value	Reason
Jan-18-2021 08:04:12 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample ID: BR8VJK</b>	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Jan-18-2021 08:04:12 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BR8VJK	Initial Entry

5.b

Date	Location	User	Value	Reason
Jan-18-2021 08:04:21 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample ID: BSH97C</b>	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Jan-18-2021 08:04:21 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BSH97C	Initial Entry

5.c

090177e196ae2fd9\Final\Final On: 01-Apr-2021 03:53 (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:** 1177

**Site Name:** (1177) East-West Medical Research Institute

**Subject No:** 11771317

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 12:55

Date	Location	User	Value	Reason
Jan-18-2021 08:04:29 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample ID:</b> BSH97D	Initial Entry

*5.c Sample ID*

Date	Location	User	Value	Reason
Jan-18-2021 08:04:29 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BSH97D	Initial Entry

090177e196ae2fd9\Final\Final On: 01-Apr-2021 03:53 (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:** 1177

**Site Name:** (1177) East-West Medical Research Institute

**Subject No:** 11771317

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 12:55

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**1. Data Origin**

Date	Location	User	Value	Reason
Jan-18-2021 08:04:55 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SITE	Initial Entry

**2. Sample Type**

Date	Location	User	Value	Reason
Jan-18-2021 08:04:55 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> NASAL_SWAB	Initial Entry

**3. Sample Collected?**

Date	Location	User	Value	Reason
Jan-18-2021 08:05:03 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Jan-18-2021 08:04:55 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Jan-18-2021 08:04:55 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES Date of Collection:	Initial Entry

090177e196ae2fd9\Final\Final On: 01-Apr-2021 03:53 (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: 1177

Site Name: (1177) East-West Medical Research Institute

Subject No: 11771317

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:55

			Jan/18/2021	
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5.a

Date	Location	User	Value	Reason
Jan-18-2021 08:05:03 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample ID: BR92C9</b>	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Jan-18-2021 08:05:03 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BR92C9	Initial Entry

090177e196ae2fd9\Final\Final On: 01-Apr-2021 03:53 (GMT)



**Header Text:** C4591001

**Visit:** V101\_VAX3

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

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

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

**Site No:** 1177

**Site Name:** (1177) East-West Medical Research Institute

**Subject No:** 11771317

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 12:55

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

Date	Location	User	Value	Reason
Jan-18-2021 08:02:28 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**2. Treatment Name**

Date	Location	User	Value	Reason
Jan-18-2021 08:02:28 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> BNT162b2	Initial Entry

**3. Formulation:**

Date	Location	User	Value	Reason
Jan-18-2021 08:02:28 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> INJECTION	Initial Entry

**4. Dose Date Time:**

Date	Location	User	Value	Reason
Jan-18-2021 08:02:28 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Jan/18/2021 07:56	Initial Entry

**5. Anatomical Location:**

Date	Location	User	Value	Reason
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090177e196ae2fd9\Final\Final On: 01-Apr-2021 03:53 (GMT)

Header Text: C4591001

Visit: V101\_VAX3

Form: VACCINATION - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:26

Form Status: Data Complete, Frozen, Verified

Site No: 1177

Site Name: (1177) East-West Medical Research Institute

Subject No: 11771317

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:55

Jan-18-2021 08:02:28 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> DELTOID MUSCLE	Initial Entry
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**6. Body Side:**

Date	Location	User	Value	Reason
Jan-18-2021 08:02:28 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> LEFT	Initial Entry

**7. Route:**

Date	Location	User	Value	Reason
Jan-18-2021 08:02:28 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> INTRAMUSCULAR	Initial Entry

**8. Actual Dose:**

Date	Location	User	Value	Reason
Jan-18-2021 08:02:28 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 30.0	Initial Entry

**9. Unit:**

Date	Location	User	Value	Reason
Jan-18-2021 08:02:28 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> ug	Initial Entry

**10. Timeframe Subject Was Observed**

Date	Location	User	Value	Reason
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090177e196ae2fd9\Final\Final On: 01-Apr-2021 03:53 (GMT)

**Header Text:** C4591001

**Visit:** V101\_VAX3

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

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

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

**Site No:** 1177

**Site Name:** (1177) East-West Medical Research Institute

**Subject No:** 11771317

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 12:55

Jan-18-2021 08:02:28 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 30 MINUTES	Initial Entry
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*11. Was the subject observed for at least the protocol specified observation period after investigational product administration?*

Date	Location	User	Value	Reason
Jan-18-2021 08:02:28 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

**Header Text:** C4591001

**Visit:** V102\_VAX4

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

**Site No:** 1177

**Subject No:** 11771317

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

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

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

**Site Name:** (1177) East-West Medical Research Institute

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 12:55

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*I. Date of Visit*

Date	Location	User	Value	Reason
Feb-08-2021 07:27:08 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	Sarah Thompson (b) (4)	<u>Data Entry:</u> Feb/8/2021	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:** 1177

**Site Name:** (1177) East-West Medical Research Institute

**Subject No:** 11771317

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 12:55

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**1. Lab Panel:**

Date	Location	User	Value	Reason
Feb-08-2021 07:27:16 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	Sarah Thompson (b) (4)	<b>Data Entry:</b> Not Applicable	Initial Entry

**2. Lab Sub-Panel:**

Date	Location	User	Value	Reason
Feb-08-2021 07:27:16 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	Sarah Thompson (b) (4)	<b>Data Entry:</b> Not Applicable	Initial Entry

**3. Collection Date:**

Date	Location	User	Value	Reason
Feb-08-2021 07:27:16 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	Sarah Thompson (b) (4)	<b>Data Entry:</b> Not Applicable	Initial Entry

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

Date	Location	User	Value	Reason
Feb-08-2021 07:27:16 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	Sarah Thompson (b) (4)	<b>Data Entry:</b> Not Applicable	Initial Entry

**5. Specimen Type:**

090177e196ae2fd9\Final\Final On: 01-Apr-2021 03:53 (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: 1177

Site Name: (1177) East-West Medical Research Institute

Subject No: 11771317

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:55

Date	Location	User	Value	Reason
Feb-08-2021 07:27:16 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	Sarah Thompson (b) (4)	<b>Data Entry:</b> Not Applicable	Initial Entry

6.a

Date	Location	User	Value	Reason
Feb-08-2021 07:27:16 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	Sarah Thompson (b) (4)	<b>Data Entry:</b> <b>Sponsor-Defi</b> Not Ap <b>ned Identifier</b> plicable : <b>Test::</b> Not Ap plicable <b>Result::</b> Not Ap plicable <b>Not Done::</b> Not Ap plicable	Initial Entry

6.a Sponsor ID:

Date	Location	User	Value	Reason
Feb-08-2021 07:27:16 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	Sarah Thompson (b) (4)	<b>Data Entry:</b> Not Applicable	Initial Entry

6.a Test:

Date	Location	User	Value	Reason
Feb-08-2021 07:27:16 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	Sarah Thompson (b) (4)	<b>Data Entry:</b> Not Applicable	Initial Entry

090177e196ae2fd9\Final\Final On: 01-Apr-2021 03:53 (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:** 1177

**Site Name:** (1177) East-West Medical Research Institute

**Subject No:** 11771317

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 12:55

**6.a Result:**

Date	Location	User	Value	Reason
Feb-08-2021 07:27:16 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	Sarah Thompson (b) (4)	<b>Data Entry:</b> Not Applicable	Initial Entry

**6.a Not Done:**

Date	Location	User	Value	Reason
Feb-08-2021 07:27:16 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	Sarah Thompson (b) (4)	<b>Data Entry:</b> Not Applicable	Initial Entry

090177e196ae2fd9\Final\Final On: 01-Apr-2021 03:53 (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:** 1177

**Site Name:** (1177) East-West Medical Research Institute

**Subject No:** 11771317

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 12:55

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**1. Data Origin**

Date	Location	User	Value	Reason
Feb-08-2021 07:35:23 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SITE	Initial Entry

**2. Sample Type**

Date	Location	User	Value	Reason
Feb-08-2021 07:35:23 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> NASAL_SWAB	Initial Entry

**3. Sample Collected?**

Date	Location	User	Value	Reason
Feb-08-2021 07:36:22 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Feb-08-2021 07:35:23 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Feb-08-2021 07:35:23	ACV0PFEINFP6000	Sarah Thompson	<b>Data Entry:</b> YES	Initial Entry

090177e196ae2fd9\Final\Final On: 01-Apr-2021 03:53 (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:** 1177

**Site Name:** (1177) East-West Medical Research Institute

**Subject No:** 11771317

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 12:55

(UTC-10:00) Aleutian Islands		(b) (4)	Date of Collection:  Feb/8/2021
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**5.a**

Date	Location	User	Value	Reason
Feb-08-2021 07:36:22 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	Sarah Thompson (b) (4)	<b>Data Entry:</b> <b>Sample ID:</b> BR92JH	Initial Entry

**5.a Sample ID**

Date	Location	User	Value	Reason
Feb-08-2021 07:36:22 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	Sarah Thompson (b) (4)	<b>Data Entry:</b> BR92JH	Initial Entry

090177e196ae2fd9\Final\Final On: 01-Apr-2021 03:53 (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:** 1177

**Site Name:** (1177) East-West Medical Research Institute

**Subject No:** 11771317

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 12:55

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

Date	Location	User	Value	Reason
Feb-08-2021 07:34:58 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	Sarah Thompson (b) (4)	<b>Data Entry:</b> NO	Initial Entry

**2. Treatment Name**

Date	Location	User	Value	Reason
Feb-08-2021 07:34:58 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> BNT162b2	Initial Entry

**3. Formulation:**

Date	Location	User	Value	Reason
Feb-08-2021 07:34:58 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> INJECTION	Initial Entry

**4. Dose Date Time:**

Date	Location	User	Value	Reason
Feb-08-2021 07:34:58 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	Sarah Thompson (b) (4)	<b>Data Entry:</b> Feb/8/2021 07:22	Initial Entry

**5. Anatomical Location:**

Date	Location	User	Value	Reason
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090177e196ae2fd9\Final\Final On: 01-Apr-2021 03:53 (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: 1177

Site Name: (1177) East-West Medical Research Institute

Subject No: 11771317

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:55

Feb-08-2021 07:34:58 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> DELTOID MUSCLE	Initial Entry
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**6. Body Side:**

Date	Location	User	Value	Reason
Feb-08-2021 07:34:58 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	Sarah Thompson (b) (4)	<b>Data Entry:</b> LEFT	Initial Entry

**7. Route:**

Date	Location	User	Value	Reason
Feb-08-2021 07:34:58 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> INTRAMUSCULAR	Initial Entry

**8. Actual Dose:**

Date	Location	User	Value	Reason
Feb-08-2021 07:34:58 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 30.0	Initial Entry

**9. Unit:**

Date	Location	User	Value	Reason
Feb-08-2021 07:34:58 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> ug	Initial Entry

090177e196ae2fd9\Final\Final On: 01-Apr-2021 03:53 (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:** 1177

**Site Name:** (1177) East-West Medical Research Institute

**Subject No:** 11771317

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 12:55

**10. Timeframe Subject Was Observed**

Date	Location	User	Value	Reason
Feb-08-2021 07:34:58 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 30 MINUTES	Initial Entry

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

Date	Location	User	Value	Reason
Feb-08-2021 07:34:58 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	Sarah Thompson (b) (4)	<b>Data Entry:</b> YES	Initial Entry

090177e196ae2fd9\Final\Final On: 01-Apr-2021 03:53 (GMT)

**Header Text:** C4591001

**Visit:** V103\_MONTH1

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

**Site No:** 1177

**Subject No:** 11771317

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

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

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

**Site Name:** (1177) East-West Medical Research Institute

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 12:55

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*1. Date of Visit*

Date	Location	User	Value	Reason
Mar-08-2021 07:16:11 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Mar/8/2021	Initial Entry

**Header Text:** C4591001

**Visit:** V103\_MONTH1

**Form:** CONTACT OUTCOME - eCRF Audit Trail History

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

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

**Site No:** 1177

**Site Name:** (1177) East-West Medical Research Institute

**Subject No:** 11771317

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 12:55

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**1. Contact Type:**

Date	Location	User	Value	Reason
Mar-08-2021 07:16:22 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> TELEPHONE VISIT	Initial Entry

**2. Was contact made?**

Date	Location	User	Value	Reason
Mar-08-2021 07:16:22 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES Date of Contact:  Mar/8/2021	Initial Entry

090177e196ae2fd9\Final\Final On: 01-Apr-2021 03:53 (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:** 1177

**Site Name:** (1177) East-West Medical Research Institute

**Subject No:** 11771317

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 12:55

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

Date	Location	User	Value	Reason
Mar-08-2021 07:16:37 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Mar/8/2021	Initial Entry

**2. Phase of Disposition:**

Date	Location	User	Value	Reason
Mar-08-2021 07:16:37 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> OPEN LABEL TREATME NT	Initial Entry

**3. Status:**

Date	Location	User	Value	Reason
Mar-08-2021 07:16:37 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> COMPLETED	Initial Entry

090177e196ae2fd9\Final\Final On: 01-Apr-2021 03:53 (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:** 1177

**Site Name:** (1177) East-West Medical Research Institute

**Subject No:** 11771317

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 12:55

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**1. Subject Status**

Date	Location	User	Value	Reason
Oct-28-2020 08:29:07 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> FOLLOW-UP	Initial Entry
Sep-09-2020 12:25:23 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> ENROLLED/RANDOMIZ ED	Initial Entry
Sep-09-2020 12:23:47 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SCREENED	Initial Entry

**2. Subject Status Date**

Date	Location	User	Value	Reason
Oct-28-2020 08:29:07 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> Oct/28/2020	Initial Entry
Sep-09-2020 12:25:23 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> Sep/9/2020	Initial Entry
Sep-09-2020 12:23:47 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> Sep/9/2020	Initial Entry

090177e196ae2fd9\Final\Final On: 01-Apr-2021 03:53 (GMT)



**Header Text:** C4591001

**Visit:** Investigator Signature -  
Unscheduled

**Form:** CASEBOOK SIGNATURE FORM - eCRF Audit Trail  
History

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

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

**Site No:** 1177

**Site Name:** (1177) East-West Medical Research Institute

**Subject No:** 11771317

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 12:55

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***I. Casebook Signature***

<b>Date</b>	<b>Location</b>	<b>User</b>	<b>Value</b>	<b>Reason</b>
Nov-03-2020 08:32:28 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Click Here to Enable	Initial Entry