

Header Text: C4591001

Visit: COHORT_SELECTION

Form: COHORT_SELECTION

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: 11771222

Subject Initials: ---

Generated By:

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

(b) (4)

[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

090177e196ae2fda\Final\Final On: 01-Apr-2021 03:53 (GMT)

Header Text: C4591001

Visit: COHORT_SELECTION

Form Version: 22-Apr-2020 21:02

Site No: 1177

Subject No: 11771222

Generated By:

(b) (4)

Form: MAIN INFORMED CONSENT

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](#)

Informed Consent

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

Header Text: C4591001

Visit: COHORT_SELECTION

Form: DEMOGRAPHY

Form Version: 06-Jul-2020 21:55

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1177

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

Subject No: 11771222

Subject Initials: ---

Generated By:

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

(b) (4)

[eCRF Audit Trail History](#)

Demography

1.	Subject ID	[11771222]
2.	Birth Date:	(b) (6)/1984
3.	Sex:	FEMALE
4.	Ethnicity:	NOT HISPANIC OR LATINO(A) OR OF SPANISH ORIGIN
5.	Race: (Check X all that apply):	WHITE
6.	Racial Designation:	

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Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:02

Site No: 1177

Subject No: 11771222

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/1/2020
2.	Erroneous Visit	

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 30-Jul-2020 21:29

Site No: 1177

Subject No: 11771222

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 _____
----	--	-------------------------

090177e196ae2fda\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: 11771222

Generated By:

(b) (4)

Form: DISPOSITION - SCREENING

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 - Screening

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

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1177

Subject No: 11771222

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

[eCRF Audit Trail History](#)

Medical History Details

1.a	Line/MH Number:	[1]
	Disease/Syndrome /Surgery/Non-Drug Allergies/Drug Allergies:	[ALLERGY TO CAT DANDER]
	Start Date:	UNK/UNK/2010
	Ongoing:	YES
1.b	Line/MH Number:	[2]
	Disease/Syndrome /Surgery/Non-Drug Allergies/Drug Allergies:	[ALLERGY TO DOG DANDER]
	Start Date:	UNK/UNK/2010
	Ongoing:	YES
1.c	Line/MH Number:	[3]
	Disease/Syndrome /Surgery/Non-Drug Allergies/Drug Allergies:	[ASTHMA]
	Start Date:	UNK/UNK/1993
	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: 11771222

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.d	Line/MH Number:	[4]
	Disease/Syndrome /Surgery/Non-Drug Allergies/Drug Allergies:	[CHOLECYSTITIS]
	Start Date:	UNK/UNK/2007
	Ongoing:	NO End Date: UNK/UNK/2007
1.e	Line/MH Number:	[5]
	Disease/Syndrome /Surgery/Non-Drug Allergies/Drug Allergies:	[TONSILLITIS]
	Start Date:	UNK/UNK/2005
	Ongoing:	NO End Date: UNK/UNK/2005
1.f	Line/MH Number:	[6]
	Disease/Syndrome /Surgery/Non-Drug Allergies/Drug Allergies:	[CHILDBIRTH]
	Start Date:	UNK/UNK/2013
	Ongoing:	NO End Date: UNK/UNK/2013

090177e196ae2fda\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: 11771222

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.g	Line/MH Number:	[7]
	Disease/Syndrome /Surgery/Non-Drug Allergies/Drug Allergies:	[CHILDBIRTH]
	Start Date:	UNK/UNK/2016
	Ongoing:	NO End Date: UNK/UNK/2016
1.h	Line/MH Number:	[8]
	Disease/Syndrome /Surgery/Non-Drug Allergies/Drug Allergies:	[CESAREAN SECTION]
	Start Date:	UNK/UNK/2013
	Ongoing:	NO End Date: UNK/UNK/2013
1.i	Line/MH Number:	[9]
	Disease/Syndrome /Surgery/Non-Drug Allergies/Drug Allergies:	[CESAREAN SECTION]
	Start Date:	UNK/UNK/2016
	Ongoing:	NO End Date: UNK/UNK/2016

090177e196ae2fda\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: 11771222

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.j	Line/MH Number:	[10]
	Disease/Syndrome /Surgery/Non-Drug Allergies/Drug Allergies:	[TONSILLECTOMY]
	Start Date:	UNK/UNK/2005
	Ongoing:	NO End Date: UNK/UNK/2005
1.k	Line/MH Number:	[11]
	Disease/Syndrome /Surgery/Non-Drug Allergies/Drug Allergies:	[CHOLECYSTECTOMY]
	Start Date:	UNK/UNK/2007
	Ongoing:	NO End Date: UNK/UNK/2007
1.l	Line/MH Number:	[12]
	Disease/Syndrome /Surgery/Non-Drug Allergies/Drug Allergies:	[BUNIONS, BOTH FEET]
	Start Date:	UNK/UNK/2018
	Ongoing:	NO End Date: Jun/UNK/2020

090177e196ae2fda\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: 11771222

Subject Initials: ---

Generated By:

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

(b) (4)

1.m	Line/MH Number:	[13]
	Disease/Syndrome /Surgery/Non-Drug Allergies/Drug Allergies:	[BUNIONECTOMY, RIGHT FOOT]
	Start Date:	Dec/UNK/2019
	Ongoing:	NO End Date: Dec/UNK/2019
1.n	Line/MH Number:	[14]
	Disease/Syndrome /Surgery/Non-Drug Allergies/Drug Allergies:	[BUNIONECTOMY, LEFT FOOT]
	Start Date:	Jun/UNK/2020
	Ongoing:	NO End Date: Jun/UNK/2020
1.o	Line/MH Number:	[15]
	Disease/Syndrome /Surgery/Non-Drug Allergies/Drug Allergies:	[SEPTOPLASTY]
	Start Date:	UNK/UNK/2005
	Ongoing:	NO End Date: UNK/UNK/2005

090177e196ae2fda\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: 11771222

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.p	Line/MH Number:	[16]
	Disease/Syndrome /Surgery/Non-Drug Allergies/Drug Allergies:	[DEVIATED SEPTUM]
	Start Date:	UNK/UNK/2005
	Ongoing:	NO End Date: UNK/UNK/2005

090177e196ae2fda\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: 11771222

Generated By:

(b) (4)

Form: VITAL SIGNS - BASELINE

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](#)

Vital Signs

1.	Date:	Sep/1/2020
2.	Weight:	[88.6]
3.	Unit:	kg
4.	Height:	[169.9]
5.	Unit:	cm
6.	Body Mass Index:	[30.7]

Vital Signs Details

7.a	Record Identifier:	1
	Temperature:	[98.1]
	Unit:	F
	Temperature Location:	FOREHEAD

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 21-Aug-2020 02:49

Site No: 1177

Subject No: 11771222

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

[eCRF Audit Trail History](#)

Lab Urinalysis

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

Lab Result

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

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1177

Subject No: 11771222

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/1/2020
2.	Randomization Number:	[77093]
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: 11771222

Subject Initials: ---

Generated By:

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

(b) (4)

[eCRF Audit Trail History](#)

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	SERUM
3.	Sample Collected?	YES Date of Collection: Sep/1/2020
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	[BP0V2D]
5.b	Sample ID	[BLCG7M]
5.c	Sample ID	[BLCG7N]

090177e196ae2fda\Final\Final On: 01-Apr-2021 03:53 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB

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: 11771222

Subject Initials: ---

Generated By:

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

(b) (4)

[eCRF Audit Trail History](#)

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Sep/1/2020
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	[BM8GHW]
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090177e196ae2fda\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: 11771222

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/1/2020 08:18
5.	Anatomical Location:	DELTOID MUSCLE
6.	Body Side:	LEFT
7.	Route:	INTRAMUSCULAR
8.	Actual Dose:	[]
9.	Unit:	
10.	Timeframe Subject Was Observed	THE PROTOCOL SPECIFIED OBSERVATION PERIOD
11.	Was the subject observed for at least the protocol specified observation period after investigational product administration?	YES

090177e196ae2fda\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: 11771222

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
----	---	---

090177e196ae2fda\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: 11771222

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/21/2020
2.	Erroneous Visit	

Header Text: C4591001

Visit: V2_VAX2_L

Form Version: 15-Sep-2020 21:54

Site No: 1177

Subject No: 11771222

Generated By:

(b) (4)

Form: VITAL SIGNS - TEMP

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](#)

Vital Signs

1.	Date:	Sep/21/2020
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Vital Signs Details

2.a	Record Identifier:	1
	Temperature:	[97.7]
	Unit:	F
	Temperature Location:	FOREHEAD

090177e196ae2fda\Final\Final On: 01-Apr-2021 03:53 (GMT)

Header Text: C4591001

Visit: V2_VAX2_L

Form Version: 21-Aug-2020 02:49

Site No: 1177

Subject No: 11771222

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

[eCRF Audit Trail History](#)

Lab Urinalysis

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

Lab Result

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

090177e196ae2fda\Final\Final On: 01-Apr-2021 03:53 (GMT)

Header Text: C4591001

Visit: V2_VAX2_L

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB

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: 11771222

Subject Initials: ---

Generated By:

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

(b) (4)

[eCRF Audit Trail History](#)

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Sep/21/2020
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[]

Aliquot

Please enter barcode for each aliquot.

5.a	Sample ID	[BP8JHS]
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090177e196ae2fda\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: 11771222

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/21/2020 08:22
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

090177e196ae2fda\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: 11771222 **Subject Initials:** ---

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

(b) (4)

[eCRF Audit Trail History](#)

Date of Visit

1.	Date of Visit	Oct/19/2020
2.	Erroneous Visit	

Header Text: C4591001**Visit:** V3_MONTH1_POSTVAX2_L **Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY**Form Version:** 22-Apr-2020 21:03 **Form Status:** Data Complete, Locked, Frozen, Verified**Site No:** 1177**Site Name:** (1177) East-West Medical Research Institute**Subject No:** 11771222**Subject Initials:** ---**Generated By:****Generated Time (GMT):** 29-Mar-2021 12:55

(b) (4)

[eCRF Audit Trail History](#)**Electronic Sample Tracking**

1.	Data Origin	SITE
2.	Sample Type	SERUM
3.	Sample Collected?	YES Date of Collection: Oct/19/2020
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[]

Aliquot

Please enter barcode for each aliquot.

5.a	Sample ID	[BRJ56H]
5.b	Sample ID	[BS8BR8]
5.c	Sample ID	[BS8BR7]

Header Text: C4591001

Visit: V4_MONTH6_L

Form Version: 22-Apr-2020 21:02

Site No: 1177

Subject No: 11771222

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: V4_MONTH6_L

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: 11771222

Subject Initials: ---

Generated By:

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

(b) (4)

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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090177e196ae2fda\Final\Final On: 01-Apr-2021 03:53 (GMT)

Header Text: C4591001

Visit: V5_MONTH12_L

Form Version: 22-Apr-2020 21:02

Site No: 1177

Subject No: 11771222

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: V5_MONTH12_L

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: 11771222

Subject Initials: ---

Generated By:

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

(b) (4)

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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090177e196ae2fda\Final\Final On: 01-Apr-2021 03:53 (GMT)

Header Text: C4591001

Visit: V6_MONTH24_L

Form Version: 22-Apr-2020 21:02

Site No: 1177

Subject No: 11771222

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: V6_MONTH24_L

Form Version: 22-Apr-2020 21:03

Site No: 1177

Subject No: 11771222

Generated By:

(b) (4)

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Status: Not Started

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

Subject Initials: ---

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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090177e196ae2fda\Final\Final On: 01-Apr-2021 03:53 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL - New
Unscheduled Visit

Form: DATE OF VISIT - ILLNESS ONSET

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1177

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

Subject No: 11771222

Subject Initials: ---

Generated By:

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

(b) (4)

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

COVID-19 Illness Visit

3.	COVID-19 Illness Visit:	
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Header Text: C4591001**Visit:** POT_COVID_ILL - New
Unscheduled Visit**Form Version:** 20-Feb-2021 02:17**Site No:** 1177**Subject No:** 11771222**Generated By:**

(b) (4)

Form: SIGNS AND SYMPTOMS OF POTENTIAL
COVID-19**Form Status:** Not Started**Site Name:** (1177) East-West Medical Research Institute**Subject Initials:** ---**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:	[]
----	------------------------	-----

Header Text: C4591001

Visit: POT_COVID_ILL - New
Unscheduled Visit

Form Version: 22-Apr-2020 21:03

Site No: 1177

Subject No: 11771222

Generated By:

(b) (4)

Form: ELECTRONIC SAMPLE TRACKING - NASAL
SWAB SELF

Form Status: Not Started

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

Subject Initials: ---

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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090177e196ae2fda\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:** 11771222**Subject Initials:** ---**Generated By:****Generated Time (GMT):** 29-Mar-2021 12:55

(b) (4)

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: 11771222

Subject Initials: ---

Generated By:

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

(b) (4)

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?	
----	--	--

090177e196ae2fda\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: 11771222

Subject Initials: ---

Generated By:

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

(b) (4)

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: 11771222

Subject Initials: ---

Generated By:

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

(b) (4)

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:** 11771222**Subject Initials:** ---**Generated By:****Generated Time (GMT):** 29-Mar-2021 12:55

(b) (4)

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: Unplanned - New Unscheduled **Form:** DATE OF VISIT
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: 11771222

Subject Initials: ---

Generated By:

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

(b) (4)

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

Header Text: C4591001

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

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

Site No: 1177 **Site Name:** (1177) East-West Medical Research Institute

Subject No: 11771222 **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: 11771222

Subject Initials: ---

Generated By:

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

(b) (4)

[eCRF Audit Trail History](#)

Disposition - Treatment

1.	Date of Completion/Discontinuation /Death :	Oct/19/2020
2.	Phase of Disposition:	VACCINATION
3.	Status:	COMPLETED
4.	Specify Status:	[]

090177e196ae2fda\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: 11771222

Subject Initials: ---

Generated By:

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

(b) (4)

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 **Form:** DATE OF VISIT - REPEAT SWAB
- New Unscheduled Visit

Form Version: 10-Oct-2020 15:57 **Form Status:** Not Started

Site No: 1177

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

Subject No: 11771222

Subject Initials: ---

Generated By:

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

(b) (4)

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

COVID-19 Repeat Swab

3.	COVID-19 Repeat Swab:	
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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:** 11771222**Subject Initials:** ---**Generated By:****Generated Time (GMT):** 29-Mar-2021 12:55

(b) (4)

Electronic Sample Tracking

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

Aliquot

Please enter barcode for each aliquot.

5.	Sample ID	[]
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Header Text: C4591001

Visit: Logs

Form: ADVERSE EVENT REPORT

Form Version: 22-Apr-2020 21:02

Site No: 1177

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

Subject No: 11771222

Subject Initials: ---

Generated By:

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

(b) (4)

#	Category	AE Identifier	Adverse Event	Start Date	Is the Adverse Event Still Ongoing	Form Instance
1.	ADVERSE EVENT	1	BODY ACHES	Sep/21/2020 18:00	NO End Date Time: Sep/23/2020 07:30	Repeating Pages
2.	ADVERSE EVENT	2	HEADACHE	Sep/21/2020 18:00	NO End Date Time: Sep/23/2020 07:30	Repeating Pages
3.	ADVERSE EVENT	3	NAUSEA	Sep/21/2020 18:00	NO End Date Time: Sep/21/2020 21:00	Repeating Pages
4.	ADVERSE EVENT	4	Exposure During Pregnancy	Nov/13/2020 18:00	NO End Date Time: Dec/23/2020 12:00	Repeating Pages

090177e196ae2fda\Final\Final On: 01-Apr-2021 03:53 (GMT)

Header Text: C4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Locked, Frozen

Site No: 1177

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

Subject No: 11771222

Subject Initials: ---

Generated By:

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)	[BODY ACHES]
4.	Start Date Time:	Sep/21/2020 18:00
5.	Is the adverse event still ongoing?	NO End Date Time: Sep/23/2020 07:30
6.	Toxicity Grade:	3

090177e196ae2fda\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: 11771222

Generated By:

(b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Locked, Frozen

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

Subject Initials: ---

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

7.	Is the adverse event serious? If Yes, NOTIFY PFIZER IMMEDIATELY. Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).	NO
8.	Is this adverse event the result of a study Medication Error? If Yes, record the type of medication error on the Medication Error Log.	NO
9.	Is this event related to study treatment:	RELATED
10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE
11.	Was a Concomitant Medication given?	YES

090177e196ae2fda\Final\Final On: 01-Apr-2021 03:53 (GMT)

Header Text: C4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Locked, Frozen

Site No: 1177

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

Subject No: 11771222

Subject Initials: ---

Generated By:

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

(b) (4)

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

090177e196ae2fda\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: 11771222

Generated By:

(b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Locked, Frozen

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:	[2]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[HEADACHE]
4.	Start Date Time:	Sep/21/2020 18:00
5.	Is the adverse event still ongoing?	NO End Date Time: Sep/23/2020 07:30
6.	Toxicity Grade:	2

090177e196ae2fda\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: 11771222

Generated By:

(b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Locked, Frozen

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

Subject Initials: ---

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

7.	Is the adverse event serious? If Yes, NOTIFY PFIZER IMMEDIATELY. Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).	NO
8.	Is this adverse event the result of a study Medication Error? If Yes, record the type of medication error on the Medication Error Log.	NO
9.	Is this event related to study treatment:	RELATED
10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE
11.	Was a Concomitant Medication given?	NO

090177e196ae2fda\Final\Final On: 01-Apr-2021 03:53 (GMT)

Header Text: C4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Locked, Frozen

Site No: 1177

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

Subject No: 11771222

Subject Initials: ---

Generated By:

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

(b) (4)

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

090177e196ae2fda\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: 11771222

Generated By:

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Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Locked, Frozen

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:	[3]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[NAUSEA]
4.	Start Date Time:	Sep/21/2020 18:00
5.	Is the adverse event still ongoing?	NO End Date Time: Sep/21/2020 21:00
6.	Toxicity Grade:	1

Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1177

Subject No: 11771222

Generated By:

(b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Locked, Frozen

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

Subject Initials: ---

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

7.	Is the adverse event serious? If Yes, NOTIFY PFIZER IMMEDIATELY. Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).	NO
8.	Is this adverse event the result of a study Medication Error? If Yes, record the type of medication error on the Medication Error Log.	NO
9.	Is this event related to study treatment:	RELATED
10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE
11.	Was a Concomitant Medication given?	NO

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Header Text: C4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Locked, Frozen

Site No: 1177

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

Subject No: 11771222

Subject Initials: ---

Generated By:

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

(b) (4)

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

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Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1177

Subject No: 11771222

Generated By:

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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:	[4]	
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[Exposure During Pregnancy]	
4.	Start Date Time:	Nov/13/2020 18:00	
5.	Is the adverse event still ongoing?	NO End Date Time: Dec/23/2020 12:00	
6.	Toxicity Grade:	Not Applicable	Comments

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Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1177

Subject No: 11771222

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

7.	Is the adverse event serious? If Yes, NOTIFY PFIZER IMMEDIATELY. Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).	NO
8.	Is this adverse event the result of a study Medication Error? If Yes, record the type of medication error on the Medication Error Log.	NO
9.	Is this event related to study treatment:	NOT RELATED If Not Related to study treatment(s), this event is due to: OTHER If Other, specify: [Conception]
10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE

090177e196ae2fda\Final\Final On: 01-Apr-2021 03:53 (GMT)

Header Text: C4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT

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: 11771222

Subject Initials: ---

Generated By:

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

(b) (4)

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

090177e196ae2fda\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: 11771222

Subject Initials: ---

Generated By:

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

(b) (4)

#	Category	Medication Error	Start Date	Is the medication error Still Ongoing	Study Medication Errors Action	Form Instance
1.						Repeating Pages

Header Text: C4591001

Visit: Logs - Unscheduled

Form: MEDICATION ERROR

Form Version: 17-Jul-2020 21:54

Form Status: Not Started

Site No: 1177

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

Subject No: 11771222

Subject Initials: ---

Generated By:

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

(b) (4)

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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	[]

090177e196ae2fda\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: 11771222

Subject Initials: ---

Generated By:

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

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

Header Text: C4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - NON STUDY VACCINATIONS

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1177

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

Subject No: 11771222

Subject Initials: ---

Generated By:

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

(b) (4)

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Concomitant Medications

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

090177e196ae2fda\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: 11771222

Subject Initials: ---

Generated By:

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

(b) (4)

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

Header Text: C4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - PROHIBITED

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1177

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

Subject No: 11771222

Subject Initials: ---

Generated By:

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

(b) (4)

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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?	

090177e196ae2fda\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: 11771222

Subject Initials: ---

Generated By:

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

(b) (4)

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

Header Text: C4591001

Visit: Logs - Unscheduled

Form: RADIATION TREATMENT

Form Version: 22-Apr-2020 21:02

Form Status: Not Started

Site No: 1177

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

Subject No: 11771222

Subject Initials: ---

Generated By:

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

(b) (4)

[Back to Form](#)

Radiation Treatment

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

090177e196ae2fda\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: 11771222

Subject Initials: ---

Generated By:

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

(b) (4)

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

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: 11771222

Subject Initials: ---

Generated By:

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

(b) (4)

[Back to Form](#)

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

Header Text: C4591001

Visit: Unplanned Vaccination -
Unscheduled

Form: DATE OF VISIT

Form Version: 22-Apr-2020 21:02

Form Status: Not Started

Site No: 1177

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

Subject No: 11771222

Subject Initials: ---

Generated By:

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

(b) (4)

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: 11771222

Subject Initials: ---

Generated By:

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

(b) (4)

Vital Signs

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

Vital Signs Details

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

090177e196ae2fda\Final\Final On: 01-Apr-2021 03:53 (GMT)

Header Text: C4591001**Visit:** Unplanned Vaccination -
Unscheduled**Form:** LAB URINALYSIS - PREGNANCY TEST**Form Version:** 20-Feb-2021 02:14**Form Status:** Not Started**Site No:** 1177**Site Name:** (1177) East-West Medical Research Institute**Subject No:** 11771222**Subject Initials:** ---**Generated By:****Generated Time (GMT):** 29-Mar-2021 12:55

(b) (4)

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: 11771222

Subject Initials: ---

Generated By:

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

(b) (4)

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?	

090177e196ae2fda\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: 11771222

Subject Initials: ---

Generated By:

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

(b) (4)

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: 11771222

Subject Initials: ---

Generated By:

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

(b) (4)

Contact Outcome

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

Header Text: C4591001

Visit: V201_SURVEIL_CONSENT - **Form:** DATE OF VISIT
Unscheduled

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

Site No: 1177

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

Subject No: 11771222

Subject Initials: ---

Generated By:

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

(b) (4)

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

Header Text: C4591001

Visit: V201_SURVEIL_CONSENT -
Unscheduled

Form: INFORMED CONSENT - ASYMPTOMATIC
SURVEILLANCE

Form Version: 14-Jan-2021 02:29

Form Status: Not Started

Site No: 1177

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

Subject No: 11771222

Subject Initials: ---

Generated By:

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

(b) (4)

Informed Consent - Asymptomatic Surveillance

1.	Consent Was:	
----	--------------	--

Header Text: C4591001**Visit:** V201_SURVEIL_CONSENT -
Unscheduled**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:** 11771222**Subject Initials:** ---**Generated By:****Generated Time (GMT):** 29-Mar-2021 12:55

(b) (4)

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:** V201_SURVEIL_CONSENT -
Unscheduled**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:** 11771222**Subject Initials:** ---**Generated By:****Generated Time (GMT):** 29-Mar-2021 12:55

(b) (4)

Electronic Sample Tracking

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

Aliquot

Please enter barcode for each aliquot.

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

Header Text: C4591001

Visit: Potential ReVax Initial Contact - **Form:** DATE OF VISIT
Unscheduled

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: 11771222 **Subject Initials:** ---

Generated By: **Generated Time (GMT):** 29-Mar-2021 12:55
(b) (4)

[eCRF Audit Trail History](#)

Date of Visit		
1.	Date of Visit	Dec/17/2020
2.	Erroneous Visit	

Header Text: C4591001

Visit: Potential ReVax Initial Contact - **Form:** FURTHER VACCINATION CONFIRMATION
Unscheduled

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: 11771222 **Subject Initials:** ---

Generated By: **Generated Time (GMT):** 29-Mar-2021 12:55
(b) (4)

[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 and NOT 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: 11771222

Subject Initials: ---

Generated By:

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

(b) (4)

[eCRF Audit Trail History](#)

Treatment Unblinded

1.	Date Treatment Unblinded :	Dec/17/2020
2.	Primary Reason for Unblinding:	ASSESS ELIGIBILITY FOR ADDITIONAL VACCINATION

Header Text: C4591001

Visit: Disposition - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1177

Subject No: 11771222

Generated By:

(b) (4)

Form: WITHDRAWAL OF CONSENT

Form Status: Not Started

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

Subject Initials: ---

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: 11771222

Subject Initials: ---

Generated By:

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

(b) (4)

Death Details

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

Cause of Death

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

Header Text: C4591001

Visit: Subject Status - Unscheduled

Form: 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: 11771222

Subject Initials: ---

Generated By:

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

(b) (4)

[eCRF Audit Trail History](#)

Subject Status

1.	Subject Status	FOLLOW-UP
2.	Subject Status Date	Oct/19/2020

Header Text: C4591001

Visit: Investigator Signature -
Unscheduled

Form: CASEBOOK SIGNATURE FORM

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Signed, Verified

Site No: 1177

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

Subject No: 11771222

Subject Initials: ---

Generated By:

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

(b) (4)

[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: 11771222

Subject Initials: ---

Generated By:

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

(b) (4)

[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-09-2021 12:05:39 (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.

090177e196ae2fda\Final\Final On: 01-Apr-2021 03:53 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form: INCLUSION/EXCLUSION CRITERIA -
Comments

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: 11771222

Subject Initials: ---

Generated By:

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

(b) (4)

[Back to Form](#)

Item	Date	User	Comment
Form	Sep-01-2020 09:18:27 (UTC-10:00) Aleutian Islands	(b) (4), (b) (6)	Not Applicable

Header Text: C4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - Comments

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Locked, Frozen

Site No: 1177

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

Subject No: 11771222

Subject Initials: ---

Generated By:

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

(b) (4)

[Back to Form](#)

Item	Date	User	Comment
6	Dec-08-2020 12:07:48 (UTC-10:00) Aleutian Islands	(b) (4), (b) (6)	Not Applicable

090177e196ae2fda\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: 11771222

Subject Initials: ---

Generated By:

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

(b) (4)

[Back to Form](#)

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-09-2021 12:05:39 (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.

(b) (6) [Redacted]	N/A	Mar-09-2021 12:05:10 (UTC-10:00) Aleutian Islands		Edit - All signatures invalidated
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Affidavit:

N/A

David Fitz-Patrick	Approved	Jan-20-2021 10:42:23 (UTC-10:00) Aleutian Islands	BOOK	Signed
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090177e196ae2fda\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: 11771222

Subject Initials: ---

Generated By:

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

(b) (4)

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) [Redacted]	N/A	Dec-17-2020 18:01:46 (UTC-10:00) Aleutian Islands		Edit - All signatures invalidated
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Affidavit:

N/A

David Fitz-Patrick	Approved	Dec-09-2020 08:40:30 (UTC-10:00) Aleutian Islands	BOOK	Signed
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090177e196ae2fda\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: 11771222

Subject Initials: ---

Generated By:

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

(b) (4)

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-04-2020 12:29:06 (UTC-10:00) Aleutian Islands		Edit - All signatures invalidated
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Affidavit:

N/A

David Fitz-Patrick	Approved	Oct-27-2020 11:49:20 (UTC-10:00) Aleutian Islands	BOOK	Signed
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090177e196ae2fda\Final\Final On: 01-Apr-2021 03:53 (GMT)

Header Text: C4591001

Visit: Investigator Signature -
Unscheduled

Form Version: 22-Apr-2020 21:04

Site No: 1177

Subject No: 11771222

Generated By:

(b) (4)

Form: CASEBOOK SIGNATURE FORM - Signature
History

Form Status: Data Complete, Signed, Verified

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

Subject Initials: ---

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

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.

090177e196ae2fda\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: 11771222

Subject Initials: ---

Generated By:

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

(b) (4)

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1. Select appropriate response - Protocol version

Date	Location	User	Value	Reason
Sep-01-2020 09:17:35 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 24 JUL 2020	Initial Entry

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

Date	Location	User	Value	Reason
Sep-01-2020 09:17:35 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: STAGE 3 COHORT S	Initial Entry

090177e196ae2fda\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: 11771222

Subject Initials: ---

Generated By:

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

(b) (4)

[Back to Form](#)

1. Consent Was:

Date	Location	User	Value	Reason
Sep-01-2020 09:17:44 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: OBTAINED Date Written Consent Obtained Sep/1/2020	Initial Entry

090177e196ae2fda\Final\Final On: 01-Apr-2021 03:53 (GMT)

Header Text: C4591001

Visit: COHORT_SELECTION

Form Version: 06-Jul-2020 21:55

Site No: 1177

Subject No: 11771222

Generated By:

(b) (4)

Form: DEMOGRAPHY - 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

[Back to Form](#)

1. Subject ID

Date	Location	User	Value	Reason
Sep-01-2020 09:17:15 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 11771222	Item copied from previous form

2. Birth Date:

Date	Location	User	Value	Reason
Sep-01-2020 09:17:11 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: (b) (6)/1984	Enrollment Entry

3. Sex:

Date	Location	User	Value	Reason
Sep-01-2020 09:17:59 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: FEMALE	Initial Entry

4. Ethnicity:

Date	Location	User	Value	Reason
Sep-01-2020 09:17:59	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NOT HISPANIC OR	Initial Entry

090177e196ae2fda\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, Locked, Frozen, Verified

Site No: 1177

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

Subject No: 11771222

Subject Initials: ---

Generated By:

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

(b) (4)

(UTC-10:00)
Aleutian Islands

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

LATINO(A) OR OF
SPANISH ORIGIN

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

Date	Location	User	Value	Reason
Sep-01-2020 09:17:59 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: WHITE	Initial Entry

090177e196ae2fda\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: 11771222

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-01-2020 09:18:12 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sep/1/2020	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: 11771222

Subject Initials: ---

Generated By:

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

(b) (4)

[Back to Form](#)

1. Date of Completion/Discontinuation/Death

Date	Location	User	Value	Reason
Sep-01-2020 09:18:51 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sep/1/2020	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Sep-01-2020 09:18:51 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SCREENING	Initial Entry

3. Status:

Date	Location	User	Value	Reason
Sep-01-2020 09:18:51 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: COMPLETED	Initial Entry

090177e196ae2fda\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: 11771222

Subject Initials: ---

Generated By:

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

(b) (4)

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1.a

Date	Location	User	Value	Reason
Sep-01-2020 09:27:22 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH 1 Number: Medical History Term: ALLERGY TO CAT D ANDER Start Date: UNK/UNK/ 2010 Ongoing: YES	Initial Entry

1.a Line/MH Number:

Date	Location	User	Value	Reason
Sep-01-2020 09:27:22 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 1	Initial Entry

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

Date	Location	User	Value	Reason
Sep-01-2020 09:27:22 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: ALLERGY TO CAT DANDER	Initial Entry

090177e196ae2fda\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: 11771222

Subject Initials: ---

Generated By:

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

(b) (4)

1.a Start Date:

Date	Location	User	Value	Reason
Sep-01-2020 09:27:22 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNK/UNK/2010	Initial Entry

1.a Ongoing:

Date	Location	User	Value	Reason
Sep-01-2020 09:27:22 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

1.b

Date	Location	User	Value	Reason
Sep-01-2020 09:27:37 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH 2 Number: Medical History Term: ALLERGY TO DOG D ANDER Start Date: UNK/UNK/2010 Ongoing : YES	Initial Entry

090177e196ae2fda\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: 11771222

Subject Initials: ---

Generated By:

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

(b) (4)

1.b Line/MH Number:

Date	Location	User	Value	Reason
Sep-01-2020 09:27:37 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 2	Initial Entry

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

Date	Location	User	Value	Reason
Sep-01-2020 09:27:37 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: ALLERGY TO DOG DANDER	Initial Entry

1.b Start Date:

Date	Location	User	Value	Reason
Sep-01-2020 09:27:37 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNK/UNK/2010	Initial Entry

1.b Ongoing:

Date	Location	User	Value	Reason
Sep-01-2020 09:27:37 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

090177e196ae2fda\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: 11771222

Subject Initials: ---

Generated By:

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

(b) (4)

I.c

Date	Location	User	Value	Reason
Sep-01-2020 09:27:51 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH N umber: 3 Medical History Term: ASTHM A Start Date: UNK/U NK/1993 Ongoing: YES	Initial Entry

090177e196ae2fda\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: 11771222

Subject Initials: ---

Generated By:

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

(b) (4)

I.c Line/MH Number:

Date	Location	User	Value	Reason
Sep-01-2020 09:27:51 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 3	Initial Entry

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

Date	Location	User	Value	Reason
Sep-01-2020 09:27:51 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: ASTHMA	Initial Entry

I.c Start Date:

Date	Location	User	Value	Reason
Sep-01-2020 09:27:51 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNK/UNK/1993	Initial Entry

I.c Ongoing:

Date	Location	User	Value	Reason
Sep-01-2020 09:27:51 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

090177e196ae2fda\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: 11771222

Subject Initials: ---

Generated By:

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

(b) (4)

1.d

Date	Location	User	Value	Reason
Sep-01-2020 09:29:10 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH 4 Number: Medical History Term: CHOLEC YSTITIS m: Start Date UNK/UN : K/2007 Ongoing: NO End Date : UNK/U NK/200 7	Initial Entry

090177e196ae2fda\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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Site No: 1177

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

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Subject Initials: ---

Generated By:

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

(b) (4)

1.d Line/MH Number:

Date	Location	User	Value	Reason
Sep-01-2020 09:29:10 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 4	Initial Entry

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

Date	Location	User	Value	Reason
Sep-01-2020 09:29:10 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: CHOLECYSTITIS	Initial Entry

1.d Start Date:

Date	Location	User	Value	Reason
Sep-01-2020 09:29:10 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNK/UNK/2007	Initial Entry

1.d Ongoing:

Date	Location	User	Value	Reason
Sep-01-2020 09:29:10 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO End Date:	Initial Entry

090177e196ae2fda\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: 11771222

Subject Initials: ---

Generated By:

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

(b) (4)

UNK/UNK/2007

I.e

Date	Location	User	Value	Reason
Sep-01-2020 09:29:26 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH 5 Number: Medical History Term: TONSILLITIS Start Date: UNK/UNK/2005 Ongoing: NO End Date: UNK/UNK/2005	Initial Entry

090177e196ae2fda\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: 11771222

Subject Initials: ---

Generated By:

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

(b) (4)

1.e Line/MH Number:

Date	Location	User	Value	Reason
Sep-01-2020 09:29:26 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 5	Initial Entry

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

Date	Location	User	Value	Reason
Sep-01-2020 09:29:26 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: TONSILLITIS	Initial Entry

1.e Start Date:

Date	Location	User	Value	Reason
Sep-01-2020 09:29:26 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNK/UNK/2005	Initial Entry

1.e Ongoing:

Date	Location	User	Value	Reason
Sep-01-2020 09:29:26 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO End Date:	Initial Entry

090177e196ae2fda\Final\Final On: 01-Apr-2021 03:53 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

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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: 11771222

Subject Initials: ---

Generated By:

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

(b) (4)

UNK/UNK/2005

If

Date	Location	User	Value	Reason
Sep-01-2020 09:29:58 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Line/M 6 H Number: Medical History Term: CHILDB IRTH Start Date: UNK/UNK/2013 Ongoing: NO : End Date: UNK/ UNK/ 2013	Transcription Error
Sep-01-2020 09:29:44 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/M 6 H Number: Medical History Term: CHILDB RITH Start Date: UNK/UNK/2013	Initial Entry

090177e196ae2fda\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: 11771222

Generated By:

(b) (4)

Form: GENERAL MEDICAL HISTORY - 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

			Ongoing NO : End Da te: UNK/ UNK/ 2013	
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Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

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Site No: 1177

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

Subject No: 11771222

Subject Initials: ---

Generated By:

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

(b) (4)

If Line/MH Number:

Date	Location	User	Value	Reason
Sep-01-2020 09:29:44 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 6	Initial Entry

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

Date	Location	User	Value	Reason
Sep-01-2020 09:29:58 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: CHILDBIRTH	Transcription Error
Sep-01-2020 09:29:44 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: CHILDBRITH	Initial Entry

If Start Date:

Date	Location	User	Value	Reason
Sep-01-2020 09:29:44 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNK/UNK/2013	Initial Entry

If Ongoing:

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: 11771222

Subject Initials: ---

Generated By:

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

(b) (4)

Sep-01-2020 09:29:44 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO End Date: UNK/UNK/2013	Initial Entry
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I.g

Date	Location	User	Value	Reason
Sep-01-2020 09:30:11 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH 7 Number: Medical History Term: CHILDBI RTH Start Date: UNK/UNK/2016 Ongoing: NO End Date: UNK/UNK/2016	Initial Entry

090177e196ae2fda\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: 11771222

Subject Initials: ---

Generated By:

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

(b) (4)

1.g Line/MH Number:

Date	Location	User	Value	Reason
Sep-01-2020 09:30:11 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 7	Initial Entry

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

Date	Location	User	Value	Reason
Sep-01-2020 09:30:11 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: CHILDBIRTH	Initial Entry

1.g Start Date:

Date	Location	User	Value	Reason
Sep-01-2020 09:30:11 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNK/UNK/2016	Initial Entry

1.g Ongoing:

Date	Location	User	Value	Reason
Sep-01-2020 09:30:11 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO End Date:	Initial Entry

090177e196ae2fda\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: 11771222

Subject Initials: ---

Generated By:

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

(b) (4)

UNK/UNK/2016

1.h

Date	Location	User	Value	Reason
Sep-01-2020 09:30:43 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH 8 Number: Medical History CESAREA Term: T N SECTIO Start Date: UNK/UNK /2013 Ongoing: NO End Date: UNK/U NK/201 3	Initial Entry

090177e196ae2fda\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 Name: (1177) East-West Medical Research Institute

Site No: 1177

Subject No: 11771222

Subject Initials: ---

Generated By:

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

(b) (4)

1.h Line/MH Number:

Date	Location	User	Value	Reason
Sep-01-2020 09:30:43 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 8	Initial Entry

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

Date	Location	User	Value	Reason
Sep-01-2020 09:30:43 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: CESAREAN SECTI ON	Initial Entry

1.h Start Date:

Date	Location	User	Value	Reason
Sep-01-2020 09:30:43 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNK/UNK/2013	Initial Entry

1.h Ongoing:

Date	Location	User	Value	Reason
Sep-01-2020 09:30:43 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO End Date:	Initial Entry

090177e196ae2fda\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: 11771222

Subject Initials: ---

Generated By:

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

(b) (4)

UNK/UNK/2013

1.i

Date	Location	User	Value	Reason
Sep-01-2020 09:30:56 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH 9 Number: Medical History CESAREA Term: T N SECTIO Start Date: UNK/UNK /2016 Ongoing: NO End Date: UNK/U NK/201 6	Initial Entry

090177e196ae2fda\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 Name: (1177) East-West Medical Research Institute

Site No: 1177

Subject No: 11771222

Subject Initials: ---

Generated By:

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

(b) (4)

1.i Line/MH Number:

Date	Location	User	Value	Reason
Sep-01-2020 09:30:56 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 9	Initial Entry

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

Date	Location	User	Value	Reason
Sep-01-2020 09:30:56 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: CESAREAN SECTI ON	Initial Entry

1.i Start Date:

Date	Location	User	Value	Reason
Sep-01-2020 09:30:56 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNK/UNK/2016	Initial Entry

1.i Ongoing:

Date	Location	User	Value	Reason
Sep-01-2020 09:30:56 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO End Date:	Initial Entry

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Header Text: C4591001

Visit: V1_DAY1_VAX1_L

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

Subject No: 11771222

Subject Initials: ---

Generated By:

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

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I,j

Date	Location	User	Value	Reason
Sep-01-2020 09:31:15 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH 10 Number: Medical History Term: TONSILLECTOMY Start Date: UNK/UNK/2005 Ongoing: NO End Date: UNK/UNK/2005	Initial Entry

090177e196ae2fda\Final\Final On: 01-Apr-2021 03:53 (GMT)

Header Text: C4591001

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Subject No: 11771222

Subject Initials: ---

Generated By:

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(b) (4)

1.j Line/MH Number:

Date	Location	User	Value	Reason
Sep-01-2020 09:31:15 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 10	Initial Entry

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

Date	Location	User	Value	Reason
Sep-01-2020 09:31:15 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: TONSILLECTOMY	Initial Entry

090177e196ae2fda\Final\Final On: 01-Apr-2021 03:53 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

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Subject No: 11771222

Subject Initials: ---

Generated By:

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(b) (4)

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1.j Start Date:

Date	Location	User	Value	Reason
Sep-01-2020 09:31:15 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNK/UNK/2005	Initial Entry

1.j Ongoing:

Date	Location	User	Value	Reason
Sep-01-2020 09:31:15 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO End Date: UNK/UNK/2005	Initial Entry

1.k

Date	Location	User	Value	Reason
Sep-01-2020 09:31:39 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH 11 Number: Medical History T CHOLECY STECTOM erm: Y Start Date: UNK/UNK/ 2007	Initial Entry

090177e196ae2fda\Final\Final On: 01-Apr-2021 03:53 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

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Subject No: 11771222

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(b) (4)

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

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

			Ongoing: NO	
			End Date:	
			UNK/U	
			NK/200	
			7	

Header Text: C4591001

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Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

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Site No: 1177

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

Subject No: 11771222

Subject Initials: ---

Generated By:

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

(b) (4)

1.k Line/MH Number:

Date	Location	User	Value	Reason
Sep-01-2020 09:31:39 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 11	Initial Entry

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

Date	Location	User	Value	Reason
Sep-01-2020 09:31:39 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: CHOLECYSTECTO MY	Initial Entry

1.k Start Date:

Date	Location	User	Value	Reason
Sep-01-2020 09:31:39 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNK/UNK/2007	Initial Entry

1.k Ongoing:

Date	Location	User	Value	Reason
Sep-01-2020 09:31:39 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO End Date:	Initial Entry

090177e196ae2fda\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: 11771222

Subject Initials: ---

Generated By:

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

(b) (4)

UNK/UNK/2007

1.1

Date	Location	User	Value	Reason
Sep-01-2020 09:32:09 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH 12 Number: Medical History BUNIONS, BOTH FEE Term: T Start Date: UNK/UNK/2018 Ongoing: NO End Date: Jun/UNK/2020	Initial Entry

090177e196ae2fda\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 Name: (1177) East-West Medical Research Institute

Site No: 1177

Subject No: 11771222

Subject Initials: ---

Generated By:

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

(b) (4)

1.1 Line/MH Number:

Date	Location	User	Value	Reason
Sep-01-2020 09:32:09 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 12	Initial Entry

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

Date	Location	User	Value	Reason
Sep-01-2020 09:32:09 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BUNIONS, BOTH F EET	Initial Entry

1.1 Start Date:

Date	Location	User	Value	Reason
Sep-01-2020 09:32:09 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNK/UNK/2018	Initial Entry

1.1 Ongoing:

Date	Location	User	Value	Reason
Sep-01-2020 09:32:09 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO End Date:	Initial Entry

090177e196ae2fda\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: 11771222

Subject Initials: ---

Generated By:

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

(b) (4)

Jun/UNK/2020

1.m

Date	Location	User	Value	Reason
Sep-01-2020 09:32:42 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/M 13 H Num ber: Medical BUNIONEC History TOMY, RIG Term: HT FOOT Start D Dec/UNK/20 ate: 19 Ongoin NO g: End Date: Dec/UNK /2019	Initial Entry

090177e196ae2fda\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: 11771222

Subject Initials: ---

Generated By:

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

(b) (4)

1.m Line/MH Number:

Date	Location	User	Value	Reason
Sep-01-2020 09:32:42 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 13	Initial Entry

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

Date	Location	User	Value	Reason
Sep-01-2020 09:32:42 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BUNIONECTOMY, RIGHT FOOT	Initial Entry

1.m Start Date:

Date	Location	User	Value	Reason
Sep-01-2020 09:32:42 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Dec/UNK/2019	Initial Entry

1.m Ongoing:

Date	Location	User	Value	Reason
Sep-01-2020 09:32:42 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO End Date:	Initial Entry

090177e196ae2fda\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: 11771222

Subject Initials: ---

Generated By:

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

(b) (4)

Dec/UNK/2019

1.n

Date	Location	User	Value	Reason
Sep-01-2020 09:33:08 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/M 14 H Num ber: Medical BUNIONEC History TOMY, LEF Term: T FOOT Start D Jun/UNK/20 ate: 20 Ongoin NO g: End Date: Jun/UNK/ 2020	Initial Entry

090177e196ae2fda\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: 11771222

Subject Initials: ---

Generated By:

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

(b) (4)

1.n Line/MH Number:

Date	Location	User	Value	Reason
Sep-01-2020 09:33:08 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 14	Initial Entry

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

Date	Location	User	Value	Reason
Sep-01-2020 09:33:08 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BUNIONECTOMY, LEFT FOOT	Initial Entry

1.n Start Date:

Date	Location	User	Value	Reason
Sep-01-2020 09:33:08 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Jun/UNK/2020	Initial Entry

1.n Ongoing:

Date	Location	User	Value	Reason
Sep-01-2020 09:33:08 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO End Date:	Initial Entry

090177e196ae2fda\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: 11771222

Subject Initials: ---

Generated By:

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

(b) (4)

Jun/UNK/2020

1.o

Date	Location	User	Value	Reason
Sep-01-2020 09:40:12 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH 15 Number: Medical History Term: SEPTOPLASTY Start Date: UNK/UNK/2005 Ongoing: NO End Date: UNK/UNK/2005	Initial Entry

090177e196ae2fda\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: 11771222

Subject Initials: ---

Generated By:

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

(b) (4)

1.o Line/MH Number:

Date	Location	User	Value	Reason
Sep-01-2020 09:40:12 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 15	Initial Entry

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

Date	Location	User	Value	Reason
Sep-01-2020 09:40:12 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: SEPTOPLASTY	Initial Entry

1.o Start Date:

Date	Location	User	Value	Reason
Sep-01-2020 09:40:12 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNK/UNK/2005	Initial Entry

1.o Ongoing:

Date	Location	User	Value	Reason
Sep-01-2020 09:40:12 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO End Date:	Initial Entry

090177e196ae2fda\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: 11771222

Subject Initials: ---

Generated By:

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

(b) (4)

UNK/UNK/2005

1.p

Date	Location	User	Value	Reason
Sep-01-2020 09:40:41 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH 16 Number: Medical DEVIATE History T D SEPTU erm: M Start Dat UNK/UNK e: /2005 Ongoing: NO End Date: UNK/U NK/200 5	Initial Entry

090177e196ae2fda\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: 11771222

Subject Initials: ---

Generated By:

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

(b) (4)

1.p Line/MH Number:

Date	Location	User	Value	Reason
Sep-01-2020 09:40:41 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 16	Initial Entry

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

Date	Location	User	Value	Reason
Sep-01-2020 09:40:41 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: DEVIATED SEPTU M	Initial Entry

1.p Start Date:

Date	Location	User	Value	Reason
Sep-01-2020 09:40:41 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNK/UNK/2005	Initial Entry

1.p Ongoing:

Date	Location	User	Value	Reason
Sep-01-2020 09:40:41 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO End Date:	Initial Entry

090177e196ae2fda\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: 11771222

Subject Initials: ---

Generated By:

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

(b) (4)

UNK/UNK/2005

090177e196ae2fda\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: 11771222

Subject Initials: ---

Generated By:

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

(b) (4)

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1. Date:

Date	Location	User	Value	Reason
Sep-01-2020 09:43:07 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sep/1/2020	Initial Entry

2. Weight:

Date	Location	User	Value	Reason
Sep-01-2020 09:43:07 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 88.6	Initial Entry

3. Unit:

Date	Location	User	Value	Reason
Sep-01-2020 09:43:07 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: kg	Initial Entry

4. Height:

Date	Location	User	Value	Reason
Sep-01-2020	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Initial Entry

090177e196ae2fda\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: 11771222

Subject Initials: ---

Generated By:

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

(b) (4)

09:43:07 (UTC-10:00) Aleutian Islands		(b) (4), (b) (6)	169.9	
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5. Unit:

Date	Location	User	Value	Reason
Sep-01-2020 09:43:07 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: cm	Initial Entry

6. Body Mass Index:

Date	Location	User	Value	Reason
Sep-01-2020 09:43:07 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 30.7	Initial Entry

7.a

Date	Location	User	Value	Reason
Sep-01-2020 09:43:07 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Record Identifier:: 1 Temperature: 98.1 Temperature Unit: F	Initial Entry

090177e196ae2fda\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: 11771222

Subject Initials: ---

Generated By:

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

(b) (4)

			Temperatur FORE e Location:: HEAD	
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7.a Record Identifier:

Date	Location	User	Value	Reason
Sep-01-2020 09:43:07 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 1	Initial Entry

7.a Temperature:

Date	Location	User	Value	Reason
Sep-01-2020 09:43:07 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 98.1	Initial Entry

7.a Unit:

Date	Location	User	Value	Reason
Sep-01-2020 09:43:07 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: F	Initial Entry

7.a Temperature Location:

Date	Location	User	Value	Reason
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090177e196ae2fda\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: 11771222

Subject Initials: ---

Generated By:

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

(b) (4)

Sep-01-2020 09:43:07 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: FOREHEAD	Initial Entry
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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: 11771222

Subject Initials: ---

Generated By:

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

(b) (4)

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1. Lab Panel:

Date	Location	User	Value	Reason
Sep-01-2020 09:26:26 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: URINALYSIS	Initial Entry

2. Lab Sub-Panel:

Date	Location	User	Value	Reason
Sep-01-2020 09:26:26 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: PREGNANCY	Initial Entry

3. Collection Date:

Date	Location	User	Value	Reason
Sep-01-2020 09:26:26 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sep/1/2020	Initial Entry

4. Laboratory Name and Address (Derived)

Date	Location	User	Value	Reason
Sep-01-2020	ACV0PFEINFP6000	auto calc	Data Entry:	Initial Entry

090177e196ae2fda\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: 11771222

Subject Initials: ---

Generated By:

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

(b) (4)

09:26:26 (UTC-10:00) Aleutian Islands		(autocalc)	STUDY SITE	
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5. Specimen Type:

Date	Location	User	Value	Reason
Sep-01-2020 09:26:26 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: URINE	Initial Entry

6.a

Date	Location	User	Value	Reason
Sep-01-2020 09:26:26 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sponsor- 113 Defined Identifier: Test:: Choriogon adotropin Beta_PX11 3 Result:: NEGATIV E Not Done ::	Initial Entry

6.a Sponsor ID:

Date	Location	User	Value	Reason
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090177e196ae2fda\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: 11771222

Subject Initials: ---

Generated By:

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

(b) (4)

Sep-01-2020 09:26:26 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 113	Initial Entry
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6.a Test:

Date	Location	User	Value	Reason
Sep-01-2020 09:26:26 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Choriogonadotropin Beta_PX113	Initial Entry

6.a Result:

Date	Location	User	Value	Reason
Sep-01-2020 09:26:26 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NEGATIVE	Initial Entry

090177e196ae2fda\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: 11771222

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-01-2020 09:21:39 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sep/1/2020	Initial Entry

2. Randomization Number:

Date	Location	User	Value	Reason
Sep-01-2020 09:21:39 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 77093	Initial Entry

090177e196ae2fda\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: 11771222

Generated By:

(b) (4)

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - 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

[Back to Form](#)

1. Data Origin

Date	Location	User	Value	Reason
Sep-01-2020 09:51:38 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Sep-01-2020 09:51:38 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SERUM	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Sep-01-2020 09:51:48 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Sep-01-2020 09:51:38 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered.

090177e196ae2fda\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: 11771222

Subject Initials: ---

Generated By:

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

(b) (4)

				Please review and correct as appropriate.
Sep-01-2020 09:51:38 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Collection : Sep/1/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Sep-01-2020 09:51:48 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID BPOV2 : D	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Sep-01-2020 09:51:48 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BPOV2D	Initial Entry

5.b

Date	Location	User	Value	Reason
Sep-01-2020 09:51:59	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Initial Entry

090177e196ae2fda\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: 11771222

Subject Initials: ---

Generated By:

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

(b) (4)

(UTC-10:00) Aleutian Islands		(b) (4), (b) (6)	Sample I BLCG7 D: M	
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5.b Sample ID

Date	Location	User	Value	Reason
Sep-01-2020 09:51:59 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BLCG7M	Initial Entry

5.c

Date	Location	User	Value	Reason
Sep-01-2020 09:52:06 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample I BLCG7 D: N	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Sep-01-2020 09:52:06 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BLCG7N	Initial Entry

090177e196ae2fda\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: 11771222

Generated By:

(b) (4)

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB - 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. Data Origin

Date	Location	User	Value	Reason
Sep-01-2020 09:52:20 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Sep-01-2020 09:52:20 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: NASAL_SWAB	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Sep-01-2020 09:52:28 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Sep-01-2020 09:52:20 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered.

090177e196ae2fda\Final\Final On: 01-Apr-2021 03:53 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1177

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

Subject No: 11771222

Subject Initials: ---

Generated By:

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

(b) (4)

				Please review and correct as appropriate.
Sep-01-2020 09:52:20 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Collection : Sep/1/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Sep-01-2020 09:52:28 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample I BM8GH D: W	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Sep-01-2020 09:52:28 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BM8GHW	Initial Entry

090177e196ae2fda\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: 11771222

Generated By:

(b) (4)

Form: VACCINATION - 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

[Back to Form](#)

1. Was there a temporary delay of vaccination?

Date	Location	User	Value	Reason
Sep-01-2020 09:53:06 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2. Treatment Name

Date	Location	User	Value	Reason
Sep-01-2020 09:52:56 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: BLINDED THERAPY	Initial Entry

3. Formulation:

Date	Location	User	Value	Reason
Sep-01-2020 09:52:56 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INJECTION	Initial Entry

4. Dose Date Time:

Date	Location	User	Value	Reason
Sep-01-2020 09:52:56	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sep/1/2020 08:18	Initial Entry

090177e196ae2fda\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: 11771222

Subject Initials: ---

Generated By:

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

(b) (4)

(UTC-10:00)
Aleutian Islands

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

5. Anatomical Location:

Date	Location	User	Value	Reason
Sep-01-2020 09:52:56 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: DELTOID MUSCLE	Initial Entry

6. Body Side:

Date	Location	User	Value	Reason
Sep-01-2020 09:52:56 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: LEFT	Initial Entry

7. Route:

Date	Location	User	Value	Reason
Sep-01-2020 09:52:56 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INTRAMUSCULAR	Initial Entry

10. Timeframe Subject Was Observed

Date	Location	User	Value	Reason
Sep-01-2020 09:52:56	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: THE PROTOCOL SPE	Initial Entry

090177e196ae2fda\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: 11771222

Subject Initials: ---

Generated By:

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

(b) (4)

(UTC-10:00)
Aleutian Islands

CIFIED OBSERVATIO
N PERIOD

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

Date	Location	User	Value	Reason
Sep-01-2020 09:52:56 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

090177e196ae2fda\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: 11771222

Subject Initials: ---

Generated By:

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

(b) (4)

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1. Select appropriate response - Reactogenicity diary collection

Date	Location	User	Value	Reason
Sep-01-2020 09:21:53 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO - REACTOGENI CITY E-DIARY NO T COLLECTED FO R THIS SUBJECT	Initial Entry

Header Text: C4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 1177

Subject No: 11771222

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-21-2020 09:16:26 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sep/21/2020	Initial Entry

Header Text: C4591001

Visit: V2_VAX2_L

Form Version: 15-Sep-2020 21:54

Site No: 1177

Subject No: 11771222

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

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1. Date:

Date	Location	User	Value	Reason
Sep-21-2020 09:16:39 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sep/21/2020	Initial Entry

2.a

Date	Location	User	Value	Reason
Sep-21-2020 09:16:39 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Record Identifier:: 1 Temperature: 97.7 Temperature Unit: Temperature Location:: HEAD	Initial Entry

2.a Record Identifier:

Date	Location	User	Value	Reason
Sep-21-2020 09:16:39 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 1	Initial Entry

090177e196ae2fda\Final\Final On: 01-Apr-2021 03:53 (GMT)

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: 11771222

Subject Initials: ---

Generated By:

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

(b) (4)

2.a Temperature:

Date	Location	User	Value	Reason
Sep-21-2020 09:16:39 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 97.7	Initial Entry

2.a Unit:

Date	Location	User	Value	Reason
Sep-21-2020 09:16:39 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: F	Initial Entry

2.a Temperature Location:

Date	Location	User	Value	Reason
Sep-21-2020 09:16:39 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: FOREHEAD	Initial Entry

090177e196ae2fda\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: 11771222

Subject Initials: ---

Generated By:

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

(b) (4)

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1. Lab Panel:

Date	Location	User	Value	Reason
Sep-21-2020 09:16:51 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: URINALYSIS	Initial Entry

2. Lab Sub-Panel:

Date	Location	User	Value	Reason
Sep-21-2020 09:16:51 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: PREGNANCY	Initial Entry

3. Collection Date:

Date	Location	User	Value	Reason
Sep-21-2020 09:16:51 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sep/21/2020	Initial Entry

4. Laboratory Name and Address (Derived)

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

090177e196ae2fda\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: 11771222

Subject Initials: ---

Generated By:

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

(b) (4)

09:16:51 (UTC-10:00) Aleutian Islands		(autocalc)	STUDY SITE	
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5. Specimen Type:

Date	Location	User	Value	Reason
Sep-21-2020 09:16:51 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: URINE	Initial Entry

6.a

Date	Location	User	Value	Reason
Sep-21-2020 09:16:51 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sponsor- 113 Defined I dentifier: Test:: Choriogon adotropin Beta_PX11 3 Result:: NEGATIV E Not Done ::	Initial Entry

6.a Sponsor ID:

Date	Location	User	Value	Reason
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090177e196ae2fda\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: 11771222

Subject Initials: ---

Generated By:

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

(b) (4)

Sep-21-2020 09:16:51 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 113	Initial Entry
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6.a Test:

Date	Location	User	Value	Reason
Sep-21-2020 09:16:51 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Choriogonadotropin Beta_PX113	Initial Entry

6.a Result:

Date	Location	User	Value	Reason
Sep-21-2020 09:16:51 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NEGATIVE	Initial Entry

090177e196ae2fda\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: 11771222

Subject Initials: ---

Generated By:

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

(b) (4)

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1. Data Origin

Date	Location	User	Value	Reason
Sep-21-2020 09:49:27 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Sep-21-2020 09:49:27 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: NASAL_SWAB	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Sep-21-2020 09:49:39 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Sep-21-2020 09:49:27 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered.

090177e196ae2fda\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: 11771222

Subject Initials: ---

Generated By:

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

(b) (4)

				Please review and correct as appropriate.
Sep-21-2020 09:49:27 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Collection : Sep/21/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Sep-21-2020 09:49:39 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID BP8JH : S	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Sep-21-2020 09:49:39 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BP8JHS	Initial Entry

090177e196ae2fda\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: 11771222

Generated By:

(b) (4)

Form: VACCINATION - 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. Was there a temporary delay of vaccination?

Date	Location	User	Value	Reason
Sep-21-2020 09:52:14 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2. Treatment Name

Date	Location	User	Value	Reason
Sep-21-2020 09:52:14 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: BLINDED THERAPY	Initial Entry

3. Formulation:

Date	Location	User	Value	Reason
Sep-21-2020 09:52:14 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INJECTION	Initial Entry

4. Dose Date Time:

Date	Location	User	Value	Reason
Sep-21-2020 09:52:14	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sep/21/2020 08:22	Initial Entry

090177e196ae2fda\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: 11771222

Subject Initials: ---

Generated By:

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

(b) (4)

(UTC-10:00) Aleutian Islands		(b) (4), (b) (6)		
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5. Anatomical Location:

Date	Location	User	Value	Reason
Sep-21-2020 09:52:14 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: DELTOID MUSCLE	Initial Entry

6. Body Side:

Date	Location	User	Value	Reason
Sep-21-2020 09:52:14 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: LEFT	Initial Entry

7. Route:

Date	Location	User	Value	Reason
Sep-21-2020 09:52:14 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INTRAMUSCULAR	Initial Entry

10. Timeframe Subject Was Observed

Date	Location	User	Value	Reason
Sep-21-2020 09:52:14	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: THE PROTOCOL SPE	Initial Entry

090177e196ae2fda\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: 11771222

Subject Initials: ---

Generated By:

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

(b) (4)

(UTC-10:00) Aleutian Islands			CIFIED OBSERVATIO N PERIOD	
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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
Sep-21-2020 09:52:14 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

090177e196ae2fda\Final\Final On: 01-Apr-2021 03:53 (GMT)

Header Text: C4591001

Visit: V3_MONTH1_POSTVAX2_L **Form:** DATE OF VISIT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02 **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1177 **Site Name:** (1177) East-West Medical Research Institute

Subject No: 11771222 **Subject Initials:** ---

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

(b) (4)

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1. Date of Visit

Date	Location	User	Value	Reason
Oct-19-2020 08:55:32 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Oct/19/2020	Initial Entry

Header Text: C4591001

Visit: V3_MONTH1_POSTVAX2_L **Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03 **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1177 **Site Name:** (1177) East-West Medical Research Institute

Subject No: 11771222 **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-19-2020 08:55:38 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Oct-19-2020 08:55:38 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SERUM	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Oct-19-2020 09:00:55 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Oct-19-2020 08:55:38 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered.

090177e196ae2fda\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: 11771222 **Subject Initials:** ---

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

(b) (4)

				Please review and correct as appropriate.
Oct-19-2020 08:55:38 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Collection: Oct/19/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Oct-19-2020 09:00:55 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID BRJ56 : H	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Oct-19-2020 09:00:55 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BRJ56H	Initial Entry

5.b

Date	Location	User	Value	Reason
Oct-19-2020 09:01:05 (UTC-10:00)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID BS8BR	Initial Entry

090177e196ae2fda\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: 11771222 **Subject Initials:** ---

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

(b) (4)

Aleutian Islands		:	8	
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5.b Sample ID

Date	Location	User	Value	Reason
Oct-19-2020 09:01:05 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BS8BR8	Initial Entry

5.c

Date	Location	User	Value	Reason
Oct-19-2020 09:01:12 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID BS8BR : 7	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Oct-19-2020 09:01:12 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BS8BR7	Initial Entry

090177e196ae2fda\Final\Final On: 01-Apr-2021 03:53 (GMT)

Header Text: C4591001

Visit: End of Treatment - Unscheduled **Form:** DISPOSITION - TREATMENT - eCRF Audit Trail History

Form Version: 15-Sep-2020 21:55

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1177

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

Subject No: 11771222

Subject Initials: ---

Generated By:

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

(b) (4)

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1. Date of Completion/Discontinuation/Death :

Date	Location	User	Value	Reason
Oct-19-2020 08:55:48 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Oct/19/2020	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Oct-19-2020 08:55:48 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: VACCINATION	Initial Entry

3. Status:

Date	Location	User	Value	Reason
Oct-19-2020 08:55:48 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: COMPLETED	Initial Entry

090177e196ae2fda\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: 11771222

Generated By:

(b) (4)

Form: ADVERSE EVENT REPORT - Audit Trail

Form Status:

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

Subject Initials: ---

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

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Date	Location	User	Value	Reason
Sep-22-2020 16:17:14 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

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: 11771222

Subject Initials: ---

Generated By:

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

(b) (4)

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Date	Location	User	Value	Reason
Sep-22-2020 16:17:50 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

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: 11771222

Subject Initials: ---

Generated By:

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

(b) (4)

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Date	Location	User	Value	Reason
Sep-22-2020 16:18:38 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

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: 11771222

Subject Initials: ---

Generated By:

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

(b) (4)

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Date	Location	User	Value	Reason
Dec-04-2020 12:29:06 (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, Locked, Frozen

Site No: 1177

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

Subject No: 11771222

Subject Initials: ---

Generated By:

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

(b) (4)

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1. Category:

Date	Location	User	Value	Reason
Sep-22-2020 16:17:14 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: ADVERSE EVENT	Initial Entry

2. AE ID:

Date	Location	User	Value	Reason
Sep-22-2020 16:17:14 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 1	Initial Entry

3. Adverse Event:

(If possible specify diagnosis, not individual symptoms)

Date	Location	User	Value	Reason
Sep-22-2020 16:17:14 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BODY ACHES	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason
Sep-22-2020	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Initial Entry

090177e196ae2fda\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, Locked, Frozen

Site No: 1177

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

Subject No: 11771222

Subject Initials: ---

Generated By:

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

(b) (4)

16:17:14 (UTC-10:00) Aleutian Islands		(b) (4), (b) (6)	Sep/21/2020 18:00	
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5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Sep-28-2020 11:53:33 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO End Date Time: Sep/23/2020 07: 30	New Information
Sep-28-2020 04:44:18 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Sep-25-2020 14:34:17 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Original value is correct
Sep-25-2020 12:06:44 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	ClinQuery: Please verify if Body Aches is truly ongoing, then update the END DATE and OUTCOME as appropriate.

090177e196ae2fda\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, Locked, Frozen

Site No: 1177

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

Subject No: 11771222

Subject Initials: ---

Generated By:

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

(b) (4)

Sep-22-2020 16:17:14 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry
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6. Toxicity Grade:

Date	Location	User	Value	Reason
Sep-22-2020 16:17:14 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 3	Initial Entry

7. Is the adverse event serious?

If Yes, NOTIFY PFIZER IMMEDIATELY.

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

Date	Location	User	Value	Reason
Sep-22-2020 16:17:14 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

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

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

Date	Location	User	Value	Reason
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090177e196ae2fda\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, Locked, Frozen

Site No: 1177

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

Subject No: 11771222

Subject Initials: ---

Generated By:

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

(b) (4)

Sep-22-2020 16:17:14 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry
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9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Sep-22-2020 16:17:14 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: RELATED	Initial Entry

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Sep-22-2020 16:17:14 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NOT APPLICABLE	Initial Entry

11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
Sep-22-2020 16:17:14 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

12. Was a Non-Drug Treatment given?

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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, Locked, Frozen

Site No: 1177

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

Subject No: 11771222

Subject Initials: ---

Generated By:

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

(b) (4)

Date	Location	User	Value	Reason
Sep-22-2020 16:17:14 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

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

Date	Location	User	Value	Reason
Sep-28-2020 11:53:42 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Sep-28-2020 11:53:42 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: RECOVERED/RE SOLVED	New Information
Sep-28-2020 11:53:33 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	For AE BODY ACHES: Response to "What was the outcome of this adverse event?" is 'Not Recovered/Not Resolved' but AE End Date/Time is present.

090177e196ae2fda\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, Locked, Frozen

Site No: 1177

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

Subject No: 11771222

Subject Initials: ---

Generated By:

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

(b) (4)

Sep-22-2020 16:17:14 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NOT RECOVERE D/NOT RESOLVE D	Initial Entry
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14. Did the adverse event cause the subject to be discontinued from the study?

Date	Location	User	Value	Reason
Sep-22-2020 16:17:14 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

090177e196ae2fda\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, Locked, Frozen

Site No: 1177

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

Subject No: 11771222

Subject Initials: ---

Generated By:

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

(b) (4)

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1. Category:

Date	Location	User	Value	Reason
Sep-22-2020 16:17:50 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: ADVERSE EVENT	Initial Entry

2. AE ID:

Date	Location	User	Value	Reason
Sep-22-2020 16:17:50 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 2	Initial Entry

3. Adverse Event:

(If possible specify diagnosis, not individual symptoms)

Date	Location	User	Value	Reason
Sep-22-2020 16:17:50 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: HEADACHE	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason
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090177e196ae2fda\Final\Final On: 01-Apr-2021 03:53 (GMT)

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Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

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Form Status: Data Complete, Locked, Frozen

Site No: 1177

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

Subject No: 11771222

Subject Initials: ---

Generated By:

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

(b) (4)

Sep-22-2020 16:17:50 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sep/21/2020 18:00	Initial Entry
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5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Sep-28-2020 11:52:45 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO End Date Time: Sep/23/2020 07: 30	New Information
Sep-28-2020 04:44:41 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Sep-25-2020 14:34:30 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Original value is correct
Sep-25-2020 12:07:18 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	ClinQuery: Please verify if Headache is truly ongoing, then update the END DATE and OUTCOME as appropriate.

090177e196ae2fda\Final\Final On: 01-Apr-2021 03:53 (GMT)

Header Text: C4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

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Form Status: Data Complete, Locked, Frozen

Site No: 1177

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

Subject No: 11771222

Subject Initials: ---

Generated By:

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

(b) (4)

Sep-22-2020 16:17:50 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry
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6. Toxicity Grade:

Date	Location	User	Value	Reason
Sep-22-2020 16:17:50 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 2	Initial Entry

7. Is the adverse event serious?

If Yes, NOTIFY PFIZER IMMEDIATELY.

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

Date	Location	User	Value	Reason
Sep-22-2020 16:17:50 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

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

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

Date	Location	User	Value	Reason
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090177e196ae2fda\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, Locked, Frozen

Site No: 1177

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

Subject No: 11771222

Subject Initials: ---

Generated By:

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

(b) (4)

Sep-22-2020 16:17:50 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry
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9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Sep-22-2020 16:17:50 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: RELATED	Initial Entry

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Sep-22-2020 16:17:50 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NOT APPLICABLE	Initial Entry

11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
Sep-22-2020 16:17:50 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

12. Was a Non-Drug Treatment given?

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Header Text: C4591001

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Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Locked, Frozen

Site No: 1177

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

Subject No: 11771222

Subject Initials: ---

Generated By:

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

(b) (4)

Date	Location	User	Value	Reason
Sep-22-2020 16:17:50 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

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

Date	Location	User	Value	Reason
Sep-28-2020 11:53:08 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Sep-28-2020 11:53:08 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: RECOVERED/RE SOLVED	New Information
Sep-28-2020 11:52:45 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	For AE HEADACHE: Response to "What was the outcome of this adverse event?" is 'Not Recovered/Not Resolved' but AE End Date/Time is present.

090177e196ae2fda\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, Locked, Frozen

Site No: 1177

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

Subject No: 11771222

Subject Initials: ---

Generated By:

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

(b) (4)

Sep-22-2020 16:17:50 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NOT RECOVERE D/NOT RESOLVE D	Initial Entry
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14. Did the adverse event cause the subject to be discontinued from the study?

Date	Location	User	Value	Reason
Sep-22-2020 16:17:50 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

090177e196ae2fda\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, Locked, Frozen

Site No: 1177

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

Subject No: 11771222

Subject Initials: ---

Generated By:

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

(b) (4)

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1. Category:

Date	Location	User	Value	Reason
Sep-22-2020 16:18:38 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: ADVERSE EVENT	Initial Entry

2. AE ID:

Date	Location	User	Value	Reason
Sep-22-2020 16:18:38 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 3	Initial Entry

3. Adverse Event:

(If possible specify diagnosis, not individual symptoms)

Date	Location	User	Value	Reason
Sep-22-2020 16:18:38 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NAUSEA	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason
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090177e196ae2fda\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, Locked, Frozen

Site No: 1177

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

Subject No: 11771222

Subject Initials: ---

Generated By:

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

(b) (4)

Sep-22-2020 16:18:38 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sep/21/2020 18:00	Initial Entry
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5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Sep-22-2020 16:18:38 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO End Date Time: Sep/21/2020 21:0 0	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
Sep-22-2020 16:18:38 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 1	Initial Entry

7. Is the adverse event serious?

If Yes, NOTIFY PFIZER IMMEDIATELY.

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

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Header Text: C4591001

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Form Status: Data Complete, Locked, Frozen

Site No: 1177

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

Subject No: 11771222

Subject Initials: ---

Generated By:

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

(b) (4)

Date	Location	User	Value	Reason
Sep-22-2020 16:18:38 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

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

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

Date	Location	User	Value	Reason
Sep-22-2020 16:18:38 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Sep-22-2020 16:18:38 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: RELATED	Initial Entry

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Sep-22-2020 16:18:38 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NOT APPLICABLE	Initial Entry

090177e196ae2fda\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, Locked, Frozen

Site No: 1177

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

Subject No: 11771222

Subject Initials: ---

Generated By:

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

(b) (4)

11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
Sep-22-2020 16:18:38 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Sep-22-2020 16:18:38 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

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

Date	Location	User	Value	Reason
Sep-22-2020 16:18:38 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: RECOVERED/RESOLVED	Initial Entry

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

Date	Location	User	Value	Reason
Sep-22-2020 16:18:38 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

090177e196ae2fda\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: 11771222

Subject Initials: ---

Generated By:

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

(b) (4)

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1. Category:

Date	Location	User	Value	Reason
Dec-04-2020 12:29:06 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: ADVERSE EVENT	Initial Entry

2. AE ID:

Date	Location	User	Value	Reason
Dec-04-2020 12:29:06 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 4	Initial Entry

3. Adverse Event:

(If possible specify diagnosis, not individual symptoms)

Date	Location	User	Value	Reason
Dec-10-2020 11:19:53 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Dec-10-2020 11:13:08 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	The EDP was submitted

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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: 11771222

Subject Initials: ---

Generated By:

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

(b) (4)

Dec-08-2020 12:20:36 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	ClinQuery: If Exposure During Pregnancy occurs in a subject or subject's partner, the investigator must report this to Pfizer Safety on the Vaccines SAE report Form and an EDP supplemental form. Please confirm the EDP supplemental form was completed.
Dec-04-2020 12:29:06 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Exposure During P regnancy	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason
Dec-04-2020 12:29:06	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Nov/13/2020 18:00	Initial Entry

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Header Text: C4591001

Visit: Logs - Unscheduled

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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: 11771222

Subject Initials: ---

Generated By:

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

(b) (4)

(UTC-10:00) Aleutian Islands	(b) (4), (b) (6)
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5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Mar-09-2021 12:05:33 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO End Date Time: Dec/23/2020 12: 00	New Information
Dec-04-2020 12:29:06 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
Dec-08-2020 12:19:37 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Dec-08-2020 12:07:48 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry
Dec-08-2020 12:07:38	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Transcription Error

090177e196ae2fda\Final\Final On: 01-Apr-2021 03:53 (GMT)

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: 11771222

Subject Initials: ---

Generated By:

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

(b) (4)

(UTC-10:00) Aleutian Islands				
Dec-08-2020 12:07:38 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Transcription Error
Dec-08-2020 10:21:42 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	ClinQuery: Toxicity grade is noted as 1. However, per Safety Related update, the grade for EDP should be entered as Not Applicable. Please review and update as appropriate.
Dec-04-2020 12:29:06 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 1	Initial Entry

7. Is the adverse event serious?

If Yes, NOTIFY PFIZER IMMEDIATELY.

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

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Header Text: C4591001

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Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

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Site No: 1177

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

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Subject Initials: ---

Generated By:

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

(b) (4)

prevent above outcomes).

Date	Location	User	Value	Reason
Dec-04-2020 12:29:06 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

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

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

Date	Location	User	Value	Reason
Dec-04-2020 12:29:06 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Dec-04-2020 12:29:06 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NOT RELATED If Not Related to study treatment(s), this event is due to: OTHER <i>If Other, specify:</i> Conception	Initial Entry

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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: 11771222

Subject Initials: ---

Generated By:

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

(b) (4)

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Dec-04-2020 12:29:06 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NOT APPLICABLE	Initial Entry

11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
Dec-04-2020 12:29:06 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Dec-04-2020 12:29:06 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

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

Date	Location	User	Value	Reason
Mar-10-2021 22:47:19 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Reissued: Candidate	For Clinical review

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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: 11771222

Subject Initials: ---

Generated By:

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

(b) (4)

Mar-10-2021 17:27:28 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Answered	New information was known and Subject is no longer pregnant
Mar-09-2021 22:04:20 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Reissued:Opened	Per 3 Nov EDP guidance , outcome should be recorded as UNKNOWN. Please confirm and update accordingly.
Mar-09-2021 12:05:10 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Answered	New Information
Mar-09-2021 12:05:10 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: RECOVERED /RESOLVED	New Information
Mar-08-2021 18:30:27 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Opened	SAE RECON: AER#2020481520, the outcome in AE CRF was reported as NOT RECOVERED/NOT RESOLVED. Per 3 Nov EDP guidance , outcome should be recorded as UNKNOWN. Please confirm and

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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

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Subject Initials: ---

Generated By:

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

(b) (4)

				update accordingly.
Dec-07-2020 21:11:33 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Dec-07-2020 10:25:40 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Answer Auto Query
Dec-07-2020 10:25:40 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NOT RECOVERED/NOT RESOLVED	Changed Information
Dec-06-2020 19:48:14 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued:Opened	Response does not satisfy query. AE is marked as Ongoing but Outcome of AE is completed. Please review and correct.
Dec-04-2020 12:31:12 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Original value is correct
Dec-04-2020 12:29:06 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	For AE Exposure During Pregnancy: Response to "What was the outcome of this adverse event?" is 'Unknown' but

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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

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Subject Initials: ---

Generated By:

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

(b) (4)

				End Date/Time is provided or "Is the adverse event still ongoing?" is marked "Yes".
Dec-04-2020 12:29:06 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNKNOWN	Initial Entry

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

Date	Location	User	Value	Reason
Dec-04-2020 12:29:06 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

090177e196ae2fda\Final\Final On: 01-Apr-2021 03:53 (GMT)

Header Text: C4591001

Visit: Potential ReVax Initial Contact - **Form:** DATE OF VISIT - eCRF Audit Trail History
Unscheduled

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: 11771222 **Subject Initials:** ---

Generated By: (b) (4) **Generated Time (GMT):** 29-Mar-2021 12:55

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1. Date of Visit

Date	Location	User	Value	Reason
Dec-17-2020 18:01:56 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Dec/17/2020	Initial Entry

Header Text: C4591001

Visit: Potential ReVax Initial Contact - **Form:** FURTHER VACCINATION CONFIRMATION -
Unscheduled 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: 11771222 **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
Dec-17-2020 18:02:07 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Participant is willing to return for Vaccina tion 3 Participant is: eligible and NOT confirmed to hav e received only pl acebo at Vaccinat ion 1/2	Initial Entry

090177e196ae2fda\Final\Final On: 01-Apr-2021 03:53 (GMT)

Header Text: C4591001

Visit: Disposition - Unscheduled

Form: TREATMENT UNBLINDED - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1177

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

Subject No: 11771222

Subject Initials: ---

Generated By:

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

(b) (4)

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1. Date Treatment Unblinded :

Date	Location	User	Value	Reason
Dec-17-2020 18:01:46 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Dec/17/2020	Initial Entry

2. Primary Reason for Unblinding:

Date	Location	User	Value	Reason
Dec-17-2020 18:01:46 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: ASSESS ELIGIBILI TY FOR ADDITIO NAL VACCINATIO N	Initial Entry

090177e196ae2fda\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: 11771222

Subject Initials: ---

Generated By:

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

(b) (4)

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1. Subject Status

Date	Location	User	Value	Reason
Oct-19-2020 08:55:48 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: FOLLOW-UP	Initial Entry
Sep-01-2020 09:21:39 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: ENROLLED/RANDOMIZED	Initial Entry
Sep-01-2020 09:18:51 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SCREENED	Initial Entry

2. Subject Status Date

Date	Location	User	Value	Reason
Oct-19-2020 08:55:48 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Oct/19/2020	Initial Entry
Sep-01-2020 09:21:39 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sep/1/2020	Initial Entry

090177e196ae2fda\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: 11771222

Subject Initials: ---

Generated By:

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

(b) (4)

Sep-01-2020 09:18:51 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sep/1/2020	Initial Entry
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Header Text: C4591001

Visit: Investigator Signature -
Unscheduled

Form Version: 22-Apr-2020 21:04

Site No: 1177

Subject No: 11771222

Generated By:

(b) (4)

Form: CASEBOOK SIGNATURE FORM - eCRF Audit
Trail History

Form Status: Data Complete, Signed, Verified

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

Subject Initials: ---

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

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1. Casebook Signature

Date	Location	User	Value	Reason
Oct-26-2020 16:05:36 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Click Here to Enable	Initial Entry

090177e196ae2fda\Final\Final On: 01-Apr-2021 03:53 (GMT)