

Header Text: C4591001

Visit: COHORT_SELECTION

Form Version: 30-Jul-2020 21:29

Site No: 1177

Subject No: 11771204

Generated By: (b) (4)

Form: COHORT_SELECTION

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Cohort Selection

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

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

Header Text: C4591001

Visit: COHORT_SELECTION

Form Version: 22-Apr-2020 21:02

Site No: 1177

Subject No: 11771204

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 Aug/31/2020
----	--------------	--

Header Text: C4591001

Visit: COHORT_SELECTION

Form Version: 06-Jul-2020 21:55

Site No: 1177

Subject No: 11771204

Generated By: (b) (4)

Form: DEMOGRAPHY

Form Status: Data Complete, Frozen, Verified

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

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Demography

1.	Subject ID	[11771204]
2.	Birth Date:	(b) (6)/1951
3.	Sex:	MALE
4.	Ethnicity:	NOT HISPANIC OR LATINO(A) OR OF SPANISH ORIGIN
5.	Race: (Check X all that apply):	ASIAN
6.	Racial Designation:	JAPANESE

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:02

Site No: 1177

Subject No: 11771204

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	Aug/31/2020
2.	Erroneous Visit	

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 30-Jul-2020 21:29

Site No: 1177

Subject No: 11771204

Generated By: (b) (4)

Form: INCLUSION/EXCLUSION CRITERIA

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

Form Comments

Inclusion Criteria Not Met

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

Exclusion Criteria Met

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

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1177

Subject No: 11771204

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	Aug/31/2020
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: 11771204

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:	[Hypertension]
	Start Date:	UNK/UNK/2017
	Ongoing:	YES
1.b	Line/MH Number:	[2]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Dyslipidemia]
	Start Date:	UNK/UNK/2017
	Ongoing:	YES
1.c	Line/MH Number:	[3]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Benign Prostatic Hyperplasia]
	Start Date:	UNK/UNK/2019
	Ongoing:	YES
1.d	Line/MH Number:	[4]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Chronic Obstructive Pulmonary Disease]
	Start Date:	UNK/UNK/2015
	Ongoing:	YES
1.e	Line/MH Number:	[5]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Intolerance to Benazepril]
	Start Date:	UNK/UNK/2017
	Ongoing:	YES

090177e196ae2fdb\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: 11771204

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.f	Line/MH Number:	[6]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Intolerance to Lisinopril]
	Start Date:	UNK/UNK/2017
	Ongoing:	YES
1.g	Line/MH Number:	[7]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Adhesive Capsulitis, Right Shoulder]
	Start Date:	UNK/UNK/2015
	Ongoing:	NO End Date: UNK/UNK/2015
1.h	Line/MH Number:	[8]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Inguinal Hernia]
	Start Date:	UNK/UNK/1990
	Ongoing:	NO End Date: UNK/UNK/1990
1.i	Line/MH Number:	[9]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Adhesive Capsulitis, Right Shoulder]
	Start Date:	UNK/UNK/2015
	Ongoing:	NO End Date: UNK/UNK/2015

(b)

090177e196ae2fdb\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: 11771204

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:	[Inguinal Hernia Repair]
	Start Date:	UNK/UNK/1990
	Ongoing:	NO End Date: UNK/UNK/1990
1.k	Line/MH Number:	[11]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Joint Manipulation, Right Shoulder]
	Start Date:	UNK/UNK/2015
	Ongoing:	YES

090177e196ae2fdb\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: 11771204

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:	Aug/31/2020
2.	Weight:	[66.0]
3.	Unit:	kg
4.	Height:	[169.0]
5.	Unit:	cm
6.	Body Mass Index:	[23.1]

Vital Signs Details

7.a	Record Identifier:	1
	Temperature:	[98.2]
	Unit:	F
	Temperature Location:	FOREHEAD

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1177

Subject No: 11771204

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 :	Aug/31/2020
2.	Randomization Number:	[247464]
3.	Randomization Group:	[]

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1177

Subject No: 11771204

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	SERUM
3.	Sample Collected?	YES Date of Collection: Aug/31/2020
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	[BPOV1T]
5.b	Sample ID	[BLCG6F]
5.c	Sample ID	[BLCG6G]

090177e196ae2fdb\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: 11771204

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Aug/31/2020
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	[BM8GH8]
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090177e196ae2fdb\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: 11771204

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:	Aug/31/2020 09:45
5.	Anatomical Location:	DELTOID MUSCLE
6.	Body Side:	RIGHT
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

090177e196ae2fdb\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: 11771204

Generated By: (b) (4)

Form: REACTOGENICITY DIARY

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Reactogenicity Diary

1.	Select appropriate response - Reactogenicity diary collection	NO - REACTOGENICITY E-DIARY NOT COLLECTED FOR THIS SUBJECT
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Header Text: C4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 1177

Subject No: 11771204

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: 11771204

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:	[98.0]
	Unit:	F
	Temperature Location:	FOREHEAD

Header Text: C4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:03

Site No: 1177

Subject No: 11771204

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Sep/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	[BP8JHY]
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090177e196ae2fdb\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: 11771204

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 09:14
5.	Anatomical Location:	DELTOID MUSCLE
6.	Body Side:	RIGHT
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

090177e196ae2fdb\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: 11771204

Subject Initials: ---

Generated By: (b) (4)

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

[eCRF Audit Trail History](#)

Date of Visit

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

Header Text: C4591001

Visit: V3_MONTH1_POSTVAX2_L

Form Version: 22-Apr-2020 21:03

Site No: 1177

Subject No: 11771204

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	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	[BS8BRH]
5.b	Sample ID	[BS8BRJ]
5.c	Sample ID	[BRJ56M]

090177e196ae2fdb\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: 11771204

Subject Initials: ---

Generated By: (b) (4)

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

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

COVID-19 Illness Visit

3.	COVID-19 Illness Visit:	
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Header Text: C4591001

Visit: POT_COVID_ILL - New Unscheduled Visit **Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19

Form Version: 20-Feb-2021 02:17

Form Status: Not Started

Site No: 1177

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

Subject No: 11771204

Subject Initials: ---

Generated By: (b) (4)

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

Signs and Symptoms

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

Symptoms

4.	Symptoms:	
	Was symptom present?	

Symptoms - Other

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

Header Text: C4591001

Visit: POT_COVID_ILL - New Unscheduled Visit **Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB SELF

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1177

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

Subject No: 11771204

Subject Initials: ---

Generated By: (b) (4)

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

Electronic Sample Tracking

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

Aliquot

Please enter barcode for each aliquot.

5.	Sample ID	[]
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Header Text: C4591001

Visit: POT_COVID_ILL - New Unscheduled Visit **Form:** 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: 11771204

Subject Initials: ---

Generated By: (b) (4)

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

Electronic Sample Tracking

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

Aliquot

Please enter barcode for each aliquot.

5.	Sample ID	[]
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Header Text: C4591001

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

Form Version: 20-Feb-2021 02:19

Form Status: Not Started

Site No: 1177

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

Subject No: 11771204

Subject Initials: ---

Generated By: (b) (4)

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

Health Care Utilization

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

Health Care Utilization Other

2.	Other Type of Practitioner Specify:	[]
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Health Care Utilization

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

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: 11771204

Subject Initials: ---

Generated By: (b) (4)

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

Illness Details

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

Header Text: C4591001

Visit: POT_COVID_CONVA - New Unscheduled Visit **Form:** DATE OF VISIT - ILLNESS CONVALESCENT

Form Version: 22-Apr-2020 21:04

Form Status: Not Started

Site No: 1177

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

Subject No: 11771204

Subject Initials: ---

Generated By: (b) (4)

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

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

COVID-19 Illness Visit

3.	COVID-19 Illness Visit:	
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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: 11771204

Subject Initials: ---

Generated By: (b) (4)

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

Electronic Sample Tracking

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

Aliquot

Please enter barcode for each aliquot.

5.	Sample ID	[]
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Header Text: C4591001

Visit: Unplanned - New Unscheduled Visit

Form: DATE OF VISIT

Form Version: 22-Apr-2020 21:02

Form Status: Not Started

Site No: 1177

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

Subject No: 11771204

Subject Initials: ---

Generated By: (b) (4)

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

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

Header Text: C4591001

Visit: Unplanned - 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: 11771204

Subject Initials: ---

Generated By: (b) (4)

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

Unplanned Assessments

1.	Assessments	
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Header Text: C4591001

Visit: End of Treatment - Unscheduled

Form Version: 15-Sep-2020 21:55

Site No: 1177

Subject No: 11771204

Generated By: (b) (4)

Form: DISPOSITION - TREATMENT

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 - Treatment

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

Header Text: C4591001

Visit: Follow-Up - Unscheduled

Form Version: 15-Sep-2020 21:53

Site No: 1177

Subject No: 11771204

Generated By: (b) (4)

Form: DISPOSITION - FOLLOW-UP

Form Status: Not Started

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

Subject Initials: ---

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

Disposition - Follow-Up

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

Header Text: C4591001

Visit: POT_COVID_REPEAT_SWAB - New
Unscheduled Visit

Form: DATE OF VISIT - REPEAT SWAB

Form Version: 10-Oct-2020 15:57

Form Status: Not Started

Site No: 1177

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

Subject No: 11771204

Subject Initials: ---

Generated By: (b) (4)

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

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

COVID-19 Repeat Swab

3.	COVID-19 Repeat Swab:	
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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: 11771204

Subject Initials: ---

Generated By: (b) (4)

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

Electronic Sample Tracking

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

Aliquot

Please enter barcode for each aliquot.

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

Header Text: C4591001

Visit: Logs

Form: ADVERSE EVENT REPORT

Form Version: 22-Apr-2020 21:02

Site No: 1177

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

Subject No: 11771204

Subject Initials: ---

Generated By: (b) (4)

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

#	Category	AE Identifier	Adverse Event	Start Date	Is the Adverse Event Still Ongoing	Form Instance
1.	ADVERSE EVENT	1	Bladder Cancer	Oct/24/2020 13:00	YES	Repeating Pages

Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1177

Subject No: 11771204

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Verified

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

Subject Initials: ---

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

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[Form Audit Trail](#)

Adverse Event Report

1.	Category:	ADVERSE EVENT
2.	AE ID:	[1]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[Bladder Cancer]
4.	Start Date Time:	Oct/24/2020 13:00
5.	Is the adverse event still ongoing?	YES
6.	Toxicity Grade:	3
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).	YES Is this serious event associated with congenital anomaly or birth defect? NO Did this serious event result in death? NO Did this serious event require or prolong hospitalization? NO Did this serious event result in persistent or significant disability/incapacity? NO Is this serious event life threatening? NO Other medically important serious event YES
8.	Is this adverse event the result of a study Medication Error? If Yes, record the type of medication error on the Medication Error Log.	NO
9.	Is this event related to study treatment:	NOT RELATED If Not Related to study treatment(s), this event is due to: OTHER If Other, specify: [Neoplasia]
10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE

090177e196ae2fdb\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: 11771204

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

11.	Was a Concomitant Medication given?	YES
12.	Was a Non-Drug Treatment given?	YES
13.	What was the outcome of this adverse event?:	RECOVERING/RESOLVING
14.	Did the adverse event cause the subject to be discontinued from the study?	NO
15.	Serious Adverse Event Number: For Pfizer Use Only	[2021036341]

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: 11771204

Subject Initials: ---

Generated By: (b) (4)

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

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

090177e196ae2fdb\Final\Final On: 01-Apr-2021 03:53 (GMT)

Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 17-Jul-2020 21:54

Site No: 1177

Subject No: 11771204

Generated By: (b) (4)

Form: MEDICATION ERROR

Form Status: Not Started

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

Subject Initials: ---

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

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Medication Error

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

090177e196ae2fdb\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: 11771204

Subject Initials: ---

Generated By: (b) (4)

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

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

090177e196ae2fdb\Final\Final On: 01-Apr-2021 03:53 (GMT)

Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1177

Subject No: 11771204

Generated By: (b) (4)

Form: CONCOMITANT MEDICATIONS - NON STUDY VACCINATIONS

Form Status: Not Started

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

Subject Initials: ---

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

[Back to Form](#)

Concomitant Medications

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

090177e196ae2fdb\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: 11771204

Subject Initials: ---

Generated By: (b) (4)

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

#	Sponsor-Defined Identifier	Category for Medication	Concomitant Medications Pre-specified	Name of Medication	Dose Description	Form Instance
1.	1	CONCOMITANT IMMUNOSUPPRESSIVE THERAPY	NO	Gemzar	Unknown	Repeating Pages
2.	2	CONCOMITANT IMMUNOSUPPRESSIVE THERAPY	NO	Cisplatin	Unknown	Repeating Pages

Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1177

Subject No: 11771204

Generated By: (b) (4)

Form: CONCOMITANT MEDICATIONS - PROHIBITED

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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Concomitant Medications

1.	What is the medication identifier?	[1]	
2.	Category:	CONCOMITANT IMMUNOSUPPRESSIVE THERAPY	
3.	Concomitant Medications Pre-specified:	NO	
4.	Medication: Provide the complete generic drug name (including salt form, where applicable). Where generic name is unknown, enter the full trade or proprietary name. Include clarifying information in the Medication text (e.g., Ingredient(s), route, use, formulation).	[Gemzar]	
5.	Dose:	Unknown _____ []	Comments
6.	Dose Unit:	Unknown _____	Comments
7.	Dose Frequency:	UNKNOWN	
8.	Route:	INTRAVENOUS	
9.	Start Date:	Dec/15/2020	
10.	Ongoing?	YES	

090177e196ae2fdb\Final\Final On: 01-Apr-2021 03:53 (GMT)

Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1177

Subject No: 11771204

Generated By: (b) (4)

Form: CONCOMITANT MEDICATIONS - PROHIBITED

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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Concomitant Medications

1.	What is the medication identifier?	[2]	
2.	Category:	CONCOMITANT IMMUNOSUPPRESSIVE THERAPY	
3.	Concomitant Medications Pre-specified:	NO	
4.	Medication: Provide the complete generic drug name (including salt form, where applicable). Where generic name is unknown, enter the full trade or proprietary name. Include clarifying information in the Medication text (e.g., Ingredient(s), route, use, formulation).	[Cisplatin]	
5.	Dose:	Unknown _____ []	Comments
6.	Dose Unit:	Unknown _____	Comments
7.	Dose Frequency:	UNKNOWN	
8.	Route:	INTRAVENOUS	
9.	Start Date:	Dec/22/2020	
10.	Ongoing?	YES	

090177e196ae2fdb\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: 11771204

Subject Initials: ---

Generated By: (b) (4)

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

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

Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1177

Subject No: 11771204

Generated By: (b) (4)

Form: RADIATION TREATMENT

Form Status: Not Started

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

Subject Initials: ---

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

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Radiation Treatment

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

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: 11771204

Subject Initials: ---

Generated By: (b) (4)

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

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

Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1177

Subject No: 11771204

Generated By: (b) (4)

Form: TRANSFUSIONS

Form Status: Not Started

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

Subject Initials: ---

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

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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: 11771204

Subject Initials: ---

Generated By: (b) (4)

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

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

Header Text: C4591001

Visit: Unplanned Vaccination - Unscheduled

Form: VITAL SIGNS - TEMP

Form Version: 20-Feb-2021 02:16

Form Status: Not Started

Site No: 1177

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

Subject No: 11771204

Subject Initials: ---

Generated By: (b) (4)

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

Vital Signs

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

Vital Signs Details

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

Header Text: C4591001

Visit: Unplanned Vaccination - Unscheduled

Form: 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: 11771204

Subject Initials: ---

Generated By: (b) (4)

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

Vaccination

1.	Was there a temporary delay of vaccination?	
2.	Treatment Name	[]
3.	Formulation:	
4.	Dose Date Time:	//
5.	Anatomical Location:	
6.	Body Side:	
7.	Route:	
8.	Actual Dose:	[]
9.	Unit:	
10.	Timeframe Subject Was Observed	
11.	Was the subject observed for at least the protocol specified observation period after investigational product administration?	

090177e196ae2fdb\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: 11771204

Subject Initials: ---

Generated By: (b) (4)

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

Contact Outcome

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

Header Text: C4591001

Visit: Unplanned Vaccination - Unscheduled

Form: CONTACT OUTCOME - MONTH 6

Form Version: 10-Oct-2020 16:01

Form Status: Not Started

Site No: 1177

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

Subject No: 11771204

Subject Initials: ---

Generated By: (b) (4)

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

Contact Outcome

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

Header Text: C4591001

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

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen, Verified

Site No: 1177

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

Subject No: 11771204

Subject Initials: ---

Generated By: (b) (4)

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

[eCRF Audit Trail History](#)

Date of Visit

1.	Date of Visit	Jan/14/2021
2.	Erroneous Visit	

Header Text: C4591001

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

Form Version: 10-Dec-2020 02:25

Form Status: Data Complete, Frozen, Verified

Site No: 1177

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

Subject No: 11771204

Subject Initials: ---

Generated By: (b) (4)

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

[eCRF Audit Trail History](#)

Further Vaccination Confirmation

1.	Select appropriate response - Is participant willing to return for Vaccination 3?	Participant is willing to return for Vaccination 3 Participant is: eligible per local/national recommendations and confirmed to have received only placebo at Vaccination 1/2
----	---	---

Header Text: C4591001

Visit: Disposition - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1177

Subject No: 11771204

Generated By: (b) (4)

Form: TREATMENT UNBLINDED

Form Status: Data Complete, Frozen, Verified

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

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Treatment Unblinded

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

Header Text: C4591001

Visit: Disposition - Unscheduled

Form: WITHDRAWAL OF CONSENT

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1177

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

Subject No: 11771204

Subject Initials: ---

Generated By: (b) (4)

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

Withdrawal Of Consent

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

Header Text: C4591001

Visit: Disposition - Unscheduled

Form: DEATH DETAILS CODED

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1177

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

Subject No: 11771204

Subject Initials: ---

Generated By: (b) (4)

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

Death Details

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

Cause of Death

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

Header Text: C4591001

Visit: V101_VAX3

Form Version: 22-Apr-2020 21:02

Site No: 1177

Subject No: 11771204

Generated By: (b) (4)

Form: DATE OF VISIT

Form Status: Data Complete, Frozen, Verified

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

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Date of Visit

1.	Date of Visit	Feb/4/2021
2.	Erroneous Visit	

Header Text: C4591001

Visit: V101_VAX3

Form Version: 10-Dec-2020 02:31

Site No: 1177

Subject No: 11771204

Generated By: (b) (4)

Form: INFORMED CONSENT - FURTHER VACCINATION

Form Status: Data Complete, Frozen, Verified

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

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Informed Consent - Further Vaccination

1.	Consent Was:	OBTAINED Date Written Consent Obtained Feb/4/2021
----	--------------	---

090177e196ae2fdb\Final\Final On: 01-Apr-2021 03:53 (GMT)

Header Text: C4591001

Visit: V101_VAX3

Form Version: 10-Dec-2020 02:30

Site No: 1177

Subject No: 11771204

Generated By: (b) (4)

Form: INCLUSION/EXCLUSION CRITERIA - FURTHER VACCINATION

Form Status: Data Complete, Frozen, Verified

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

Subject Initials: ---

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

Form Comments

Inclusion Criteria Not Met

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

Exclusion Criteria Met

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

Header Text: C4591001

Visit: V101_VAX3

Form Version: 10-Dec-2020 02:31

Site No: 1177

Subject No: 11771204

Generated By: (b) (4)

Form: DISPOSITION - SCREENING FOR FURTHER VACCINATION

Form Status: Data Complete, Frozen, Verified

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

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Disposition - Screening for Further Vaccination

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

Header Text: C4591001

Visit: V101_VAX3

Form Version: 22-Apr-2020 21:03

Site No: 1177

Subject No: 11771204

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Status: Data Complete, Frozen, Verified

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

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Electronic Sample Tracking

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

Aliquot

Please enter barcode for each aliquot.

5.a	Sample ID	[BS6TW0]
5.b	Sample ID	[BS6TW1]
5.c	Sample ID	[BR8VMM]

090177e196ae2fdb\Final\Final On: 01-Apr-2021 03:53 (GMT)

Header Text: C4591001

Visit: V101_VAX3

Form Version: 22-Apr-2020 21:03

Site No: 1177

Subject No: 11771204

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB

Form Status: Data Complete, Frozen, Verified

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

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Electronic Sample Tracking

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

Aliquot

Please enter barcode for each aliquot.

5.a	Sample ID	[BR92HK]
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090177e196ae2fdb\Final\Final On: 01-Apr-2021 03:53 (GMT)

Header Text: C4591001

Visit: V101_VAX3

Form Version: 10-Dec-2020 02:26

Site No: 1177

Subject No: 11771204

Generated By: (b) (4)

Form: VACCINATION

Form Status: Data Complete, Frozen, Verified

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

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Vaccination

1.	Was there a temporary delay of vaccination?	NO
2.	Treatment Name	[BNT162b2]
3.	Formulation:	INJECTION
4.	Dose Date Time:	Feb/4/2021 10:21
5.	Anatomical Location:	DELTOID MUSCLE
6.	Body Side:	RIGHT
7.	Route:	INTRAMUSCULAR
8.	Actual Dose:	[30.0]
9.	Unit:	ug
10.	Timeframe Subject Was Observed	30 MINUTES
11.	Was the subject observed for at least the protocol specified observation period after investigational product administration?	YES

090177e196ae2fdb\Final\Final On: 01-Apr-2021 03:53 (GMT)

Header Text: C4591001

Visit: V102_VAX4

Form Version: 22-Apr-2020 21:02

Site No: 1177

Subject No: 11771204

Generated By: (b) (4)

Form: DATE OF VISIT

Form Status: Data Complete, Frozen, Verified

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

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Date of Visit

1.	Date of Visit	Feb/25/2021
2.	Erroneous Visit	

Header Text: C4591001

Visit: V102_VAX4

Form Version: 22-Apr-2020 21:03

Site No: 1177

Subject No: 11771204

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB

Form Status: Data Complete, Frozen, Verified

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

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Feb/25/2021
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[]

Aliquot

Please enter barcode for each aliquot.

5.a	Sample ID	[BR92NH]
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090177e196ae2fdb\Final\Final On: 01-Apr-2021 03:53 (GMT)

Header Text: C4591001

Visit: V102_VAX4

Form Version: 10-Dec-2020 02:26

Site No: 1177

Subject No: 11771204

Generated By: (b) (4)

Form: VACCINATION

Form Status: Data Complete, Frozen, Verified

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

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Vaccination

1.	Was there a temporary delay of vaccination?	NO
2.	Treatment Name	[BNT162b2]
3.	Formulation:	INJECTION
4.	Dose Date Time:	Feb/25/2021 10:24
5.	Anatomical Location:	DELTOID MUSCLE
6.	Body Side:	RIGHT
7.	Route:	INTRAMUSCULAR
8.	Actual Dose:	[30.0]
9.	Unit:	ug
10.	Timeframe Subject Was Observed	30 MINUTES
11.	Was the subject observed for at least the protocol specified observation period after investigational product administration?	YES

090177e196ae2fdb\Final\Final On: 01-Apr-2021 03:53 (GMT)

Header Text: C4591001

Visit: V103_MONTH1

Form Version: 22-Apr-2020 21:02

Site No: 1177

Subject No: 11771204

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: V103_MONTH1

Form Version: 22-Apr-2020 21:04

Site No: 1177

Subject No: 11771204

Generated By: (b) (4)

Form: CONTACT OUTCOME

Form Status: Not Started

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

Subject Initials: ---

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

Contact Outcome

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

Header Text: C4591001

Visit: V104_MONTH6

Form Version: 22-Apr-2020 21:02

Site No: 1177

Subject No: 11771204

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: V104_MONTH6

Form Version: 22-Apr-2020 21:04

Site No: 1177

Subject No: 11771204

Generated By: (b) (4)

Form: CONTACT OUTCOME

Form Status: Not Started

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

Subject Initials: ---

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

Contact Outcome

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

Header Text: C4591001

Visit: V105_MONTH18

Form Version: 22-Apr-2020 21:02

Site No: 1177

Subject No: 11771204

Generated By: (b) (4)

Form: DATE OF VISIT

Form Status: Not Started

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

Subject Initials: ---

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

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

Header Text: C4591001

Visit: V105_MONTH18

Form Version: 22-Apr-2020 21:04

Site No: 1177

Subject No: 11771204

Generated By: (b) (4)

Form: CONTACT OUTCOME

Form Status: Not Started

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

Subject Initials: ---

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

Contact Outcome

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

Header Text: C4591001

Visit: FURTHER_VACCINATION_EOT -
Unscheduled

Form: DISPOSITION - TREATMENT

Form Version: 20-Feb-2021 02:26

Form Status: Not Started

Site No: 1177

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

Subject No: 11771204

Subject Initials: ---

Generated By: (b) (4)

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

Disposition - Treatment

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

Header Text: C4591001

Visit: Subject Status - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1177

Subject No: 11771204

Generated By: (b) (4)

Form: SUBJECT STATUS

Form Status: Data Complete, Verified

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

Subject Initials: ---

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

[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 Version: 22-Apr-2020 21:04

Site No: 1177

Subject No: 11771204

Generated By: (b) (4)

Form: CASEBOOK SIGNATURE FORM

Form Status: Data Complete, Signed, Verified

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

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Casebook Signature Form

1.	Casebook Signature	Click Here to Enable
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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: 11771204

Subject Initials: ---

Generated By: (b) (4)

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

[Audit Trail](#)

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

- CRF_Sign

Name	Signature Meaning	Date	Type	Action
David Fitz-Patrick	Approved	Mar-07-2021 14:07:27 (UTC-10:00) Aleutian Islands	BOOK	Signed

Affidavit:

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

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

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

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 30-Jul-2020 21:29

Site No: 1177

Subject No: 11771204

Generated By: (b) (4)

Form: INCLUSION/EXCLUSION CRITERIA - Comments

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

[Back to Form](#)

Item	Date	User	Comment
Form	Aug-31-2020 12:11:01 (UTC-10:00) Aleutian Islands	(b) (4), (b) (6)	Not Applicable

Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1177

Subject No: 11771204

Generated By: (b) (4)

Form: CONCOMITANT MEDICATIONS - PROHIBITED - Comments

Form Status: Data Complete, Verified

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

Subject Initials: ---

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

[Back to Form](#)

Item	Date	User	Comment
5	Jan-20-2021 08:23:04 (UTC-10:00) Aleutian Islands	(b) (4), (b) (6)	Unknown

Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1177

Subject No: 11771204

Generated By: (b) (4)

Form: CONCOMITANT MEDICATIONS - PROHIBITED - Comments

Form Status: Data Complete, Verified

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

Subject Initials: ---

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

[Back to Form](#)

Item	Date	User	Comment
6	Jan-20-2021 08:23:13 (UTC-10:00) Aleutian Islands	(b) (4), (b) (6)	Unknown

Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1177

Subject No: 11771204

Generated By: (b) (4)

Form: CONCOMITANT MEDICATIONS - PROHIBITED - Comments

Form Status: Data Complete, Verified

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

Subject Initials: ---

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

[Back to Form](#)

Item	Date	User	Comment
5	Jan-20-2021 08:24:06 (UTC-10:00) Aleutian Islands	(b) (4), (b) (6)	Unknown

Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1177

Subject No: 11771204

Generated By: (b) (4)

Form: CONCOMITANT MEDICATIONS - PROHIBITED - Comments

Form Status: Data Complete, Verified

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

Subject Initials: ---

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

[Back to Form](#)

Item	Date	User	Comment
6	Jan-20-2021 08:24:16 (UTC-10:00) Aleutian Islands	(b) (4), (b) (6)	Unknown

Header Text: C4591001

Visit: V101_VAX3

Form: INCLUSION/EXCLUSION CRITERIA - FURTHER VACCINATION
- Comments

Form Version: 10-Dec-2020 02:30

Form Status: Data Complete, Frozen, Verified

Site No: 1177

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

Subject No: 11771204

Subject Initials: ---

Generated By: (b) (4)

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

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Item	Date	User	Comment
Form	Feb-04-2021 11:44:45 (UTC-10:00) Aleutian Islands	(b) (4), (b) (6)	Not Applicable

Header Text: C4591001

Visit: Investigator Signature - Unscheduled

Form: CASEBOOK SIGNATURE FORM - Signature History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Signed, Verified

Site No: 1177

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

Subject No: 11771204

Subject Initials: ---

Generated By: (b) (4)

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

[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-07-2021 14:07:27 (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)	N/A	Feb-04-2021 11:44:30 (UTC-10:00) Aleutian Islands		Edit - All signatures invalidated
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Affidavit:

N/A

David Fitz-Patrick	Approved	Jan-20-2021 10:38:53 (UTC-10:00) Aleutian Islands	BOOK	Signed
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Affidavit:

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

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

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

(b) (6)	N/A	Jan-14-2021 17:30:23 (UTC-10:00) Aleutian Islands		Edit - All signatures invalidated
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Affidavit:

N/A

David Fitz-Patrick	Approved	Dec-10-2020 15:05:26 (UTC-10:00) Aleutian Islands	BOOK	Signed
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090177e196ae2fdb\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: 11771204

Subject Initials: ---

Generated By: (b) (4)

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.

(b) (6)	N/A	Dec-10-2020 13:36:28 (UTC-10:00) Aleutian Islands		Edit - All signatures invalidated
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Affidavit:

N/A

David Fitz-Patrick	Approved	Oct-27-2020 11:43:33 (UTC-10:00) Aleutian Islands	BOOK	Signed
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Affidavit:

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

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

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

090177e196ae2fdb\Final\Final On: 01-Apr-2021 03:53 (GMT)

Header Text: C4591001

Visit: COHORT_SELECTION

Form Version: 30-Jul-2020 21:29

Site No: 1177

Subject No: 11771204

Generated By: (b) (4)

Form: COHORT_SELECTION - 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. Select appropriate response - Protocol version

Date	Location	User	Value	Reason
Aug-31-2020 12:10:33 (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
Aug-31-2020 12:10:33 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: STAGE 3 COHORTS	Initial Entry

Header Text: C4591001

Visit: COHORT_SELECTION

Form Version: 22-Apr-2020 21:02

Site No: 1177

Subject No: 11771204

Generated By: (b) (4)

Form: MAIN INFORMED CONSENT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

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I. Consent Was:

Date	Location	User	Value	Reason
Aug-31-2020 12:10:39 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: OBTAINED Date Written Consent Obtained Aug/31/2020	Initial Entry

Header Text: C4591001

Visit: COHORT_SELECTION

Form: DEMOGRAPHY - eCRF Audit Trail History

Form Version: 06-Jul-2020 21:55

Form Status: Data Complete, Frozen, Verified

Site No: 1177

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

Subject No: 11771204

Subject Initials: ---

Generated By: (b) (4)

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

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1. Subject ID

Date	Location	User	Value	Reason
Aug-31-2020 12:10:25 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 11771204	Item copied from previous form

2. Birth Date:

Date	Location	User	Value	Reason
Aug-31-2020 12:10:21 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: (b) (6)/1951	Enrollment Entry

3. Sex:

Date	Location	User	Value	Reason
Aug-31-2020 12:10:46 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: MALE	Initial Entry

4. Ethnicity:

Date	Location	User	Value	Reason
Aug-31-2020 12:10:46 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NOT HISPANIC OR LATINO(A) OR OF SPANISH ORIGIN	Initial Entry

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

Date	Location	User	Value	Reason
Dec-04-2020 10:53:16 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Dec-04-2020 06:55:47 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Japanese
Dec-03-2020 11:33:11 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	Subject is indicated on Demography CRF as Asian, please specify further racial designation as Japanese (i.e. defined

090177e196ae2fdb\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: 11771204

Generated By: (b) (4)

Form: DEMOGRAPHY - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

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

Subject Initials: ---

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

				as all four grandparents born in Japan, of Japanese ancestry), or Other
Aug-31-2020 12:10:46 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: ASIAN	Initial Entry

6. Racial Designation:

Date	Location	User	Value	Reason
Dec-10-2020 13:36:28 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: JAPANESE	Initial Entry

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:02

Site No: 1177

Subject No: 11771204

Generated By: (b) (4)

Form: DATE OF VISIT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

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I. Date of Visit

Date	Location	User	Value	Reason
Aug-31-2020 12:10:53 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Aug/31/2020	Initial Entry

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1177

Subject No: 11771204

Generated By: (b) (4)

Form: DISPOSITION - SCREENING - 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. Date of Completion/Discontinuation/Death

Date	Location	User	Value	Reason
Aug-31-2020 12:11:14 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Aug/31/2020	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Aug-31-2020 12:11:14 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SCREENING	Initial Entry

3. Status:

Date	Location	User	Value	Reason
Aug-31-2020 12:11:14 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: COMPLETED	Initial Entry

090177e196ae2fdb\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: 11771204

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

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I.a

Date	Location	User	Value	Reason
Aug-31-2020 12:15:33 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 1 Medical History Term: Hypertension Start Date: UNK/UNK/2017 Ongoing: YES	Initial Entry

I.a Line/MH Number:

Date	Location	User	Value	Reason
Aug-31-2020 12:15:33 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 1	Initial Entry

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

Date	Location	User	Value	Reason
Aug-31-2020 12:15:33 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Hypertension	Initial Entry

I.a Start Date:

Date	Location	User	Value	Reason
Aug-31-2020 12:15:33 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNK/UNK/2017	Initial Entry

I.a Ongoing:

Date	Location	User	Value	Reason
Aug-31-2020 12:15:33 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

I.b

Date	Location	User	Value	Reason
Aug-31-2020 12:15:50	ACV0PFEINFP6000	auto calc	Data Entry:	Initial Entry

090177e196ae2fdb\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: 11771204

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

(UTC-10:00) Aleutian Islands		(autocalc)	Line/MH Number: 2 Medical History Term: Dyslipidemia Start Date: UNK/UNK/2017 Ongoing: YES	
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I.b Line/MH Number:

Date	Location	User	Value	Reason
Aug-31-2020 12:15:50 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 2	Initial Entry

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

Date	Location	User	Value	Reason
Aug-31-2020 12:15:50 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Dyslipidemia	Initial Entry

I.b Start Date:

Date	Location	User	Value	Reason
Aug-31-2020 12:15:50 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNK/UNK/2017	Initial Entry

I.b Ongoing:

Date	Location	User	Value	Reason
Aug-31-2020 12:15:50 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

I.c

Date	Location	User	Value	Reason
Aug-31-2020 12:16:07 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 3 Medical History Term: Benign Prostatic Hyperplasia Start Date: UNK/UNK/2019 Ongoing: YES	Initial Entry

090177e196ae2fdb\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: 11771204

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

I.c Line/MH Number:

Date	Location	User	Value	Reason
Aug-31-2020 12:16:07 (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
Aug-31-2020 12:16:07 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Benign Prostatic Hyperplasia	Initial Entry

I.c Start Date:

Date	Location	User	Value	Reason
Aug-31-2020 12:16:07 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNK/UNK/2019	Initial Entry

I.c Ongoing:

Date	Location	User	Value	Reason
Aug-31-2020 12:16:07 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

I.d

Date	Location	User	Value	Reason
Aug-31-2020 12:16:33 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 4 Medical History Term: Chronic Obstructive Pulmonary Disease Start Date: UNK/UNK/2015 Ongoing: YES	Initial Entry

090177e196ae2fdb\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: 11771204

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

I.d Line/MH Number:

Date	Location	User	Value	Reason
Aug-31-2020 12:16:33 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 4	Initial Entry

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

Date	Location	User	Value	Reason
Aug-31-2020 12:16:33 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Chronic Obstructive Pulmonary Disease	Initial Entry

I.d Start Date:

Date	Location	User	Value	Reason
Aug-31-2020 12:16:33 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNK/UNK/2015	Initial Entry

I.d Ongoing:

Date	Location	User	Value	Reason
Aug-31-2020 12:16:33 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

I.e

Date	Location	User	Value	Reason
Aug-31-2020 12:16:49 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: r: Medical History Intolerance to Benazepril Term: Start Date: UNK/UNK/2017 Ongoing: YES	Initial Entry

090177e196ae2fdb\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: 11771204

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

I.e Line/MH Number:

Date	Location	User	Value	Reason
Aug-31-2020 12:16:49 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 5	Initial Entry

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

Date	Location	User	Value	Reason
Aug-31-2020 12:16:49 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Intolerance to Benazepril	Initial Entry

I.e Start Date:

Date	Location	User	Value	Reason
Aug-31-2020 12:16:49 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNK/UNK/2017	Initial Entry

I.e Ongoing:

Date	Location	User	Value	Reason
Aug-31-2020 12:16:49 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

I.f

Date	Location	User	Value	Reason
Aug-31-2020 12:17:02 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 6 Medical History Term: Intolerance to Lisinopril Start Date: UNK/UNK/2017 Ongoing: YES	Initial Entry

090177e196ae2fdb\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: 11771204

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

I.f Line/MH Number:

Date	Location	User	Value	Reason
Aug-31-2020 12:17:02 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 6	Initial Entry

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

Date	Location	User	Value	Reason
Aug-31-2020 12:17:02 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Intolerance to Lisinopril	Initial Entry

I.f Start Date:

Date	Location	User	Value	Reason
Aug-31-2020 12:17:02 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNK/UNK/2017	Initial Entry

I.f Ongoing:

Date	Location	User	Value	Reason
Aug-31-2020 12:17:02 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

I.g

Date	Location	User	Value	Reason
Aug-31-2020 12:17:20 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 7 Medical History Term: Adhesive Capsulitis, Right Shoulder Start Date: UNK/UNK/2015 Ongoing: NO End Date: UNK/UNK/2015	Initial Entry

090177e196ae2fdb\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: 11771204

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

I.g Line/MH Number:

Date	Location	User	Value	Reason
Aug-31-2020 12:17:20 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 7	Initial Entry

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

Date	Location	User	Value	Reason
Aug-31-2020 12:17:20 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Adhesive Capsulitis, Right Shoulder	Initial Entry

I.g Start Date:

Date	Location	User	Value	Reason
Aug-31-2020 12:17:20 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNK/UNK/2015	Initial Entry

I.g Ongoing:

Date	Location	User	Value	Reason
Aug-31-2020 12:17:20 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO End Date: UNK/UNK/2015	Initial Entry

I.h

Date	Location	User	Value	Reason
Aug-31-2020 12:17:36 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 8 Medical History Te Inguinal Hernia rm: Start Date: UNK/UNK/1990 Ongoing: NO End Date: UNK/UNK/1990	Initial Entry

090177e196ae2fdb\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: 11771204

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

I.h Line/MH Number:

Date	Location	User	Value	Reason
Aug-31-2020 12:17:36 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 8	Initial Entry

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

Date	Location	User	Value	Reason
Aug-31-2020 12:17:36 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Inguinal Hernia	Initial Entry

I.h Start Date:

Date	Location	User	Value	Reason
Aug-31-2020 12:17:36 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNK/UNK/1990	Initial Entry

I.h Ongoing:

Date	Location	User	Value	Reason
Aug-31-2020 12:17:36 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO End Date: UNK/UNK/1990	Initial Entry

I.i

Date	Location	User	Value	Reason
Sep-01-2020 08:26:36 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Line/MH Nu mber: Medical Hist Adhesive Capsulitis, ory Term: Right Shoulder Start Date: UNK/UNK/2015 Ongoing: NO End Date: UNK/UNK/2015	Transcription Error
Aug-31-2020 12:18:00 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH 9	Initial Entry

090177e196ae2fdb\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: 11771204

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

			Number: Medical History Term: Adhesive Capsulitis Joint Manipulation, Right Shoulder Start Date: UNK/UNK/2015 Ongoing: NO End Date: UNK/UNK/2015	
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Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1177

Subject No: 11771204

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

L.i Line/MH Number:

Date	Location	User	Value	Reason
Aug-31-2020 12:18:00 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 9	Initial Entry

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

Date	Location	User	Value	Reason
Sep-01-2020 12:56:00 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000.InFormAdapter.Discrepancy	PFETMS Oracle (b) (4)	Query 1: Closed	Discrepancy has been closed.
Sep-01-2020 08:26:36 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Transcription Error
Sep-01-2020 08:26:36 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Adhesive Capsulitis, Right Shoulder	Transcription Error
Sep-01-2020 02:51:39 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000.InFormAdapter.Discrepancy	PFETMS Oracle (b) (4)	Query 1: Opened	Multiple concepts in the term ADHESIVE CAPSULITIS JOINT MANIPULATION, RIGHT SHOULDER. Split the term into ADHESIVE CAPSULITIS RIGHT SHOULDER and JOINT MANIPULATION, RIGHT SHOULDER and report as 2 separate entries. Thank you.
Aug-31-2020 12:18:00 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Adhesive Capsulitis Joint Manipulation, Right Shoulder	Initial Entry

090177e196ae2fdb\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: 11771204

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

L.i Start Date:

Date	Location	User	Value	Reason
Aug-31-2020 12:18:00 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNK/UNK/2015	Initial Entry

L.i Ongoing:

Date	Location	User	Value	Reason
Aug-31-2020 12:18:00 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO End Date: UNK/UNK/2015	Initial Entry

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1177

Subject No: 11771204

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

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<i>1.j</i>				
Date	Location	User	Value	Reason
Aug-31-2020 12:18:19 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 10 Medical History Term: Inguinal Hernia Repair Start Date: UNK/UNK/1990 Ongoing: NO End Date: UNK/UNK/1990	Initial Entry
<i>1.j Line/MH Number:</i>				
Date	Location	User	Value	Reason
Aug-31-2020 12:18:19 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 10	Initial Entry
<i>1.j Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:</i>				
Date	Location	User	Value	Reason
Aug-31-2020 12:18:19 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Inguinal Hernia Repair	Initial Entry
<i>1.j Start Date:</i>				
Date	Location	User	Value	Reason
Aug-31-2020 12:18:19 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNK/UNK/1990	Initial Entry
<i>1.j Ongoing:</i>				
Date	Location	User	Value	Reason
Aug-31-2020 12:18:19 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO End Date: UNK/UNK/1990	Initial Entry

090177e196ae2fdb\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: 11771204

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

<i>I.k</i>				
Date	Location	User	Value	Reason
Sep-01-2020 08:27:42 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 11 Medical History Term: Joint Manipulation, Right Shoulder Start Date: UNK/UNK/2015 Ongoing: YES	Initial Entry

<i>I.k Line/MH Number:</i>				
Date	Location	User	Value	Reason
Sep-01-2020 08:27:42 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 11	Initial Entry

<i>I.k Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:</i>				
Date	Location	User	Value	Reason
Sep-01-2020 08:27:42 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Joint Manipulation, Right Shoulder	Initial Entry

<i>I.k Start Date:</i>				
Date	Location	User	Value	Reason
Sep-01-2020 08:27:42 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNK/UNK/2015	Initial Entry

<i>I.k Ongoing:</i>				
Date	Location	User	Value	Reason
Sep-01-2020 08:27:42 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

090177e196ae2fdb\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: 11771204

Generated By: (b) (4)

Form: VITAL SIGNS - BASELINE - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

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1. Date:

Date	Location	User	Value	Reason
Aug-31-2020 16:02:29 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Aug/31/2020	Initial Entry

2. Weight:

Date	Location	User	Value	Reason
Aug-31-2020 16:02:29 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 66.0	Initial Entry

3. Unit:

Date	Location	User	Value	Reason
Aug-31-2020 16:02:29 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: kg	Initial Entry

4. Height:

Date	Location	User	Value	Reason
Aug-31-2020 16:02:29 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 169.0	Initial Entry

5. Unit:

Date	Location	User	Value	Reason
Aug-31-2020 16:02:29 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: cm	Initial Entry

6. Body Mass Index:

Date	Location	User	Value	Reason
Aug-31-2020 16:02:29 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 23.1	Initial Entry

7.a

090177e196ae2fdb\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: 11771204

Generated By: (b) (4)

Form: VITAL SIGNS - BASELINE - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

Date	Location	User	Value	Reason
Aug-31-2020 16:02:29 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Record Identifier:: 1 Temperature: 98.2 Temperature Unit: F Temperature Location:: FOREHEAD	Initial Entry

7.a Record Identifier:

Date	Location	User	Value	Reason
Aug-31-2020 16:02:29 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 1	Initial Entry

7.a Temperature:

Date	Location	User	Value	Reason
Aug-31-2020 16:02:29 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 98.2	Initial Entry

7.a Unit:

Date	Location	User	Value	Reason
Aug-31-2020 16:02:29 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: F	Initial Entry

7.a Temperature Location:

Date	Location	User	Value	Reason
Aug-31-2020 16:02:29 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: FOREHEAD	Initial Entry

090177e196ae2fdb\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: 11771204

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
Aug-31-2020 12:18:52 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Aug/31/2020	Initial Entry

2. Randomization Number:

Date	Location	User	Value	Reason
Sep-01-2020 09:43:01 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (b) (4)	Query 1: Closed	Auto closed by Validation Check: VC_DS001_07
Sep-01-2020 08:24:21 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	data has been updated
Aug-31-2020 22:44:55 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (b) (4)	Query 1: Opened	DMW4429329;Randomization Number appears to be a duplicate with Subject 11771210. Please confirm the number has been entered correctly or clarify.
Aug-31-2020 12:18:52 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 247464	Initial Entry

090177e196ae2fdb\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: 11771204

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
Aug-31-2020 16:03:02 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Aug-31-2020 16:03:02 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SERUM	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Aug-31-2020 16:03:58 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Aug-31-2020 16:03:02 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Aug-31-2020 16:03:02 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Collection: Aug/31/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Aug-31-2020 16:03:58 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BP0V1T	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
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090177e196ae2fdb\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: 11771204

Subject Initials: ---

Generated By: (b) (4)

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

Aug-31-2020 16:03:58 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BPOV1T	Initial Entry
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5.b

Date	Location	User	Value	Reason
Sep-02-2020 09:58:10 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BLCG6F	Transcription Error
Aug-31-2020 16:04:38 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BLCG69	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Sep-02-2020 09:58:10 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BLCG6F	Transcription Error
Aug-31-2020 16:04:38 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BLCG69	Initial Entry

5.c

Date	Location	User	Value	Reason
Sep-02-2020 09:58:27 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BLCG6G	Transcription Error
Aug-31-2020 16:04:48 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BLCG6B	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Sep-02-2020 09:58:27 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BLCG6G	Transcription Error
Aug-31-2020 16:04:48 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BLCG6B	Initial Entry

090177e196ae2fdb\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: 11771204

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
Aug-31-2020 16:06:22 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Aug-31-2020 16:06:22 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: NASAL_SWAB	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Aug-31-2020 16:06:41 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Aug-31-2020 16:06:22 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Aug-31-2020 16:06:22 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Collection: Aug/31/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Aug-31-2020 16:06:41 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BM8GH8	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
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090177e196ae2fdb\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: 11771204

Subject Initials: ---

Generated By: (b) (4)

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

Aug-31-2020 16:06:41 (UTC-10:00) Aleutian Islands	ACVOPFEINFP6000	(b) (4), (b) (6)	Data Entry: BM8GH8	Initial Entry
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Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:04

Site No: 1177

Subject No: 11771204

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
Aug-31-2020 16:07:13 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2. Treatment Name

Date	Location	User	Value	Reason
Aug-31-2020 16:07:13 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: BLINDED THERAPY	Initial Entry

3. Formulation:

Date	Location	User	Value	Reason
Aug-31-2020 16:07:13 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INJECTION	Initial Entry

4. Dose Date Time:

Date	Location	User	Value	Reason
Aug-31-2020 16:07:13 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Aug/31/2020 09:45	Initial Entry

5. Anatomical Location:

Date	Location	User	Value	Reason
Aug-31-2020 16:07:13 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: DELTOID MUSCLE	Initial Entry

6. Body Side:

Date	Location	User	Value	Reason
Aug-31-2020 16:07:13 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: RIGHT	Initial Entry

7. Route:

090177e196ae2fdb\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: 11771204

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

Date	Location	User	Value	Reason
Aug-31-2020 16:07:13 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INTRAMUSCULAR	Initial Entry

10. Timeframe Subject Was Observed

Date	Location	User	Value	Reason
Aug-31-2020 16:07:13 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: THE PROTOCOL SPECIFIED OBSERVATION PERIOD	Initial Entry

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

Date	Location	User	Value	Reason
Aug-31-2020 16:07:13 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

090177e196ae2fdb\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: 11771204

Generated By: (b) (4)

Form: REACTOGENICITY DIARY - 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. Select appropriate response - Reactogenicity diary collection

Date	Location	User	Value	Reason
Aug-31-2020 12:13:45 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO - REACTOGENICITY E-DIAR Y NOT COLLECTED FOR THIS S UBJECT	Initial Entry

Header Text: C4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 1177

Subject No: 11771204

Generated By: (b) (4)

Form: DATE OF VISIT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

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I. Date of Visit

Date	Location	User	Value	Reason
Sep-21-2020 10:49:47 (UTC-10:00) Aleutian Islands	ACVOPFEINFP6000	(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: 11771204

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 11:11:50 (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 11:11:50 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Record Identifier:: 1 Temperature: 98.0 Temperature Unit: F Temperature Locatio n:: FOREHEA D	Initial Entry

2.a Record Identifier:

Date	Location	User	Value	Reason
Sep-21-2020 11:11:50 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 1	Initial Entry

2.a Temperature:

Date	Location	User	Value	Reason
Sep-21-2020 11:11:50 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 98.0	Initial Entry

2.a Unit:

Date	Location	User	Value	Reason
Sep-21-2020 11:11:50 (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 11:11:50 (UTC-10:00) Aleutian	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: FOREHEAD	Initial Entry

090177e196ae2fdb\Final\Final On: 01-Apr-2021 03:53 (GMT)

Header Text: C4591001

Visit: V2_VAX2_L

Form Version: 15-Sep-2020 21:54

Site No: 1177

Subject No: 11771204

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

Islands				
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090177e196ae2fdb\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: 11771204

Subject Initials: ---

Generated By: (b) (4)

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

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1. Data Origin

Date	Location	User	Value	Reason
Sep-21-2020 10:49:30 (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 10:49:30 (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 10:49:40 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Sep-21-2020 10:49:30 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Sep-21-2020 10:49:30 (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 10:49:40 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BP8JHY	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
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090177e196ae2fdb\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: 11771204

Subject Initials: ---

Generated By: (b) (4)

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

Sep-21-2020 10:49:40 (UTC-10:00) Aleutian Islands	ACVOPFEINFP6000	(b) (4), (b) (6)	Data Entry: BP8JHY	Initial Entry
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Header Text: C4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1177

Subject No: 11771204

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 11:06:12 (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 11:06:12 (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 11:06:12 (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 11:06:12 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sep/21/2020 09:14	Initial Entry

5. Anatomical Location:

Date	Location	User	Value	Reason
Sep-21-2020 11:06:12 (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 11:06:12 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: RIGHT	Initial Entry

7. Route:

090177e196ae2fdb\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: 11771204

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

Date	Location	User	Value	Reason
Sep-21-2020 11:06:12 (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 11:06:12 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: THE PROTOCOL SPECIFIED OBSERVATION PERIOD	Initial Entry

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

Date	Location	User	Value	Reason
Sep-21-2020 11:06:12 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

090177e196ae2fdb\Final\Final On: 01-Apr-2021 03:53 (GMT)

Header Text: C4591001

Visit: V3_MONTH1_POSTVAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 1177

Subject No: 11771204

Generated By: (b) (4)

Form: DATE OF VISIT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

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I. Date of Visit

Date	Location	User	Value	Reason
Oct-19-2020 10:49:33 (UTC-10:00) Aleutian Islands	ACVOPFEINFP6000	(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: 11771204

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 10:49:41 (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 10:49:41 (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 10:49:55 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Oct-19-2020 10:49:41 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Oct-19-2020 10:49:41 (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 10:49:55 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BS8BRH	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
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090177e196ae2fdb\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: 11771204

Subject Initials: ---

Generated By: (b) (4)

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

Oct-19-2020 10:49:55 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BS8BRH	Initial Entry
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5.b

Date	Location	User	Value	Reason
Oct-19-2020 10:50:13 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BS8BRJ	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Oct-19-2020 10:50:13 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BS8BRJ	Initial Entry

5.c

Date	Location	User	Value	Reason
Oct-19-2020 10:50:26 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BRJ56M	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Oct-19-2020 10:50:26 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BRJ56M	Initial Entry

090177e196ae2fdb\Final\Final On: 01-Apr-2021 03:53 (GMT)

Header Text: C4591001

Visit: End of Treatment - Unscheduled

Form Version: 15-Sep-2020 21:55

Site No: 1177

Subject No: 11771204

Generated By: (b) (4)

Form: DISPOSITION - TREATMENT - 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 Completion/Discontinuation/Death :

Date	Location	User	Value	Reason
Oct-19-2020 10:50:36 (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 10:50:36 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: VACCINATION	Initial Entry

3. Status:

Date	Location	User	Value	Reason
Oct-19-2020 10:50:36 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: COMPLETED	Initial Entry

090177e196ae2fdb\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: 11771204

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
Jan-15-2021 15:28:10 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1177

Subject No: 11771204

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

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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1. Category:

Date	Location	User	Value	Reason
Jan-15-2021 15:28:10 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: ADVERSE EVENT	Initial Entry

2. AE ID:

Date	Location	User	Value	Reason
Jan-15-2021 15:28:10 (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
Jan-15-2021 15:28:10 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Bladder Cancer	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason
Jan-15-2021 15:28:10 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Oct/24/2020 13:00	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Jan-15-2021 15:28:10 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
Jan-15-2021 15:28:10 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 3	Initial Entry

7. Is the adverse event serious?

Date	Location	User	Value	Reason

090177e196ae2fdb\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: 11771204

Subject Initials: ---

Generated By: (b) (4)

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

If Yes, NOTIFY PFIZER IMMEDIATELY.

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

Date	Location	User	Value	Reason
Jan-18-2021 01:12:12 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Deleted	Query can be addressed internally
Jan-15-2021 15:28:10 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	For AE Bladder Cancer: Response to "Is the adverse event serious?" is 'Yes' but "Serious Adverse Event Number" is blank.
Jan-15-2021 15:28:10 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Is this serious event associated with congenital anomaly or birth defect? NO Did this serious event result in death? NO Did this serious event require or prolong hospitalization? NO Did this serious event result in persistent or significant disability/incapacity? NO Is this serious event life threatening? NO Other medically important serious event YES	Initial Entry

090177e196ae2fdb\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: 11771204

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Verified

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

Subject Initials: ---

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

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

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

Date	Location	User	Value	Reason
Jan-15-2021 15:28:10 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Jan-21-2021 04:36:49 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Close per site response
Jan-20-2021 08:18:29 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Data is entered appropriately
Jan-20-2021 02:32:09 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000.InFormAdapter.Discrepancy	PFE SDQ PROD (b) (4)	Query 1: Opened	Please review "If not related to study treatment other" field, the following text was indicated in the comment field [Neoplasia]. Any symptoms, AEs or other key data should be collected on the appropriate page. Please review and update as necessary. (b) (4)
Jan-15-2021 15:28:10 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NOT RELATED If Not Related to study treatment(s), this event is due to: OTHER	Initial Entry

090177e196ae2fdb\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: 11771204

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Verified

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

Subject Initials: ---

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

				If Other, s pecify: Neoplasia
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10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Jan-26-2021 04:53:35 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Jan-25-2021 15:19:14 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	A follow up will be submitted
Jan-24-2021 23:43:57 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	SAE RECON:AER#2021036341,action taken was reported as NOT APPLICABLE in AE CRF while missing in Safety database.Please confirm. If safety update is required, please submit a follow up form
Jan-15-2021 15:28:10 (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
Jan-20-2021 08:32:16 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Jan-20-2021 08:24:35 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Data was updated
Jan-20-2021 05:26:00 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	Per AE log, subject is taking meds for chemotherapy. Please confirm and add Gemzar and Cisplatin to the Con Meds Prohibited eCRF.

090177e196ae2fdb\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: 11771204

Subject Initials: ---

Generated By: (b) (4)

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

Jan-15-2021 15:28:10 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry
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12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Jan-15-2021 15:28:10 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

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

Date	Location	User	Value	Reason
Jan-15-2021 15:28:10 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: RECOVERING/RESOLVING	Initial Entry

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

Date	Location	User	Value	Reason
Jan-15-2021 15:28:10 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

15. Serious Adverse Event Number: For Pfizer Use Only

Date	Location	User	Value	Reason
Jan-19-2021 01:17:41 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 2021036341	Initial Entry

090177e196ae2fdb\Final\Final On: 01-Apr-2021 03:53 (GMT)

Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1177

Subject No: 11771204

Generated By: (b) (4)

Form: CONCOMITANT MEDICATIONS - PROHIBITED - Audit Trail

Form Status:

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

Subject Initials: ---

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Date	Location	User	Value	Reason
Jan-20-2021 08:22:53 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1177

Subject No: 11771204

Generated By: (b) (4)

Form: CONCOMITANT MEDICATIONS - PROHIBITED - Audit Trail

Form Status:

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

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Date	Location	User	Value	Reason
Jan-20-2021 08:23:58 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

Header Text: C4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - PROHIBITED - 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: 11771204

Subject Initials: ---

Generated By: (b) (4)

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

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1. What is the medication identifier?

Date	Location	User	Value	Reason
Jan-20-2021 08:22:53 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 1	Initial Entry

2. Category:

Date	Location	User	Value	Reason
Jan-20-2021 08:22:53 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: CONCOMITANT IMMUNOSUPPRESSIVE THERAPY	Initial Entry

3. Concomitant Medications Pre-specified:

Date	Location	User	Value	Reason
Jan-20-2021 08:22:53 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: NO	Initial Entry

4. Medication:

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

Date	Location	User	Value	Reason
Jan-20-2021 08:22:53 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Gemzar	Initial Entry

5. Dose:

Date	Location	User	Value	Reason
Jan-20-2021 08:23:04 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Unknown	Initial Entry

6. Dose Unit:

Date	Location	User	Value	Reason
Jan-20-2021 08:23:13 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Unknown	Initial Entry

090177e196ae2fdb\Final\Final On: 01-Apr-2021 03:53 (GMT)

Header Text: C4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - PROHIBITED - 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: 11771204

Subject Initials: ---

Generated By: (b) (4)

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

7. Dose Frequency:

Date	Location	User	Value	Reason
Jan-20-2021 08:22:53 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNKNOWN	Initial Entry

8. Route:

Date	Location	User	Value	Reason
Jan-20-2021 08:22:53 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: INTRAVENOUS	Initial Entry

9. Start Date:

Date	Location	User	Value	Reason
Jan-20-2021 08:22:53 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Dec/15/2020	Initial Entry

10. Ongoing?

Date	Location	User	Value	Reason
Jan-20-2021 08:22:53 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

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Header Text: C4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - PROHIBITED - 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: 11771204

Subject Initials: ---

Generated By: (b) (4)

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

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1. What is the medication identifier?

Date	Location	User	Value	Reason
Jan-20-2021 08:23:58 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 2	Initial Entry

2. Category:

Date	Location	User	Value	Reason
Jan-20-2021 08:23:58 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: CONCOMITANT IMMUNOSUPPRESSIVE THERAPY	Initial Entry

3. Concomitant Medications Pre-specified:

Date	Location	User	Value	Reason
Jan-20-2021 08:23:58 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: NO	Initial Entry

4. Medication:

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

Date	Location	User	Value	Reason
Jan-20-2021 08:23:58 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Cisplatin	Initial Entry

5. Dose:

Date	Location	User	Value	Reason
Jan-20-2021 08:24:06 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Unknown	Initial Entry

6. Dose Unit:

Date	Location	User	Value	Reason
Jan-20-2021 08:24:16 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Unknown	Initial Entry

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Header Text: C4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - PROHIBITED - 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: 11771204

Subject Initials: ---

Generated By: (b) (4)

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

Islands		(b) (4), (b) (6)	
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7. Dose Frequency:

Date	Location	User	Value	Reason
Jan-20-2021 08:23:58 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNKNOWN	Initial Entry

8. Route:

Date	Location	User	Value	Reason
Jan-20-2021 08:23:58 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: INTRAVENOUS	Initial Entry

9. Start Date:

Date	Location	User	Value	Reason
Jan-20-2021 08:23:58 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Dec/22/2020	Initial Entry

10. Ongoing?

Date	Location	User	Value	Reason
Jan-20-2021 08:23:58 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

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Header Text: C4591001

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

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen, Verified

Site No: 1177

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

Subject No: 11771204

Subject Initials: ---

Generated By: (b) (4)

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

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I. Date of Visit

Date	Location	User	Value	Reason
Jan-14-2021 17:30:30 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Jan/14/2021	Initial Entry

Header Text: C4591001

Visit: Potential ReVax Initial Contact - Unscheduled **Form:** FURTHER VACCINATION CONFIRMATION - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:25

Form Status: Data Complete, Frozen, Verified

Site No: 1177

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

Subject No: 11771204

Subject Initials: ---

Generated By: (b) (4)

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

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

Date	Location	User	Value	Reason
Jan-14-2021 17:30:43 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Participant is willing to return for Vaccination 3 Participant is: eligible per local/national recommendations and confirmed to have received only placebo at Vaccination 1/2	Initial Entry

Header Text: C4591001

Visit: Disposition - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1177

Subject No: 11771204

Generated By: (b) (4)

Form: TREATMENT UNBLINDED - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

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

Subject Initials: ---

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

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1. Date Treatment Unblinded :

Date	Location	User	Value	Reason
Jan-14-2021 17:30:23 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Jan/14/2021	Initial Entry

2. Primary Reason for Unblinding:

Date	Location	User	Value	Reason
Jan-14-2021 17:30:23 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: ASSESS ELIGIBILITY FOR ADDI TIONAL VACCINATION	Initial Entry

Header Text: C4591001

Visit: V101_VAX3

Form Version: 22-Apr-2020 21:02

Site No: 1177

Subject No: 11771204

Generated By: (b) (4)

Form: DATE OF VISIT - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

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

Subject Initials: ---

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

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I. Date of Visit

Date	Location	User	Value	Reason
Feb-04-2021 11:44:30 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Feb/4/2021	Initial Entry

Header Text: C4591001

Visit: V101_VAX3

Form: INFORMED CONSENT - FURTHER VACCINATION - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:31

Form Status: Data Complete, Frozen, Verified

Site No: 1177

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

Subject No: 11771204

Subject Initials: ---

Generated By: (b) (4)

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

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I. Consent Was:

Date	Location	User	Value	Reason
Feb-04-2021 11:44:36 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: OBTAINED Date Written Consent Obtained Feb/4/2021	Initial Entry

Header Text: C4591001

Visit: V101_VAX3

Form: DISPOSITION - SCREENING FOR FURTHER VACCINATION - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:31

Form Status: Data Complete, Frozen, Verified

Site No: 1177

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

Subject No: 11771204

Subject Initials: ---

Generated By: (b) (4)

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

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1. Date of Completion/Discontinuation/Death :

Date	Location	User	Value	Reason
Feb-04-2021 11:45:08 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Feb/4/2021	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Feb-04-2021 11:45:08 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: REPEAT SCREENING 1	Initial Entry

3. Status:

Date	Location	User	Value	Reason
Feb-04-2021 11:45:08 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: COMPLETED	Initial Entry

090177e196ae2fdb\Final\Final On: 01-Apr-2021 03:53 (GMT)

Header Text: C4591001

Visit: V101_VAX3

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1177

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

Subject No: 11771204

Subject Initials: ---

Generated By: (b) (4)

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

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1. Data Origin

Date	Location	User	Value	Reason
Feb-04-2021 11:47:26 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Feb-04-2021 11:47:26 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SERUM	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Feb-04-2021 11:48:11 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Feb-04-2021 11:47:26 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Feb-04-2021 11:47:26 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Collection: Feb/4/2021	Initial Entry

5.a

Date	Location	User	Value	Reason
Feb-04-2021 11:48:11 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BS6TW0	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Feb-04-2021 11:48:11	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Initial Entry

090177e196ae2fdb\Final\Final On: 01-Apr-2021 03:53 (GMT)

Header Text: C4591001

Visit: V101_VAX3

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF
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Form Status: Data Complete, Frozen, Verified

Site No: 1177

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Subject No: 11771204

Subject Initials: ---

Generated By: (b) (4)

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(UTC-10:00) Aleutian Islands		(b) (4), (b) (6)	BS6TW0	
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5.b

Date	Location	User	Value	Reason
Feb-04-2021 11:48:21 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BS6TW1	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Feb-04-2021 11:48:21 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BS6TW1	Initial Entry

5.c

Date	Location	User	Value	Reason
Feb-04-2021 12:26:31 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BR8VMM	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Feb-04-2021 12:26:31 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BR8VMM	Initial Entry

090177e196ae2fdb\Final\Final On: 01-Apr-2021 03:53 (GMT)

Header Text: C4591001**Visit:** V101_VAX3**Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB - eCRF Audit Trail History**Form Version:** 22-Apr-2020 21:03**Form Status:** Data Complete, Frozen, Verified**Site No:** 1177**Site Name:** (1177) East-West Medical Research Institute**Subject No:** 11771204**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 12:55[Back to Form](#)**1. Data Origin**

Date	Location	User	Value	Reason
Feb-04-2021 11:48:32 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Feb-04-2021 11:48:32 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: NASAL_SWAB	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Feb-04-2021 12:26:47 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Feb-04-2021 11:48:32 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Feb-04-2021 11:48:32 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Collection: Feb/4/2021	Initial Entry

5.a

Date	Location	User	Value	Reason
Feb-04-2021 12:26:47 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BR92HK	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Feb-04-2021 12:26:47	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Initial Entry

Header Text: C4591001

Visit: V101_VAX3

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1177

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

Subject No: 11771204

Subject Initials: ---

Generated By: (b) (4)

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

(UTC-10:00) Aleutian Islands

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

BR92HK

Header Text: C4591001

Visit: V101_VAX3

Form Version: 10-Dec-2020 02:26

Site No: 1177

Subject No: 11771204

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

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

Subject Initials: ---

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

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1. Was there a temporary delay of vaccination?

Date	Location	User	Value	Reason
Feb-04-2021 11:45:42 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

2. Treatment Name

Date	Location	User	Value	Reason
Feb-04-2021 11:45:42 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> BNT162b2	Initial Entry

3. Formulation:

Date	Location	User	Value	Reason
Feb-04-2021 11:45:42 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> INJECTION	Initial Entry

4. Dose Date Time:

Date	Location	User	Value	Reason
Feb-04-2021 11:45:42 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Feb/4/2021 10:21	Initial Entry

5. Anatomical Location:

Date	Location	User	Value	Reason
Feb-04-2021 11:45:42 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> DELTOID MUSCLE	Initial Entry

6. Body Side:

Date	Location	User	Value	Reason
Feb-04-2021 11:45:42 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> RIGHT	Initial Entry

7. Route:

090177e196ae2fdb\Final\Final On: 01-Apr-2021 03:53 (GMT)

Header Text: C4591001

Visit: V101_VAX3

Form: VACCINATION - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:26

Form Status: Data Complete, Frozen, Verified

Site No: 1177

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

Subject No: 11771204

Subject Initials: ---

Generated By: (b) (4)

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

Date	Location	User	Value	Reason
Feb-04-2021 11:45:42 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> INTRAMUSCULAR	Initial Entry

8. Actual Dose:

Date	Location	User	Value	Reason
Feb-04-2021 11:45:42 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> 30.0	Initial Entry

9. Unit:

Date	Location	User	Value	Reason
Feb-04-2021 11:45:42 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> ug	Initial Entry

10. Timeframe Subject Was Observed

Date	Location	User	Value	Reason
Feb-04-2021 11:45:42 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> 30 MINUTES	Initial Entry

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

Date	Location	User	Value	Reason
Feb-04-2021 11:45:42 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> YES	Initial Entry

090177e196ae2fdb\Final\Final On: 01-Apr-2021 03:53 (GMT)

Header Text: C4591001

Visit: V102_VAX4

Form Version: 22-Apr-2020 21:02

Site No: 1177

Subject No: 11771204

Generated By: (b) (4)

Form: DATE OF VISIT - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

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

Subject Initials: ---

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

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I. Date of Visit

Date	Location	User	Value	Reason
Feb-25-2021 11:44:48 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Feb/25/2021	Initial Entry

Header Text: C4591001

Visit: V102_VAX4

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1177

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

Subject No: 11771204

Subject Initials: ---

Generated By: (b) (4)

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

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1. Data Origin

Date	Location	User	Value	Reason
Feb-25-2021 11:45:00 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Feb-25-2021 11:45:00 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: NASAL_SWAB	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Feb-25-2021 11:45:00 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Collection: Feb/25/2021	Initial Entry

5.a

Date	Location	User	Value	Reason
Feb-25-2021 11:12:51 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BR92NH	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Feb-25-2021 11:12:51 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BR92NH	Initial Entry

090177e196ae2fdb\Final\Final On: 01-Apr-2021 03:53 (GMT)

Header Text: C4591001

Visit: V102_VAX4

Form Version: 10-Dec-2020 02:26

Site No: 1177

Subject No: 11771204

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

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

Subject Initials: ---

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

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1. Was there a temporary delay of vaccination?

Date	Location	User	Value	Reason
Feb-25-2021 11:45:53 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

2. Treatment Name

Date	Location	User	Value	Reason
Feb-25-2021 11:45:53 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> BNT162b2	Initial Entry

3. Formulation:

Date	Location	User	Value	Reason
Feb-25-2021 11:45:53 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> INJECTION	Initial Entry

4. Dose Date Time:

Date	Location	User	Value	Reason
Feb-25-2021 11:45:53 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Feb/25/2021 10:24	Initial Entry

5. Anatomical Location:

Date	Location	User	Value	Reason
Feb-25-2021 11:45:53 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> DELTOID MUSCLE	Initial Entry

6. Body Side:

Date	Location	User	Value	Reason
Feb-25-2021 11:45:53 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> RIGHT	Initial Entry

7. Route:

090177e196ae2fdb\Final\Final On: 01-Apr-2021 03:53 (GMT)

Header Text: C4591001

Visit: V102_VAX4

Form: VACCINATION - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:26

Form Status: Data Complete, Frozen, Verified

Site No: 1177

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

Subject No: 11771204

Subject Initials: ---

Generated By: (b) (4)

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

Date	Location	User	Value	Reason
Feb-25-2021 11:45:53 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> INTRAMUSCULAR	Initial Entry

8. Actual Dose:

Date	Location	User	Value	Reason
Feb-25-2021 11:45:53 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> 30.0	Initial Entry

9. Unit:

Date	Location	User	Value	Reason
Feb-25-2021 11:45:53 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> ug	Initial Entry

10. Timeframe Subject Was Observed

Date	Location	User	Value	Reason
Feb-25-2021 11:45:53 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> 30 MINUTES	Initial Entry

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

Date	Location	User	Value	Reason
Feb-25-2021 11:45:53 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> YES	Initial Entry

090177e196ae2fdb\Final\Final On: 01-Apr-2021 03:53 (GMT)

Header Text: C4591001

Visit: Subject Status - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1177

Subject No: 11771204

Generated By: (b) (4)

Form: SUBJECT STATUS - eCRF Audit Trail History

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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I. Subject Status

Date	Location	User	Value	Reason
Oct-19-2020 10:50:36 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: FOLLOW-UP	Initial Entry
Aug-31-2020 12:18:52 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: ENROLLED/RANDOMIZED	Initial Entry
Aug-31-2020 12:11:14 (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 10:50:36 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Oct/19/2020	Initial Entry
Aug-31-2020 12:18:52 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Aug/31/2020	Initial Entry
Aug-31-2020 12:11:14 (UTC-10:00) Aleutian Islands	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Aug/31/2020	Initial Entry

090177e196ae2fdb\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: 11771204

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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I. Casebook Signature

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