

Header Text: c4591001

Visit: COHORT_SELECTION

Form Version: 10-Oct-2020 16:01

Site No: 1135

Subject No: 11351563

Generated By: (b) (4)

Form: COHORT_SELECTION

Form Status: Data Complete, Frozen, Verified

Site Name: (1135) Anaheim Clinical Trials

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:34

[eCRF Audit Trail History](#)

Cohort Selection

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

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

Header Text: c4591001

Visit: COHORT_SELECTION

Form Version: 22-Apr-2020 21:02

Site No: 1135

Subject No: 11351563

Generated By: (b) (4)

Form: MAIN INFORMED CONSENT

Form Status: Data Complete, Frozen, Verified

Site Name: (1135) Anaheim Clinical Trials

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:34

[eCRF Audit Trail History](#)

Informed Consent

1.	Consent Was:	OBTAINED Date Written Consent Obtained Oct/27/2020
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Header Text: c4591001

Visit: COHORT_SELECTION

Form: DEMOGRAPHY

Form Version: 15-Sep-2020 21:54

Form Status: Data Complete, Frozen, Verified

Site No: 1135

Site Name: (1135) Anaheim Clinical Trials

Subject No: 11351563

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:34

[eCRF Audit Trail History](#)

Demography

1.	Subject ID	[11351563]
2.	Birth Date:	(b) (6)/1992
3.	Sex:	FEMALE
4.	Ethnicity:	NOT HISPANIC OR LATINO(A) OR OF SPANISH ORIGIN
5.	Race: (Check X all that apply):	WHITE
6.	Racial Designation:	

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:02

Site No: 1135

Subject No: 11351563

Generated By: (b) (4)

Form: DATE OF VISIT

Form Status: Data Complete, Frozen, Verified

Site Name: (1135) Anaheim Clinical Trials

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:34

[eCRF Audit Trail History](#)

Date of Visit

1.	Date of Visit	Oct/27/2020
2.	Erroneous Visit	

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 10-Oct-2020 16:00

Site No: 1135

Subject No: 11351563

Generated By: (b) (4)

Form: INCLUSION/EXCLUSION CRITERIA

Form Status: Data Complete, Frozen, Verified

Site Name: (1135) Anaheim Clinical Trials

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:34

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: 15-Sep-2020 21:52

Site No: 1135

Subject No: 11351563

Generated By: (b) (4)

Form: DISPOSITION - SCREENING

Form Status: Data Complete, Frozen, Verified

Site Name: (1135) Anaheim Clinical Trials

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:34

[eCRF Audit Trail History](#)

Disposition - Screening

1.	Date of Completion/Discontinuation /Death	Oct/27/2020
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: 1135

Subject No: 11351563

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY

Form Status: Data Complete, Frozen, Verified

Site Name: (1135) Anaheim Clinical Trials

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:34

eCRF Audit Trail History

Medical History Details

1.a	Line/MH Number:	[1]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[nearsighted]
	Start Date:	UNK/UNK/2002
	Ongoing:	YES
1.b	Line/MH Number:	[2]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[hypothyroidism]
	Start Date:	UNK/UNK/2005
	Ongoing:	YES
1.c	Line/MH Number:	[3]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[overweight]
	Start Date:	UNK/UNK/2015
	Ongoing:	YES
1.d	Line/MH Number:	[4]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[obese]
	Start Date:	UNK/UNK/2015
	Ongoing:	YES
1.e	Line/MH Number:	[5]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[fibromyalgia]
	Start Date:	UNK/UNK/2017
	Ongoing:	YES
1.f	Line/MH Number:	[6]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[gastric bypass]
	Start Date:	UNK/UNK/2016
	Ongoing:	YES

090177e196ae3d55\Final\Final On: 01-Apr-2021 04:31 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1135

Subject No: 11351563

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY

Form Status: Data Complete, Frozen, Verified

Site Name: (1135) Anaheim Clinical Trials

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:34

1.g	Line/MH Number:	[7]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[depression]
	Start Date:	UNK/UNK/2013
	Ongoing:	YES
1.h	Line/MH Number:	[8]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[gastric bypass surgery]
	Start Date:	UNK/UNK/2016
	Ongoing:	YES

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 15-Sep-2020 21:57

Site No: 1135

Subject No: 11351563

Generated By: (b) (4)

Form: HIV STATUS

Form Status: Data Complete, Frozen, Verified

Site Name: (1135) Anaheim Clinical Trials

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:34

[eCRF Audit Trail History](#)

HIV Status

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

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 10-Oct-2020 16:04

Site No: 1135

Subject No: 11351563

Generated By: (b) (4)

Form: VITAL SIGNS - BASELINE

Form Status: Data Complete, Frozen, Verified

Site Name: (1135) Anaheim Clinical Trials

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:34

[eCRF Audit Trail History](#)

Vital Signs

1.	Date:	Oct/27/2020
2.	Weight:	[100.4]
3.	Unit:	kg
4.	Height:	[162.0]
5.	Unit:	cm
6.	Body Mass Index:	[38.3]

Vital Signs Details

7.a	Record Identifier:	1
	Temperature:	[37.1]
	Unit:	C
	Temperature Location:	ORAL CAVITY

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 10-Oct-2020 15:58

Site No: 1135

Subject No: 11351563

Generated By: (b) (4)

Form: LAB URINALYSIS - PREGNANCY TEST

Form Status: Data Complete, Frozen, Verified

Site Name: (1135) Anaheim Clinical Trials

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:34

[eCRF Audit Trail History](#)

Lab Urinalysis

1.	Lab Panel:	URINALYSIS
2.	Lab Sub-Panel:	PREGNANCY
3.	Collection Date:	Oct/27/2020
4.	Laboratory Name and Address (Derived)	[STUDY SITE]
5.	Specimen Type:	URINE

Lab Result

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

090177e196ae3d55\Final\Final On: 01-Apr-2021 04:31 (GMT)

Header Text: c4591001	Form: RANDOMIZATION
Visit: V1_DAY1_VAX1_L	Form Status: Data Complete, Frozen, Verified
Form Version: 22-Apr-2020 21:03	Site Name: (1135) Anaheim Clinical Trials
Site No: 1135	Subject Initials: ---
Subject No: 11351563	Generated Time (GMT): 29-Mar-2021 11:34
Generated By: (b) (4)	

[eCRF Audit Trail History](#)

Disposition		
1.	Randomization Date :	Oct/27/2020
2.	Randomization Number:	[401109]
3.	Randomization Group:	[]

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1135

Subject No: 11351563

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Status: Data Complete, Frozen, Verified

Site Name: (1135) Anaheim Clinical Trials

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:34

[eCRF Audit Trail History](#)

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	SERUM
3.	Sample Collected?	YES Date of Collection: Oct/27/2020
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	[BP93J1]
5.b	Sample ID	[BMNXCB]
5.c	Sample ID	[BMNXCD]

090177e196ae3d55\Final\Final On: 01-Apr-2021 04:31 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1135

Subject No: 11351563

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB

Form Status: Data Complete, Frozen, Verified

Site Name: (1135) Anaheim Clinical Trials

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:34

[eCRF Audit Trail History](#)

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Oct/27/2020
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	[BRFZB4]
-----	-----------	----------

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:04

Site No: 1135

Subject No: 11351563

Generated By: (b) (4)

Form: VACCINATION

Form Status: Data Complete, Frozen, Verified

Site Name: (1135) Anaheim Clinical Trials

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:34

eCRF Audit Trail History

Vaccination

1.	Was there a temporary delay of vaccination?	NO
2.	Treatment Name	[BLINDED THERAPY]
3.	Formulation:	INJECTION
4.	Dose Date Time:	Oct/27/2020 13:16
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

090177e196ae3d55\Final\Final On: 01-Apr-2021 04:31 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 06-Jul-2020 21:53

Site No: 1135

Subject No: 11351563

Generated By: (b) (4)

Form: REACTOGENICITY DIARY

Form Status: Data Complete, Frozen, Verified

Site Name: (1135) Anaheim Clinical Trials

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:34

[eCRF Audit Trail History](#)

Reactogenicity Diary

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

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 1135

Subject No: 11351563

Generated By: (b) (4)

Form: DATE OF VISIT

Form Status: Data Complete, Frozen, Verified

Site Name: (1135) Anaheim Clinical Trials

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:34

[eCRF Audit Trail History](#)

Date of Visit

1.	Date of Visit	Nov/20/2020
2.	Erroneous Visit	

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 10-Oct-2020 16:01

Site No: 1135

Subject No: 11351563

Generated By: (b) (4)

Form: VITAL SIGNS - TEMP

Form Status: Data Complete, Frozen, Verified

Site Name: (1135) Anaheim Clinical Trials

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:34

[eCRF Audit Trail History](#)

Vital Signs

1.	Date:	Nov/20/2020
----	-------	-------------

Vital Signs Details

2.a	Record Identifier:	1
	Temperature:	[36.7]
	Unit:	C
	Temperature Location:	ORAL CAVITY

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 10-Oct-2020 15:58

Site No: 1135

Subject No: 11351563

Generated By: (b) (4)

Form: LAB URINALYSIS - PREGNANCY TEST

Form Status: Data Complete, Frozen, Verified

Site Name: (1135) Anaheim Clinical Trials

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:34

[eCRF Audit Trail History](#)

Lab Urinalysis

1.	Lab Panel:	URINALYSIS
2.	Lab Sub-Panel:	PREGNANCY
3.	Collection Date:	Nov/20/2020
4.	Laboratory Name and Address (Derived)	[STUDY SITE]
5.	Specimen Type:	URINE

Lab Result

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

090177e196ae3d55\Final\Final On: 01-Apr-2021 04:31 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:03

Site No: 1135

Subject No: 11351563

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB

Form Status: Data Complete, Frozen, Verified

Site Name: (1135) Anaheim Clinical Trials

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:34

[eCRF Audit Trail History](#)

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Nov/20/2020
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	[BRFZM9]
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Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1135

Subject No: 11351563

Generated By: (b) (4)

Form: VACCINATION

Form Status: Data Complete, Frozen, Verified

Site Name: (1135) Anaheim Clinical Trials

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:34

eCRF Audit Trail History

Vaccination

1.	Was there a temporary delay of vaccination?	NO
2.	Treatment Name	[BLINDED THERAPY]
3.	Formulation:	INJECTION
4.	Dose Date Time:	Nov/20/2020 10:43
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

090177e196ae3d55\Final\Final On: 01-Apr-2021 04:31 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form: DATE OF VISIT

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen, Verified

Site No: 1135

Site Name: (1135) Anaheim Clinical Trials

Subject No: 11351563

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:34

[eCRF Audit Trail History](#)

Date of Visit

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

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1135

Site Name: (1135) Anaheim Clinical Trials

Subject No: 11351563

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:34

[eCRF Audit Trail History](#)

Electronic Sample Tracking

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

Aliquot

Please enter barcode for each aliquot.

5.a	Sample ID	[BRCD4C]
5.b	Sample ID	[BSJVGD]
5.c	Sample ID	[BSJVGF]

090177e196ae3d55\Final\Final On: 01-Apr-2021 04:31 (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: 1135

Site Name: (1135) Anaheim Clinical Trials

Subject No: 11351563

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:34

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

COVID-19 Illness Visit

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

Header Text: c4591001

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

Form Version: 20-Feb-2021 02:17

Form Status: Not Started

Site No: 1135

Site Name: (1135) Anaheim Clinical Trials

Subject No: 11351563

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:34

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: 1135

Site Name: (1135) Anaheim Clinical Trials

Subject No: 11351563

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:34

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: 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: 1135

Site Name: (1135) Anaheim Clinical Trials

Subject No: 11351563

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:34

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

Form Version: 20-Feb-2021 02:19

Form Status: Not Started

Site No: 1135

Site Name: (1135) Anaheim Clinical Trials

Subject No: 11351563

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:34

Health Care Utilization

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

Health Care Utilization Other

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

Health Care Utilization

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

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: 1135

Site Name: (1135) Anaheim Clinical Trials

Subject No: 11351563

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:34

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: 1135

Site Name: (1135) Anaheim Clinical Trials

Subject No: 11351563

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:34

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

COVID-19 Illness Visit

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

Header Text: c4591001

Visit: POT_COVID_CONVA - New Unscheduled Visit **Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1135

Site Name: (1135) Anaheim Clinical Trials

Subject No: 11351563

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:34

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: 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: 1135

Site Name: (1135) Anaheim Clinical Trials

Subject No: 11351563

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:34

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

COVID-19 Repeat Swab

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

Header Text: c4591001

Visit: POT_COVID_REPEAT_SWAB - New
Unscheduled Visit

Form: ELECTRONIC SAMPLE TRACKING - REPEAT SWAB

Form Version: 10-Oct-2020 15:57

Form Status: Not Started

Site No: 1135

Site Name: (1135) Anaheim Clinical Trials

Subject No: 11351563

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:34

Electronic Sample Tracking

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

Aliquot

Please enter barcode for each aliquot.

5.	Sample ID	[]
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Header Text: c4591001

Visit: Logs

Form: ADVERSE EVENT REPORT

Form Version: 22-Apr-2020 21:02

Site No: 1135

Site Name: (1135) Anaheim Clinical Trials

Subject No: 11351563

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:34

#	Category	AE Identifier	Adverse Event	Start Date	Is the Adverse Event Still Ongoing	Form Instance
1.	ADVERSE EVENT	1	acute pancreatitis	Nov/21/2020 UNK:UNK	NO End Date Time: Nov/24/2020 UNK:UNK	Repeating Pages

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1135

Subject No: 11351563

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Frozen

Site Name: (1135) Anaheim Clinical Trials

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:34

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

Adverse Event Report

1.	Category:	ADVERSE EVENT
2.	AE ID:	[1]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[acute pancreatitis]
4.	Start Date Time:	Nov/21/2020 UNK:UNK
5.	Is the adverse event still ongoing?	NO End Date Time: Nov/24/2020 UNK:UNK
6.	Toxicity Grade:	2
7.	Is the adverse event serious? If Yes, NOTIFY PFIZER IMMEDIATELY. Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).	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? YES Did this serious event result in persistent or significant disability/incapacity? NO Is this serious event life threatening? NO Other medically important serious event NO
8.	Is this adverse event the result of a study Medication Error? If Yes, record the type of medication error on the Medication Error Log.	NO
9.	Is this event related to study treatment:	NOT RELATED If Not Related to study treatment(s), this event is due to: OTHER If Other, specify: [pending records]
10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE

090177e196ae3d55\Final\Final On: 01-Apr-2021 04:31 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1135

Subject No: 11351563

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Frozen

Site Name: (1135) Anaheim Clinical Trials

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:34

11.	Was a Concomitant Medication given?	YES
12.	Was a Non-Drug Treatment given?	NO
13.	What was the outcome of this adverse event?:	RECOVERED/RESOLVED
14.	Did the adverse event cause the subject to be discontinued from the study?	NO
15.	Serious Adverse Event Number: For Pfizer Use Only	[2020498809]

Header Text: c4591001

Visit: Logs

Form: MEDICATION ERROR

Form Version: 17-Jul-2020 21:54

Site No: 1135

Site Name: (1135) Anaheim Clinical Trials

Subject No: 11351563

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:34

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

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 17-Jul-2020 21:54

Site No: 1135

Subject No: 11351563

Generated By: (b) (4)

Form: MEDICATION ERROR

Form Status: Not Started

Site Name: (1135) Anaheim Clinical Trials

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:34

[Back to Form](#)

Medication Error

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

090177e196ae3d55\Final\Final On: 01-Apr-2021 04:31 (GMT)

Header Text: c4591001

Visit: Logs

Form: CONCOMITANT MEDICATIONS - NON STUDY VACCINATIONS

Form Version: 22-Apr-2020 21:03

Site No: 1135

Site Name: (1135) Anaheim Clinical Trials

Subject No: 11351563

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:34

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

090177e196ae3d55\Final\Final On: 01-Apr-2021 04:31 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1135

Subject No: 11351563

Generated By: (b) (4)

Form: CONCOMITANT MEDICATIONS - NON STUDY VACCINATIONS

Form Status: Not Started

Site Name: (1135) Anaheim Clinical Trials

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:34

[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:	//

090177e196ae3d55\Final\Final On: 01-Apr-2021 04:31 (GMT)

Header Text: c4591001

Visit: Logs

Form: CONCOMITANT MEDICATIONS - PROHIBITED

Form Version: 22-Apr-2020 21:03

Site No: 1135

Site Name: (1135) Anaheim Clinical Trials

Subject No: 11351563

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:34

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

090177e196ae3d55\Final\Final On: 01-Apr-2021 04:31 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1135

Subject No: 11351563

Generated By: (b) (4)

Form: CONCOMITANT MEDICATIONS - PROHIBITED

Form Status: Not Started

Site Name: (1135) Anaheim Clinical Trials

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:34

[Back to Form](#)

Concomitant Medications

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

090177e196ae3d55\Final\Final On: 01-Apr-2021 04:31 (GMT)

Header Text: c4591001

Visit: Logs

Form: RADIATION TREATMENT

Form Version: 22-Apr-2020 21:02

Site No: 1135

Site Name: (1135) Anaheim Clinical Trials

Subject No: 11351563

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:34

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

090177e196ae3d55\Final\Final On: 01-Apr-2021 04:31 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1135

Subject No: 11351563

Generated By: (b) (4)

Form: RADIATION TREATMENT

Form Status: Not Started

Site Name: (1135) Anaheim Clinical Trials

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:34

[Back to Form](#)

Radiation Treatment

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

Header Text: c4591001

Visit: Logs

Form: TRANSFUSIONS

Form Version: 22-Apr-2020 21:03

Site No: 1135

Site Name: (1135) Anaheim Clinical Trials

Subject No: 11351563

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:34

#	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: 1135

Subject No: 11351563

Generated By: (b) (4)

Form: TRANSFUSIONS

Form Status: Not Started

Site Name: (1135) Anaheim Clinical Trials

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:34

[Back to Form](#)

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

Header Text: c4591001

Visit: Unplanned - New Unscheduled Visit

Form: DATE OF VISIT

Form Version: 22-Apr-2020 21:02

Form Status: Not Started

Site No: 1135

Site Name: (1135) Anaheim Clinical Trials

Subject No: 11351563

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:34

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: 1135

Site Name: (1135) Anaheim Clinical Trials

Subject No: 11351563

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:34

Unplanned Assessments

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

Header Text: c4591001

Visit: Unplanned Vaccination - Unscheduled

Form: DATE OF VISIT

Form Version: 22-Apr-2020 21:02

Form Status: Not Started

Site No: 1135

Site Name: (1135) Anaheim Clinical Trials

Subject No: 11351563

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:34

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: 1135

Site Name: (1135) Anaheim Clinical Trials

Subject No: 11351563

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:34

Vital Signs

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

Vital Signs Details

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

Header Text: c4591001

Visit: Unplanned Vaccination - Unscheduled

Form: LAB URINALYSIS - PREGNANCY TEST

Form Version: 20-Feb-2021 02:14

Form Status: Not Started

Site No: 1135

Site Name: (1135) Anaheim Clinical Trials

Subject No: 11351563

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:34

Lab Urinalysis

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

Lab Result

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

090177e196ae3d55\Final\Final On: 01-Apr-2021 04:31 (GMT)

Header Text: c4591001

Visit: Unplanned Vaccination - Unscheduled

Form: VACCINATION

Form Version: 10-Dec-2020 02:26

Form Status: Not Started

Site No: 1135

Site Name: (1135) Anaheim Clinical Trials

Subject No: 11351563

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:34

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?	

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: 1135

Site Name: (1135) Anaheim Clinical Trials

Subject No: 11351563

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:34

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: 1135

Site Name: (1135) Anaheim Clinical Trials

Subject No: 11351563

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:34

Contact Outcome

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

Header Text: c4591001

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

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen, Verified

Site No: 1135

Site Name: (1135) Anaheim Clinical Trials

Subject No: 11351563

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:34

[eCRF Audit Trail History](#)

Date of Visit

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

090177e196ae3d55\Final\Final On: 01-Apr-2021 04:31 (GMT)

Header Text: c4591001

Visit: V201_SURVEIL_CONSENT - Unscheduled **Form:** INFORMED CONSENT - ASYMPTOMATIC SURVEILLANCE

Form Version: 14-Jan-2021 02:29

Form Status: Data Complete, Frozen, Verified

Site No: 1135

Site Name: (1135) Anaheim Clinical Trials

Subject No: 11351563

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:34

[eCRF Audit Trail History](#)

Informed Consent - Asymptomatic Surveillance

1.	Consent Was:	OBTAINED Date Written Consent Obtained Feb/2/2021
----	--------------	---

Header Text: c4591001

Visit: V201_SURVEIL_CONSENT - Unscheduled **Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1135

Site Name: (1135) Anaheim Clinical Trials

Subject No: 11351563

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:34

[eCRF Audit Trail History](#)

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	SERUM
3.	Sample Collected?	YES Date of Collection: Feb/2/2021
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	[BR9MGH]
5.b	Sample ID	[BSG9RV]
5.c	Sample ID	[BSG9RX]

090177e196ae3d55\Final\Final On: 01-Apr-2021 04:31 (GMT)

Header Text: c4591001

Visit: V201_SURVEIL_CONSENT - Unscheduled **Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1135

Site Name: (1135) Anaheim Clinical Trials

Subject No: 11351563

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:34

[eCRF Audit Trail History](#)

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Feb/2/2021
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	[BR9MGT]
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Header Text: c4591001

Visit: V202_SURVEIL_SWAB 1 - Unscheduled
Visit on Feb/15/2021

Form: DATE OF VISIT - ASYMPTOMATIC SURVEILLANCE

Form Version: 14-Jan-2021 02:22

Form Status: Data Complete, Frozen, Verified

Site No: 1135

Site Name: (1135) Anaheim Clinical Trials

Subject No: 11351563

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:34

[eCRF Audit Trail History](#)

Date of Visit

1.	Date of Visit	Feb/15/2021
2.	Erroneous Visit	

COVID-19 Surveillance Visit

3.	COVID-19 Surveillance Visit:	SSWAB_WEEK2
----	------------------------------	-------------

090177e196ae3d55\Final\Final On: 01-Apr-2021 04:31 (GMT)

Header Text: c4591001

Visit: V202_SURVEIL_SWAB 1 - Unscheduled
Visit on Feb/15/2021

Form: ELECTRONIC SAMPLE TRACKING - REPEAT SWAB

Form Version: 10-Oct-2020 15:57

Form Status: Data Complete, Frozen, Verified

Site No: 1135

Site Name: (1135) Anaheim Clinical Trials

Subject No: 11351563

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:34

[eCRF Audit Trail History](#)

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB_SELF
3.	Sample Collected?	YES Date of Collection: Feb/15/2021
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	[AA61650]
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090177e196ae3d55\Final\Final On: 01-Apr-2021 04:31 (GMT)

Header Text: c4591001

Visit: End of Treatment - Unscheduled

Form: DISPOSITION - TREATMENT

Form Version: 10-Dec-2020 02:29

Form Status: Data Complete, Frozen, Verified

Site No: 1135

Site Name: (1135) Anaheim Clinical Trials

Subject No: 11351563

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:34

[eCRF Audit Trail History](#)

Disposition - Treatment

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

Header Text: c4591001

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

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen, Verified

Site No: 1135

Site Name: (1135) Anaheim Clinical Trials

Subject No: 11351563

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:34

[eCRF Audit Trail History](#)

Date of Visit

1.	Date of Visit	Feb/16/2021
2.	Erroneous Visit	

Header Text: c4591001

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

Form Version: 10-Dec-2020 02:25

Form Status: Data Complete, Frozen

Site No: 1135

Site Name: (1135) Anaheim Clinical Trials

Subject No: 11351563

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:34

[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
----	---	---

090177e196ae3d55\Final\Final On: 01-Apr-2021 04:31 (GMT)

Header Text: c4591001

Visit: Follow-Up - Unscheduled

Form Version: 15-Sep-2020 21:53

Site No: 1135

Subject No: 11351563

Generated By: (b) (4)

Form: DISPOSITION - FOLLOW-UP

Form Status: Not Started

Site Name: (1135) Anaheim Clinical Trials

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:34

Disposition - Follow-Up

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

Header Text: c4591001

Visit: Disposition - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1135

Subject No: 11351563

Generated By: (b) (4)

Form: TREATMENT UNBLINDED

Form Status: Data Complete, Frozen, Verified

Site Name: (1135) Anaheim Clinical Trials

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:34

[eCRF Audit Trail History](#)

Treatment Unblinded

1.	Date Treatment Unblinded :	Feb/16/2021
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: 1135

Site Name: (1135) Anaheim Clinical Trials

Subject No: 11351563

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:34

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: 1135

Site Name: (1135) Anaheim Clinical Trials

Subject No: 11351563

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:34

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: 1135

Subject No: 11351563

Generated By: (b) (4)

Form: DATE OF VISIT

Form Status: Data Complete, Frozen, Verified

Site Name: (1135) Anaheim Clinical Trials

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:34

[eCRF Audit Trail History](#)

Date of Visit

1.	Date of Visit	Feb/17/2021
2.	Erroneous Visit	

Header Text: c4591001

Visit: V101_VAX3

Form Version: 10-Dec-2020 02:31

Site No: 1135

Subject No: 11351563

Generated By: (b) (4)

Form: INFORMED CONSENT - FURTHER VACCINATION

Form Status: Data Complete, Frozen, Verified

Site Name: (1135) Anaheim Clinical Trials

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:34

[eCRF Audit Trail History](#)

Informed Consent - Further Vaccination

1.	Consent Was:	OBTAINED Date Written Consent Obtained Feb/17/2021
----	--------------	--

090177e196ae3d55\Final\Final On: 01-Apr-2021 04:31 (GMT)

Header Text: c4591001

Visit: V101_VAX3

Form Version: 10-Dec-2020 02:30

Site No: 1135

Subject No: 11351563

Generated By: (b) (4)

Form: INCLUSION/EXCLUSION CRITERIA - FURTHER VACCINATION

Form Status: Data Complete, Frozen, Verified

Site Name: (1135) Anaheim Clinical Trials

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:34

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: 1135

Subject No: 11351563

Generated By: (b) (4)

Form: DISPOSITION - SCREENING FOR FURTHER VACCINATION

Form Status: Data Complete, Frozen, Verified

Site Name: (1135) Anaheim Clinical Trials

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:34

[eCRF Audit Trail History](#)

Disposition - Screening for Further Vaccination

1.	Date of Completion/Discontinuation /Death :	Feb/17/2021
2.	Phase of Disposition:	REPEAT SCREENING 1
3.	Status:	COMPLETED
4.	Specify Status:	[]

Header Text: c4591001

Visit: V101_VAX3

Form Version: 14-Jan-2021 02:21

Site No: 1135

Subject No: 11351563

Generated By: (b) (4)

Form: LAB URINALYSIS - PREGNANCY TEST

Form Status: Data Complete, Frozen, Verified

Site Name: (1135) Anaheim Clinical Trials

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:34

[eCRF Audit Trail History](#)

Lab Urinalysis

1.	Lab Panel:	URINALYSIS
2.	Lab Sub-Panel:	PREGNANCY
3.	Collection Date:	Feb/17/2021
4.	Laboratory Name and Address (Derived)	[STUDY SITE]
5.	Specimen Type:	URINE

Lab Result

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

Header Text: c4591001

Visit: V101_VAX3

Form Version: 22-Apr-2020 21:03

Site No: 1135

Subject No: 11351563

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Status: Data Complete, Frozen, Verified

Site Name: (1135) Anaheim Clinical Trials

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:34

[eCRF Audit Trail History](#)

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	SERUM
3.	Sample Collected?	YES Date of Collection: Feb/17/2021
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	[BRGVBK]
5.b	Sample ID	[BSG9YT]
5.c	Sample ID	[BSG9YV]

090177e196ae3d55\Final\Final On: 01-Apr-2021 04:31 (GMT)

Header Text: c4591001

Visit: V101_VAX3

Form Version: 22-Apr-2020 21:03

Site No: 1135

Subject No: 11351563

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB

Form Status: Data Complete, Frozen, Verified

Site Name: (1135) Anaheim Clinical Trials

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:34

[eCRF Audit Trail History](#)

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Feb/17/2021
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	[BRGVBL]
-----	-----------	----------

Header Text: c4591001

Visit: V101_VAX3

Form Version: 10-Dec-2020 02:26

Site No: 1135

Subject No: 11351563

Generated By: (b) (4)

Form: VACCINATION

Form Status: Data Complete, Frozen, Verified

Site Name: (1135) Anaheim Clinical Trials

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:34

[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/17/2021 11:44
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

090177e196ae3d55\Final\Final On: 01-Apr-2021 04:31 (GMT)

Header Text: c4591001

Visit: V102_VAX4

Form Version: 22-Apr-2020 21:02

Site No: 1135

Subject No: 11351563

Generated By: (b) (4)

Form: DATE OF VISIT

Form Status: Data Complete, Verified

Site Name: (1135) Anaheim Clinical Trials

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:34

[eCRF Audit Trail History](#)

Date of Visit

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

Header Text: c4591001

Visit: V102_VAX4

Form: LAB URINALYSIS - PREGNANCY TEST

Form Version: 14-Jan-2021 02:21

Form Status: Data Complete, Verified

Site No: 1135

Site Name: (1135) Anaheim Clinical Trials

Subject No: 11351563

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:34

[eCRF Audit Trail History](#)

Lab Urinalysis

1.	Lab Panel:	URINALYSIS
2.	Lab Sub-Panel:	PREGNANCY
3.	Collection Date:	Mar/10/2021
4.	Laboratory Name and Address (Derived)	[STUDY SITE]
5.	Specimen Type:	URINE

Lab Result

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

090177e196ae3d55\Final\Final On: 01-Apr-2021 04:31 (GMT)

Header Text: c4591001

Visit: V102_VAX4

Form Version: 22-Apr-2020 21:03

Site No: 1135

Subject No: 11351563

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB

Form Status: Data Complete, Verified

Site Name: (1135) Anaheim Clinical Trials

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:34

[eCRF Audit Trail History](#)

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Mar/10/2021
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	[BR9MPM]
-----	-----------	----------

Header Text: c4591001

Visit: V102_VAX4

Form Version: 10-Dec-2020 02:26

Site No: 1135

Subject No: 11351563

Generated By: (b) (4)

Form: VACCINATION

Form Status: Data Complete, Verified

Site Name: (1135) Anaheim Clinical Trials

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:34

[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:	Mar/10/2021 10:11
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

090177e196ae3d55\Final\Final On: 01-Apr-2021 04:31 (GMT)

Header Text: c4591001

Visit: V103_MONTH1

Form Version: 22-Apr-2020 21:02

Site No: 1135

Subject No: 11351563

Generated By: (b) (4)

Form: DATE OF VISIT

Form Status: Not Started

Site Name: (1135) Anaheim Clinical Trials

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:34

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: 1135

Subject No: 11351563

Generated By: (b) (4)

Form: CONTACT OUTCOME

Form Status: Not Started

Site Name: (1135) Anaheim Clinical Trials

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:34

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: 1135

Subject No: 11351563

Generated By: (b) (4)

Form: DATE OF VISIT

Form Status: Not Started

Site Name: (1135) Anaheim Clinical Trials

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:34

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: 1135

Subject No: 11351563

Generated By: (b) (4)

Form: CONTACT OUTCOME

Form Status: Not Started

Site Name: (1135) Anaheim Clinical Trials

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:34

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: 1135

Subject No: 11351563

Generated By: (b) (4)

Form: DATE OF VISIT

Form Status: Not Started

Site Name: (1135) Anaheim Clinical Trials

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:34

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: 1135

Subject No: 11351563

Generated By: (b) (4)

Form: CONTACT OUTCOME

Form Status: Not Started

Site Name: (1135) Anaheim Clinical Trials

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:34

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: 1135

Site Name: (1135) Anaheim Clinical Trials

Subject No: 11351563

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:34

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: 1135

Subject No: 11351563

Generated By: (b) (4)

Form: SUBJECT STATUS

Form Status: Data Complete, Verified

Site Name: (1135) Anaheim Clinical Trials

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:34

[eCRF Audit Trail History](#)

Subject Status

1.	Subject Status	FOLLOW-UP
2.	Subject Status Date	Dec/16/2020

Header Text: c4591001

Visit: Investigator Signature - Unscheduled

Form: CASEBOOK SIGNATURE FORM

Form Version: 22-Apr-2020 21:04

Form Status: Not Started

Site No: 1135

Site Name: (1135) Anaheim Clinical Trials

Subject No: 11351563

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:34

Casebook Signature Form

1.	Casebook Signature	
----	--------------------	--

Header Text: c4591001

Visit: Investigator Signature - Unscheduled

Form: CASEBOOK SIGNATURE FORM

Form Version: 22-Apr-2020 21:04

Form Status: Not Started

Site No: 1135

Site Name: (1135) Anaheim Clinical Trials

Subject No: 11351563

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:34

[Audit Trail](#)

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

- CRF_Sign
- CRF_Sign_1

Name	Signature Meaning	Date	Type	Action
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Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 10-Oct-2020 16:00

Site No: 1135

Subject No: 11351563

Generated By: (b) (4)

Form: INCLUSION/EXCLUSION CRITERIA - Comments

Form Status: Data Complete, Frozen, Verified

Site Name: (1135) Anaheim Clinical Trials

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:34

[Back to Form](#)

Item	Date	User	Comment
Form	Oct-28-2020 10:12:46 (UTC-08:00) Pacific Time (US & Canada)	(b)(4),(b)(6)	Not Applicable

Header Text: c4591001

Visit: V101_VAX3

Form: INCLUSION/EXCLUSION CRITERIA - FURTHER VACCINATION -
Comments

Form Version: 10-Dec-2020 02:30

Form Status: Data Complete, Frozen, Verified

Site No: 1135

Site Name: (1135) Anaheim Clinical Trials

Subject No: 11351563

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:34

[Back to Form](#)

Item	Date	User	Comment
Form	Feb-17-2021 11:22:45 (UTC-08:00) Pacific Time (US & Canada)	(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: Not Started

Site No: 1135

Site Name: (1135) Anaheim Clinical Trials

Subject No: 11351563

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:34

[Back to Form](#)

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

- CRF_Sign
- CRF_Sign_1

Name	Signature Meaning	Date	Type	Action
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Header Text: c4591001

Visit: COHORT_SELECTION

Form Version: 10-Oct-2020 16:01

Site No: 1135

Subject No: 11351563

Generated By: (b) (4)

Form: COHORT_SELECTION - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1135) Anaheim Clinical Trials

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:34

[Back to Form](#)

1. Select appropriate response - Protocol version

Date	Location	User	Value	Reason
Oct-28-2020 10:12:08 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: 06 OCT 2020	Initial Entry

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

Date	Location	User	Value	Reason
Oct-28-2020 10:12:08 (UTC-08:00) Pacific Time (US & Canada)	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: 1135

Subject No: 11351563

Generated By: (b) (4)

Form: MAIN INFORMED CONSENT - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1135) Anaheim Clinical Trials

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:34

[Back to Form](#)

I. Consent Was:

Date	Location	User	Value	Reason
Oct-28-2020 10:12:18 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: OBTAINED Date Written Consent Obtained Oct/27/2020	Initial Entry

Header Text: c4591001

Visit: COHORT_SELECTION

Form: DEMOGRAPHY - eCRF Audit Trail History

Form Version: 15-Sep-2020 21:54

Form Status: Data Complete, Frozen, Verified

Site No: 1135

Site Name: (1135) Anaheim Clinical Trials

Subject No: 11351563

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:34

[Back to Form](#)

1. Subject ID

Date	Location	User	Value	Reason
Oct-28-2020 10:12:01 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> 11351563	Item copied from previous form

2. Birth Date:

Date	Location	User	Value	Reason
Oct-28-2020 10:11:58 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> (b) (6)/1992	Enrollment Entry

3. Sex:

Date	Location	User	Value	Reason
Oct-28-2020 10:12:30 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	<u>Data Entry:</u> FEMALE	Initial Entry

4. Ethnicity:

Date	Location	User	Value	Reason
Oct-28-2020 10:12:30 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	<u>Data Entry:</u> NOT HISPANIC OR LATINO(A) OR OF SPANISH ORIGIN	Initial Entry

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

Date	Location	User	Value	Reason
Oct-28-2020 10:12:30 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	<u>Data Entry:</u> WHITE	Initial Entry

090177e196ae3d55\Final\Final On: 01-Apr-2021 04:31 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:02

Site No: 1135

Subject No: 11351563

Generated By: (b) (4)

Form: DATE OF VISIT - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1135) Anaheim Clinical Trials

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:34

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1. Date of Visit

Date	Location	User	Value	Reason
Oct-28-2020 10:12:39 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	<u>Data Entry:</u> Oct/27/2020	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 15-Sep-2020 21:52

Site No: 1135

Subject No: 11351563

Generated By: (b) (4)

Form: DISPOSITION - SCREENING - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1135) Anaheim Clinical Trials

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:34

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1. Date of Completion/Discontinuation/Death

Date	Location	User	Value	Reason
Oct-28-2020 10:13:23 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: Oct/27/2020	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Oct-28-2020 10:13:23 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SCREENING	Initial Entry

3. Status:

Date	Location	User	Value	Reason
Oct-28-2020 10:13:23 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: COMPLETED	Initial Entry

090177e196ae3d55\Final\Final On: 01-Apr-2021 04:31 (GMT)

Header Text: c4591001**Visit:** V1_DAY1_VAX1_L**Form Version:** 22-Apr-2020 21:03**Site No:** 1135**Subject No:** 11351563**Generated By:** (b) (4)**Form:** GENERAL MEDICAL HISTORY - eCRF Audit Trail History**Form Status:** Data Complete, Frozen, Verified**Site Name:** (1135) Anaheim Clinical Trials**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 11:34[Back to Form](#)**I.a**

Date	Location	User	Value	Reason
Oct-28-2020 10:14:26 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 1 Medical History Term: nearsighted Start Date: UNK/UNK/2002 Ongoing: YES	Initial Entry

I.a Line/MH Number:

Date	Location	User	Value	Reason
Oct-28-2020 10:14:26 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 1	Initial Entry

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

Date	Location	User	Value	Reason
Oct-28-2020 10:14:26 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: nearsighted	Initial Entry

I.a Start Date:

Date	Location	User	Value	Reason
Oct-28-2020 10:14:26 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: UNK/UNK/2002	Initial Entry

I.a Ongoing:

Date	Location	User	Value	Reason
Oct-28-2020 10:14:26 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: YES	Initial Entry

I.b

Date	Location	User	Value	Reason
Oct-28-2020 10:15:18	ACV0PFEINFP6000	auto calc	Data Entry:	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1135

Subject No: 11351563

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1135) Anaheim Clinical Trials

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:34

(UTC-08:00) Pacific Time (US & Canada)		(autocalc)	Line/MH Number: 2 Medical History Term: hypothyroidism Start Date: UNK/UNK/2005 Ongoing: YES	
---	--	------------	---	--

I.b Line/MH Number:

Date	Location	User	Value	Reason
Oct-28-2020 10:15:18 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 2	Initial Entry

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

Date	Location	User	Value	Reason
Oct-28-2020 10:15:18 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: hypothyroidism	Initial Entry

I.b Start Date:

Date	Location	User	Value	Reason
Oct-28-2020 10:15:18 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: UNK/UNK/2005	Initial Entry

I.b Ongoing:

Date	Location	User	Value	Reason
Oct-28-2020 10:15:18 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: YES	Initial Entry

I.c

Date	Location	User	Value	Reason
Oct-28-2020 10:15:35 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 3 Medical History Term: overweight Start Date: UNK/UNK/2015 Ongoing: YES	Initial Entry

090177e196ae3d55\Final\Final On: 01-Apr-2021 04:31 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1135

Subject No: 11351563

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1135) Anaheim Clinical Trials

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:34

I.c Line/MH Number:

Date	Location	User	Value	Reason
Oct-28-2020 10:15:35 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 3	Initial Entry

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

Date	Location	User	Value	Reason
Oct-28-2020 10:15:35 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: overweight	Initial Entry

I.c Start Date:

Date	Location	User	Value	Reason
Oct-28-2020 10:15:35 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: UNK/UNK/2015	Initial Entry

I.c Ongoing:

Date	Location	User	Value	Reason
Oct-28-2020 10:15:35 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: YES	Initial Entry

I.d

Date	Location	User	Value	Reason
Oct-28-2020 10:15:48 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 4 Medical History Term: obese Start Date: UNK/UNK/2015 Ongoing: YES	Initial Entry

090177e196ae3d55\Final\Final On: 01-Apr-2021 04:31 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1135

Site Name: (1135) Anaheim Clinical Trials

Subject No: 11351563

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:34

I.d Line/MH Number:

Date	Location	User	Value	Reason
Oct-28-2020 10:15:48 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 4	Initial Entry

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

Date	Location	User	Value	Reason
Oct-28-2020 10:15:48 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: obese	Initial Entry

I.d Start Date:

Date	Location	User	Value	Reason
Oct-28-2020 10:15:48 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: UNK/UNK/2015	Initial Entry

I.d Ongoing:

Date	Location	User	Value	Reason
Oct-28-2020 10:15:48 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: YES	Initial Entry

I.e

Date	Location	User	Value	Reason
Oct-28-2020 10:16:16 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 5 Medical History Term: fibromyalgia Start Date: UNK/UNK/2017 Ongoing: YES	Initial Entry

090177e196ae3d55\Final\Final On: 01-Apr-2021 04:31 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1135

Site Name: (1135) Anaheim Clinical Trials

Subject No: 11351563

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:34

I.e Line/MH Number:

Date	Location	User	Value	Reason
Oct-28-2020 10:16:16 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 5	Initial Entry

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

Date	Location	User	Value	Reason
Oct-28-2020 10:16:16 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: fibromyalgia	Initial Entry

I.e Start Date:

Date	Location	User	Value	Reason
Oct-28-2020 10:16:16 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: UNK/UNK/2017	Initial Entry

I.e Ongoing:

Date	Location	User	Value	Reason
Oct-28-2020 10:16:16 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: YES	Initial Entry

I.f

Date	Location	User	Value	Reason
Oct-28-2020 10:18:33 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 6 Medical History Term: gastric bypass Start Date: UNK/UNK/2016 Ongoing: YES	Initial Entry

090177e196ae3d55\Final\Final On: 01-Apr-2021 04:31 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1135

Site Name: (1135) Anaheim Clinical Trials

Subject No: 11351563

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:34

I.f Line/MH Number:

Date	Location	User	Value	Reason
Oct-28-2020 10:18:33 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 6	Initial Entry

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

Date	Location	User	Value	Reason
Oct-28-2020 10:18:33 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: gastric bypass	Initial Entry

I.f Start Date:

Date	Location	User	Value	Reason
Oct-28-2020 10:18:33 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: UNK/UNK/2016	Initial Entry

I.f Ongoing:

Date	Location	User	Value	Reason
Oct-28-2020 10:18:33 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: YES	Initial Entry

I.g

Date	Location	User	Value	Reason
Oct-28-2020 10:18:50 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 7 Medical History Term: depression Start Date: UNK/UNK/2013 Ongoing: YES	Initial Entry

090177e196ae3d55\Final\Final On: 01-Apr-2021 04:31 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1135

Subject No: 11351563

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1135) Anaheim Clinical Trials

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:34

I.g Line/MH Number:

Date	Location	User	Value	Reason
Oct-28-2020 10:18:50 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 7	Initial Entry

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

Date	Location	User	Value	Reason
Oct-28-2020 10:18:50 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: depression	Initial Entry

I.g Start Date:

Date	Location	User	Value	Reason
Oct-28-2020 10:18:50 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: UNK/UNK/2013	Initial Entry

I.g Ongoing:

Date	Location	User	Value	Reason
Oct-28-2020 10:18:50 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: YES	Initial Entry

I.h

Date	Location	User	Value	Reason
Oct-28-2020 10:19:13 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number 8 : Medical History T gastric bypass sur erm: gery Start Date: UNK/UNK/2016 Ongoing: YES	Initial Entry

090177e196ae3d55\Final\Final On: 01-Apr-2021 04:31 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1135

Site Name: (1135) Anaheim Clinical Trials

Subject No: 11351563

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:34

I.h Line/MH Number:

Date	Location	User	Value	Reason
Oct-28-2020 10:19:13 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 8	Initial Entry

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

Date	Location	User	Value	Reason
Oct-28-2020 10:19:13 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: gastric bypass surgery	Initial Entry

I.h Start Date:

Date	Location	User	Value	Reason
Oct-28-2020 10:19:13 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: UNK/UNK/2016	Initial Entry

I.h Ongoing:

Date	Location	User	Value	Reason
Oct-28-2020 10:19:13 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: YES	Initial Entry

090177e196ae3d55\Final\Final On: 01-Apr-2021 04:31 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 15-Sep-2020 21:57

Site No: 1135

Subject No: 11351563

Generated By: (b) (4)

Form: HIV STATUS - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1135) Anaheim Clinical Trials

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:34

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

Date	Location	User	Value	Reason
Oct-28-2020 10:19:28 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: The subject is NOT known to be HIV POSITIVE	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 10-Oct-2020 16:04

Site No: 1135

Subject No: 11351563

Generated By: (b) (4)

Form: VITAL SIGNS - BASELINE - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1135) Anaheim Clinical Trials

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:34

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1. Date:

Date	Location	User	Value	Reason
Oct-28-2020 10:19:49 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: Oct/27/2020	Initial Entry

2. Weight:

Date	Location	User	Value	Reason
Oct-28-2020 10:19:49 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: 100.4	Initial Entry

3. Unit:

Date	Location	User	Value	Reason
Oct-28-2020 10:19:49 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: kg	Initial Entry

4. Height:

Date	Location	User	Value	Reason
Oct-28-2020 10:19:49 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: 162.0	Initial Entry

5. Unit:

Date	Location	User	Value	Reason
Oct-28-2020 10:19:49 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: cm	Initial Entry

6. Body Mass Index:

Date	Location	User	Value	Reason
Oct-28-2020 10:19:49 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 38.3	Initial Entry

7.a

090177e196ae3d55\Final\Final On: 01-Apr-2021 04:31 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: VITAL SIGNS - BASELINE - eCRF Audit Trail History

Form Version: 10-Oct-2020 16:04

Form Status: Data Complete, Frozen, Verified

Site No: 1135

Site Name: (1135) Anaheim Clinical Trials

Subject No: 11351563

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:34

Date	Location	User	Value	Reason
Oct-28-2020 10:19:49 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: Record Identifier:: 1 Temperature: 37.1 Temperature Unit: C Temperature Location:: ORAL CAVITY	Initial Entry

7.a Record Identifier:

Date	Location	User	Value	Reason
Oct-28-2020 10:19:49 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: 1	Initial Entry

7.a Temperature:

Date	Location	User	Value	Reason
Oct-28-2020 10:19:49 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: 37.1	Initial Entry

7.a Unit:

Date	Location	User	Value	Reason
Oct-28-2020 10:19:49 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: C	Initial Entry

7.a Temperature Location:

Date	Location	User	Value	Reason
Oct-28-2020 10:19:49 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: ORAL CAVITY	Initial Entry

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Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 10-Oct-2020 15:58

Site No: 1135

Subject No: 11351563

Generated By: (b) (4)

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

Form Status: Data Complete, Frozen, Verified

Site Name: (1135) Anaheim Clinical Trials

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:34

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1. Lab Panel:

Date	Location	User	Value	Reason
Oct-28-2020 10:20:01 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: URINALYSIS	Initial Entry

2. Lab Sub-Panel:

Date	Location	User	Value	Reason
Oct-28-2020 10:20:01 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: PREGNANCY	Initial Entry

3. Collection Date:

Date	Location	User	Value	Reason
Oct-28-2020 10:20:01 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: Oct/27/2020	Initial Entry

4. Laboratory Name and Address (Derived)

Date	Location	User	Value	Reason
Oct-28-2020 10:20:01 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: STUDY SITE	Initial Entry

5. Specimen Type:

Date	Location	User	Value	Reason
Oct-28-2020 10:20:01 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: URINE	Initial Entry

6.a

Date	Location	User	Value	Reason
Oct-28-2020 10:20:01 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sponsor-Defined 113 Identifier: Test:: Choriogonadotropin Beta_PX113 Result:: NEGATIVE	Initial Entry

090177e196ae3d55\Final\Final On: 01-Apr-2021 04:31 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

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

Form Version: 10-Oct-2020 15:58

Form Status: Data Complete, Frozen, Verified

Site No: 1135

Site Name: (1135) Anaheim Clinical Trials

Subject No: 11351563

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:34

			Not Done::	
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6.a Sponsor ID:

Date	Location	User	Value	Reason
Oct-28-2020 10:20:01 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 113	Initial Entry

6.a Test:

Date	Location	User	Value	Reason
Oct-28-2020 10:20:01 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: Choriogonadotropin Beta_PX113	Initial Entry

6.a Result:

Date	Location	User	Value	Reason
Oct-28-2020 10:20:01 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: NEGATIVE	Initial Entry

090177e196ae3d55\Final\Final On: 01-Apr-2021 04:31 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1135

Subject No: 11351563

Generated By: (b) (4)

Form: RANDOMIZATION - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1135) Anaheim Clinical Trials

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:34

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1. Randomization Date :

Date	Location	User	Value	Reason
Oct-28-2020 10:20:16 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: Oct/27/2020	Initial Entry

2. Randomization Number:

Date	Location	User	Value	Reason
Oct-28-2020 10:20:16 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: 401109	Initial Entry

Header Text: c4591001**Visit:** V1_DAY1_VAX1_L**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF
Audit Trail History**Form Version:** 22-Apr-2020 21:03**Form Status:** Data Complete, Frozen, Verified**Site No:** 1135**Site Name:** (1135) Anaheim Clinical Trials**Subject No:** 11351563**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 11:34[Back to Form](#)**1. Data Origin**

Date	Location	User	Value	Reason
Oct-28-2020 10:20:24 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Oct-28-2020 10:20:24 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SERUM	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Oct-28-2020 10:23:22 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Oct-28-2020 10:20:24 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Oct-28-2020 10:20:24 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: YES Date of Collection: Oct/27/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Oct-28-2020 10:23:22 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: Sample ID: BP93J1	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Oct-28-2020 10:23:22 (UTC-08:00) Pacific Time	ACV0PFEINFP6000	(b) (6)	Data Entry: BP93J1	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1135

Site Name: (1135) Anaheim Clinical Trials

Subject No: 11351563

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:34

(US & Canada)		(b) (4)	
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5.b

Date	Location	User	Value	Reason
Oct-28-2020 10:23:33 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: Sample ID: BMNXCB	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Oct-28-2020 10:23:33 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: BMNXCB	Initial Entry

5.c

Date	Location	User	Value	Reason
Oct-28-2020 10:23:49 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: Sample ID: BMNXCD	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Oct-28-2020 10:23:49 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: BMNXCD	Initial Entry

090177e196ae3d55\Final\Final On: 01-Apr-2021 04:31 (GMT)

Header Text: c4591001**Visit:** V1_DAY1_VAX1_L**Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB - eCRF Audit Trail History**Form Version:** 22-Apr-2020 21:03**Form Status:** Data Complete, Frozen, Verified**Site No:** 1135**Site Name:** (1135) Anaheim Clinical Trials**Subject No:** 11351563**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 11:34[Back to Form](#)**1. Data Origin**

Date	Location	User	Value	Reason
Oct-28-2020 10:20:33 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Oct-28-2020 10:20:33 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: NASAL_SWAB	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Oct-28-2020 10:25:03 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Oct-28-2020 10:20:33 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Oct-28-2020 10:20:33 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: YES Date of Collection: Oct/27/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Oct-28-2020 10:25:03 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: Sample ID: BRFBZB4	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Oct-28-2020 10:25:03 (UTC-08:00) Pacific Time	ACV0PFEINFP6000	(b) (6)	Data Entry: BRFBZB4	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1135

Site Name: (1135) Anaheim Clinical Trials

Subject No: 11351563

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:34

(US & Canada)

(b) (4)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:04

Site No: 1135

Subject No: 11351563

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1135) Anaheim Clinical Trials

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:34

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1. Was there a temporary delay of vaccination?

Date	Location	User	Value	Reason
Oct-28-2020 10:22:37 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: NO	Initial Entry

2. Treatment Name

Date	Location	User	Value	Reason
Oct-28-2020 10:22:37 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: BLINDED THERAPY	Initial Entry

3. Formulation:

Date	Location	User	Value	Reason
Oct-28-2020 10:22:37 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INJECTION	Initial Entry

4. Dose Date Time:

Date	Location	User	Value	Reason
Oct-28-2020 10:22:37 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: Oct/27/2020 13:16	Initial Entry

5. Anatomical Location:

Date	Location	User	Value	Reason
Oct-28-2020 10:22:37 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: DELTOID MUSCLE	Initial Entry

6. Body Side:

Date	Location	User	Value	Reason
Oct-28-2020 10:22:37 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: RIGHT	Initial Entry

7. Route:

090177e196ae3d55\Final\Final On: 01-Apr-2021 04:31 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: VACCINATION - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Frozen, Verified

Site No: 1135

Site Name: (1135) Anaheim Clinical Trials

Subject No: 11351563

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:34

Date	Location	User	Value	Reason
Oct-28-2020 10:22:37 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INTRAMUSCULAR	Initial Entry

10. Timeframe Subject Was Observed

Date	Location	User	Value	Reason
Oct-28-2020 10:22:37 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: THE PROTOCOL SPECIFIED OBSE RVATION PERIOD	Initial Entry

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

Date	Location	User	Value	Reason
Oct-28-2020 10:22:37 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: YES	Initial Entry

090177e196ae3d55\Final\Final On: 01-Apr-2021 04:31 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 06-Jul-2020 21:53

Site No: 1135

Subject No: 11351563

Generated By: (b) (4)

Form: REACTOGENICITY DIARY - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1135) Anaheim Clinical Trials

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:34

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1. Select appropriate response - Reactogenicity diary collection

Date	Location	User	Value	Reason
Oct-28-2020 10:22:43 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: NO - REACTOGENICITY E-DIARY NOT COLLECTED FOR THIS SUBJECT	Initial Entry

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 1135

Subject No: 11351563

Generated By: (b) (4)

Form: DATE OF VISIT - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1135) Anaheim Clinical Trials

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:34

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I. Date of Visit

Date	Location	User	Value	Reason
Nov-23-2020 23:06:57 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b)(6)	Query 1: Closed	Closed as per site response, updated PD tracker for clinical review
Nov-23-2020 18:12:52 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b)(6)	Query 1: Answered	subject was out of window by 1 day, PD filed.
Nov-22-2020 22:54:26 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	PFE SDQ PROD (b) (4)	Query 1: Opened	PDQ: Date of visit at V2_VAX2_L is out of window for 1 days from V1_DAY1_VAX1_L Dose Date. Please verify and update. Else, confirm in query response appropriately. (b) (4)
Nov-20-2020 10:55:35 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Nov/20/2020	Initial Entry

090177e196ae3d55\Final\Final On: 01-Apr-2021 04:31 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 10-Oct-2020 16:01

Site No: 1135

Subject No: 11351563

Generated By: (b) (4)

Form: VITAL SIGNS - TEMP - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1135) Anaheim Clinical Trials

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:34

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1. Date:

Date	Location	User	Value	Reason
Nov-20-2020 10:55:57 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: Nov/20/2020	Initial Entry

2.a

Date	Location	User	Value	Reason
Nov-20-2020 10:55:57 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: Record Identifier:: 1 Temperature: 36.7 Temperature Unit: C Temperature Location:: ORAL CAVITY	Initial Entry

2.a Record Identifier:

Date	Location	User	Value	Reason
Nov-20-2020 10:55:57 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: 1	Initial Entry

2.a Temperature:

Date	Location	User	Value	Reason
Nov-20-2020 10:55:57 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: 36.7	Initial Entry

2.a Unit:

Date	Location	User	Value	Reason
Nov-20-2020 10:55:57 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: C	Initial Entry

2.a Temperature Location:

Date	Location	User	Value	Reason
Nov-20-2020 10:55:57 (UTC-08:00) Pacific Time	ACV0PFEINFP6000	(b) (6)	Data Entry: ORAL CAVITY	Initial Entry

090177e196ae3d55\Final\Final On: 01-Apr-2021 04:31 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 10-Oct-2020 16:01

Site No: 1135

Subject No: 11351563

Generated By: (b) (4)

Form: VITAL SIGNS - TEMP - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1135) Anaheim Clinical Trials

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:34

(US & Canada)

(b) (4)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 10-Oct-2020 15:58

Site No: 1135

Subject No: 11351563

Generated By: (b) (4)

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

Form Status: Data Complete, Frozen, Verified

Site Name: (1135) Anaheim Clinical Trials

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:34

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1. Lab Panel:

Date	Location	User	Value	Reason
Nov-20-2020 10:56:11 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: URINALYSIS	Initial Entry

2. Lab Sub-Panel:

Date	Location	User	Value	Reason
Nov-20-2020 10:56:11 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: PREGNANCY	Initial Entry

3. Collection Date:

Date	Location	User	Value	Reason
Nov-20-2020 10:56:11 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: Nov/20/2020	Initial Entry

4. Laboratory Name and Address (Derived)

Date	Location	User	Value	Reason
Nov-20-2020 10:56:11 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: STUDY SITE	Initial Entry

5. Specimen Type:

Date	Location	User	Value	Reason
Nov-20-2020 10:56:11 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: URINE	Initial Entry

6.a

Date	Location	User	Value	Reason
Nov-20-2020 10:56:11 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sponsor-Defined 113 Identifier: Test:: Choriogonadotropin Beta_PX113 Result:: NEGATIVE	Initial Entry

090177e196ae3d55\Final\Final On: 01-Apr-2021 04:31 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

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

Form Version: 10-Oct-2020 15:58

Form Status: Data Complete, Frozen, Verified

Site No: 1135

Site Name: (1135) Anaheim Clinical Trials

Subject No: 11351563

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:34

			Not Done::	
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6.a Sponsor ID:

Date	Location	User	Value	Reason
Nov-20-2020 10:56:11 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> 113	Initial Entry

6.a Test:

Date	Location	User	Value	Reason
Nov-20-2020 10:56:11 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	<u>Data Entry:</u> Choriogonadotropin Beta_PX113	Initial Entry

6.a Result:

Date	Location	User	Value	Reason
Nov-20-2020 10:56:11 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	<u>Data Entry:</u> NEGATIVE	Initial Entry

090177e196ae3d55\Final\Final On: 01-Apr-2021 04:31 (GMT)

Header Text: c4591001**Visit:** V2_VAX2_L**Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB - eCRF Audit Trail History**Form Version:** 22-Apr-2020 21:03**Form Status:** Data Complete, Frozen, Verified**Site No:** 1135**Site Name:** (1135) Anaheim Clinical Trials**Subject No:** 11351563**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 11:34[Back to Form](#)**1. Data Origin**

Date	Location	User	Value	Reason
Nov-20-2020 10:56:19 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Nov-20-2020 10:56:19 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: NASAL_SWAB	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Nov-20-2020 18:46:21 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Nov-20-2020 10:56:19 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Nov-20-2020 10:56:19 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: YES Date of Collection: Nov/20/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Nov-20-2020 18:46:21 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: Sample ID: BRFZM9	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Nov-20-2020 18:46:21 (UTC-08:00) Pacific Time	ACV0PFEINFP6000	(b) (6)	Data Entry: BRFZM9	Initial Entry

Header Text: c4591001

Visit: V2_VAX2_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1135

Site Name: (1135) Anaheim Clinical Trials

Subject No: 11351563

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:34

(US & Canada)

(b) (4)

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Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1135

Subject No: 11351563

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1135) Anaheim Clinical Trials

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:34

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1. Was there a temporary delay of vaccination?

Date	Location	User	Value	Reason
Nov-20-2020 10:56:51 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: NO	Initial Entry

2. Treatment Name

Date	Location	User	Value	Reason
Nov-20-2020 10:56:51 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: BLINDED THERAPY	Initial Entry

3. Formulation:

Date	Location	User	Value	Reason
Nov-20-2020 10:56:51 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INJECTION	Initial Entry

4. Dose Date Time:

Date	Location	User	Value	Reason
Nov-20-2020 10:56:51 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: Nov/20/2020 10:43	Initial Entry

5. Anatomical Location:

Date	Location	User	Value	Reason
Nov-20-2020 10:56:51 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: DELTOID MUSCLE	Initial Entry

6. Body Side:

Date	Location	User	Value	Reason
Nov-20-2020 10:56:51 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: RIGHT	Initial Entry

7. Route:

090177e196ae3d55\Final\Final On: 01-Apr-2021 04:31 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1135

Subject No: 11351563

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1135) Anaheim Clinical Trials

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:34

Date	Location	User	Value	Reason
Nov-20-2020 10:56:51 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INTRAMUSCULAR	Initial Entry

10. Timeframe Subject Was Observed

Date	Location	User	Value	Reason
Nov-20-2020 10:56:51 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: THE PROTOCOL SPECIFIED OBSE RVATION PERIOD	Initial Entry

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

Date	Location	User	Value	Reason
Nov-20-2020 10:56:51 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: YES	Initial Entry

090177e196ae3d55\Final\Final On: 01-Apr-2021 04:31 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form: DATE OF VISIT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen, Verified

Site No: 1135

Site Name: (1135) Anaheim Clinical Trials

Subject No: 11351563

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:34

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I. Date of Visit

Date	Location	User	Value	Reason
Dec-21-2020 01:33:49 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Clo sed	Closed per SITE response, added to PD tracker for Clinical Review
Dec-18-2020 11:29:49 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Ans wered	Original value is correct
Dec-18-2020 02:02:55 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	PFE SDQ PROD (b) (4)	Query 1: Op ened	PDQ: Date of visit at V3_MONTH1_POSTVAX2_L is out of window for 2 days from V2_VAX2_L DOV or V2 Vaccination date. Please verify and update. Else, confirm in query response appropriately. (b) (4)
Dec-16-2020 16:17:39 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry : Dec/1 6/202 0	Initial Entry

090177e196ae3d55\Final\Final On: 01-Apr-2021 04:31 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1135

Site Name: (1135) Anaheim Clinical Trials

Subject No: 11351563

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:34

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1. Data Origin

Date	Location	User	Value	Reason
Dec-16-2020 16:17:47 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Dec-16-2020 16:17:47 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> SERUM	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Dec-16-2020 17:30:35 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Dec-16-2020 16:17:47 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Dec-16-2020 16:17:47 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	<u>Data Entry:</u> YES Date of Collection: Dec/16/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Dec-16-2020 17:30:35 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Sample ID: BRCD4C	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Dec-16-2020 17:30:35 (UTC-08:00) Pacific Time	ACV0PFEINFP6000	(b) (6)	<u>Data Entry:</u> BRCD4C	Initial Entry

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Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1135

Site Name: (1135) Anaheim Clinical Trials

Subject No: 11351563

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:34

(US & Canada)		(b) (4)	
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5.b

Date	Location	User	Value	Reason
Dec-16-2020 17:30:47 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BSJVGD	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Dec-16-2020 17:30:47 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BSJVGD	Initial Entry

5.c

Date	Location	User	Value	Reason
Dec-16-2020 17:30:57 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BSJVGF	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Dec-16-2020 17:30:57 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BSJVGF	Initial Entry

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Header Text: c4591001

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Site No: 1135

Subject No: 11351563

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - Audit Trail

Form Status:

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Subject Initials: ---

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Date	Location	User	Value	Reason
Dec-17-2020 09:10:22 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

Header Text: c4591001

Visit: Logs - Unscheduled

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Site No: 1135

Subject No: 11351563

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Frozen

Site Name: (1135) Anaheim Clinical Trials

Subject Initials: ---

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1. Category:

Date	Location	User	Value	Reason
Dec-17-2020 09:10:22 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: ADVERSE EVENT	Initial Entry

2. AE ID:

Date	Location	User	Value	Reason
Dec-17-2020 09:10:22 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 1	Initial Entry

3. Adverse Event:

(If possible specify diagnosis, not individual symptoms)

Date	Location	User	Value	Reason
Mar-09-2021 06:37:42 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Giselle Castillo (b) (4)	Query 1: Closed	Closing query to FU at a later date.
Mar-04-2021 03:44:42 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Giselle Castillo (b) (4)	Query 1: Reissued:Opened	Could you pls provide any updates?
Feb-25-2021 22:28:33 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	records received by site, pending reiew
Feb-09-2021 12:13:30 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Giselle Castillo (b) (4)	Query 1: Reissued:Opened	Thanks for confirming. Please make every effort possible to obtain further information and respond to the query once additional information is available.
Feb-01-2021 15:32:49 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	site pending medical records
Dec-23-2020 12:46:48 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Giselle Castillo (b) (4)	Query 1: Opened	Clinical_ Per SAE report, "Subject's test results were elevated which lead to hospitalization". Kind

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Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

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Form Status: Data Complete, Frozen

Site No: 1135

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Subject No: 11351563

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:34

				provide lab test performed with results and if test returned to normal, the results in a FU form. Thank you.
Dec-17-2020 09:10:22 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: acute pancreatitis	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason
Dec-17-2020 09:10:22 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Nov/21/2020 UNK:UNK	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Dec-17-2020 09:10:22 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO End Date Time: Nov/24/2020 UNK:UNK	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
Dec-17-2020 09:10:22 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 2	Initial Entry

7. Is the adverse event serious?

If Yes, NOTIFY PFIZER IMMEDIATELY.

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

Date	Location	User	Value	Reason
Dec-18-2020 04:14:27 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Dec-17-2020 09:10:22 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	For AE acute pancreatitis: Response to "Is the adverse

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Header Text: c4591001

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Site No: 1135

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Generated By: (b) (4)

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				event serious?" is 'Yes' but "Serious Adverse Event Number" is blank.
Dec-17-2020 09:10:22 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<p>Data Entry: YES</p> <p>Is this serious event associated with congenital anomaly or birth defect?</p> <p>NO</p> <p>Did this serious event result in death?</p> <p>NO</p> <p>Did this serious event require or prolong hospitalization?</p> <p>YES</p> <p>Did this serious event result in persistent or significant disability/incapacity?</p> <p>NO</p> <p>Is this serious event life threatening?</p> <p>NO</p> <p>Other medically important serious event</p> <p>NO</p>	Initial Entry

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

Date	Location	User	Value	Reason
Dec-17-2020 09:10:22 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<p>Data Entry: NO</p>	Initial Entry

9. Is this event related to study treatment:

Date	Location	User	Value	Reason
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Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen

Site No: 1135

Site Name: (1135) Anaheim Clinical Trials

Subject No: 11351563

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:34

Dec-17-2020 09:10:22 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NOT RELATED If Not Related to study treatment(s), this event is due to: OTHER If Other, specify: pending records	Initial Entry
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10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Dec-17-2020 09:10:22 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NOT APPLICABLE	Initial Entry

11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
Dec-17-2020 09:10:22 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Dec-17-2020 09:10:22 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

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

Date	Location	User	Value	Reason
Dec-17-2020 09:10:22 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: RECOVERED/RESOLVED	Initial Entry

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

Date	Location	User	Value	Reason
Dec-17-2020 09:10:22 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

15. Serious Adverse Event Number: For Pfizer Use Only

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Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1135

Subject No: 11351563

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Frozen

Site Name: (1135) Anaheim Clinical Trials

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:34

Date	Location	User	Value	Reason
Dec-18-2020 04:14:27 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 2020498809	Initial Entry

Header Text: c4591001

Visit: V201_SURVEIL_CONSENT - Unscheduled **Form:** DATE OF VISIT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen, Verified

Site No: 1135

Site Name: (1135) Anaheim Clinical Trials

Subject No: 11351563

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:34

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1. Date of Visit

Date	Location	User	Value	Reason
Feb-02-2021 17:15:31 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: Feb/2/2021	Initial Entry

Header Text: c4591001

Visit: V201_SURVEIL_CONSENT - Unscheduled **Form:** INFORMED CONSENT - ASYMPTOMATIC SURVEILLANCE - eCRF Audit Trail History

Form Version: 14-Jan-2021 02:29

Form Status: Data Complete, Frozen, Verified

Site No: 1135

Site Name: (1135) Anaheim Clinical Trials

Subject No: 11351563

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:34

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I. Consent Was:

Date	Location	User	Value	Reason
Feb-02-2021 17:15:37 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: OBTAINED Date Written Consent Obtained Feb/2/2021	Initial Entry

Header Text: c4591001**Visit:** V201_SURVEIL_CONSENT - Unscheduled**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF
Audit Trail History**Form Version:** 22-Apr-2020 21:03**Form Status:** Data Complete, Frozen, Verified**Site No:** 1135**Site Name:** (1135) Anaheim Clinical Trials**Subject No:** 11351563**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 11:34[Back to Form](#)**1. Data Origin**

Date	Location	User	Value	Reason
Feb-02-2021 17:15:47 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Feb-02-2021 17:15:47 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SERUM	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Feb-02-2021 21:16:06 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Feb-02-2021 17:15:47 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Feb-02-2021 17:15:47 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: YES Date of Collection: Feb/2/2021	Initial Entry

5.a

Date	Location	User	Value	Reason
Feb-02-2021 21:16:06 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: Sample ID: BR9MGH	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Feb-02-2021 21:16:06 (UTC-08:00) Pacific Time	ACV0PFEINFP6000	(b) (6)	Data Entry: BR9MGH	Initial Entry

Header Text: c4591001
Visit: V201_SURVEIL_CONSENT - Unscheduled **Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF Audit Trail History
Form Version: 22-Apr-2020 21:03 **Form Status:** Data Complete, Frozen, Verified
Site No: 1135 **Site Name:** (1135) Anaheim Clinical Trials
Subject No: 11351563 **Subject Initials:** ---
Generated By: (b) (4) **Generated Time (GMT):** 29-Mar-2021 11:34

(US & Canada)		(b) (4)	
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5.b

Date	Location	User	Value	Reason
Feb-02-2021 21:16:18 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: Sample ID: BSG9RV	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Feb-02-2021 21:16:18 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: BSG9RV	Initial Entry

5.c

Date	Location	User	Value	Reason
Feb-02-2021 21:16:28 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: Sample ID: BSG9RX	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Feb-02-2021 21:16:28 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: BSG9RX	Initial Entry

090177e196ae3d55\Final\Final On: 01-Apr-2021 04:31 (GMT)

Header Text: c4591001**Visit:** V201_SURVEIL_CONSENT - Unscheduled**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:** 1135**Site Name:** (1135) Anaheim Clinical Trials**Subject No:** 11351563**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 11:34[Back to Form](#)**1. Data Origin**

Date	Location	User	Value	Reason
Feb-02-2021 17:15:54 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Feb-02-2021 17:15:54 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: NASAL_SWAB	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Feb-02-2021 21:16:40 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Feb-02-2021 17:15:54 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Feb-02-2021 17:15:54 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: YES Date of Collection: Feb/2/2021	Initial Entry

5.a

Date	Location	User	Value	Reason
Feb-02-2021 21:16:40 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: Sample ID: BR9MGT	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Feb-02-2021 21:16:40 (UTC-08:00) Pacific Time	ACV0PFEINFP6000	(b) (6)	Data Entry: BR9MGT	Initial Entry

Header Text: c4591001

Visit: V201_SURVEIL_CONSENT - Unscheduled

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: 1135

Site Name: (1135) Anaheim Clinical Trials

Subject No: 11351563

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:34

(US & Canada)

(b) (4)

Header Text: c4591001

Visit: V202_SURVEIL_SWAB 1 - Unscheduled
Visit on Feb/15/2021

Form: DATE OF VISIT - ASYMPTOMATIC SURVEILLANCE - eCRF Audit
Trail History

Form Version: 14-Jan-2021 02:22

Form Status: Data Complete, Frozen, Verified

Site No: 1135

Site Name: (1135) Anaheim Clinical Trials

Subject No: 11351563

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:34

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1. Date of Visit

Date	Location	User	Value	Reason
Feb-15-2021 17:42:11 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: Feb/15/2021	Initial Entry

3. COVID-19 Surveillance Visit:

Date	Location	User	Value	Reason
Feb-15-2021 17:42:11 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: SSWAB_WEEK2	Initial Entry

Header Text: c4591001**Visit:** V202_SURVEIL_SWAB 1 - Unscheduled
Visit on Feb/15/2021**Form Version:** 10-Oct-2020 15:57**Site No:** 1135**Subject No:** 11351563**Generated By:** (b) (4)**Form:** ELECTRONIC SAMPLE TRACKING - REPEAT SWAB - eCRF Audit
Trail History**Form Status:** Data Complete, Frozen, Verified**Site Name:** (1135) Anaheim Clinical Trials**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 11:34[Back to Form](#)**1. Data Origin**

Date	Location	User	Value	Reason
Feb-15-2021 17:42:20 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Feb-15-2021 17:42:20 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: NASAL_SWAB_SELF	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Feb-22-2021 20:07:46 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Feb-17-2021 04:57:08 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Feb-15-2021 17:42:20 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Feb-15-2021 17:42:20 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Collection: Feb/15/2021	Initial Entry

5.a

Date	Location	User	Value	Reason
Feb-22-2021 20:07:46 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: Sample ID: AA61650	Initial Entry

Header Text: c4591001

Visit: V202_SURVEIL_SWAB 1 - Unscheduled
Visit on Feb/15/2021

Form Version: 10-Oct-2020 15:57

Site No: 1135

Subject No: 11351563

Generated By: (b) (4)

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

Form Status: Data Complete, Frozen, Verified

Site Name: (1135) Anaheim Clinical Trials

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:34

5.a Sample ID

Date	Location	User	Value	Reason
Feb-22-2021 20:07:46 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	<u>Data Entry:</u> AA61650	Initial Entry

Header Text: c4591001

Visit: End of Treatment - Unscheduled

Form: DISPOSITION - TREATMENT - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:29

Form Status: Data Complete, Frozen, Verified

Site No: 1135

Site Name: (1135) Anaheim Clinical Trials

Subject No: 11351563

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:34

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1. Date of Completion/Discontinuation/Death :

Date	Location	User	Value	Reason
Dec-16-2020 16:17:59 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: Dec/16/2020	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Dec-16-2020 16:17:59 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: VACCINATION	Initial Entry

3. Status:

Date	Location	User	Value	Reason
Dec-16-2020 16:17:59 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: COMPLETED	Initial Entry

090177e196ae3d55\Final\Final On: 01-Apr-2021 04:31 (GMT)

Header Text: c4591001

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

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen, Verified

Site No: 1135

Site Name: (1135) Anaheim Clinical Trials

Subject No: 11351563

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:34

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1. Date of Visit

Date	Location	User	Value	Reason
Feb-17-2021 11:22:08 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: Feb/16/2021	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

Site No: 1135

Site Name: (1135) Anaheim Clinical Trials

Subject No: 11351563

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:34

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

Date	Location	User	Value	Reason
Feb-17-2021 11:22:15 (UTC-08:00) Pacific Time (US & Canada)	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: 1135

Subject No: 11351563

Generated By: (b) (4)

Form: TREATMENT UNBLINDED - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1135) Anaheim Clinical Trials

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:34

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1. Date Treatment Unblinded :

Date	Location	User	Value	Reason
Feb-16-2021 11:53:12 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: Feb/16/2021	Initial Entry

2. Primary Reason for Unblinding:

Date	Location	User	Value	Reason
Feb-16-2021 11:53:12 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: ASSESS ELIGIBILITY FOR ADDITI ONAL VACCINATION	Initial Entry

Header Text: c4591001

Visit: V101_VAX3

Form Version: 22-Apr-2020 21:02

Site No: 1135

Subject No: 11351563

Generated By: (b) (4)

Form: DATE OF VISIT - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1135) Anaheim Clinical Trials

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:34

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1. Date of Visit

Date	Location	User	Value	Reason
Feb-17-2021 11:22:29 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: Feb/17/2021	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: 1135

Site Name: (1135) Anaheim Clinical Trials

Subject No: 11351563

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:34

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I. Consent Was:

Date	Location	User	Value	Reason
Feb-17-2021 11:22:37 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: OBTAINED Date Written Consent Obtained Feb/17/2021	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: 1135

Site Name: (1135) Anaheim Clinical Trials

Subject No: 11351563

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:34

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1. Date of Completion/Discontinuation/Death :

Date	Location	User	Value	Reason
Feb-17-2021 11:22:57 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: Feb/17/2021	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Feb-17-2021 11:22:57 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: REPEAT SCREENING 1	Initial Entry

3. Status:

Date	Location	User	Value	Reason
Feb-17-2021 11:22:57 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: COMPLETED	Initial Entry

090177e196ae3d55\Final\Final On: 01-Apr-2021 04:31 (GMT)

Header Text: c4591001

Visit: V101_VAX3

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

Form Version: 14-Jan-2021 02:21

Form Status: Data Complete, Frozen, Verified

Site No: 1135

Site Name: (1135) Anaheim Clinical Trials

Subject No: 11351563

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:34

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1. Lab Panel:

Date	Location	User	Value	Reason
Feb-17-2021 11:23:17 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: URINALYSIS	Initial Entry

2. Lab Sub-Panel:

Date	Location	User	Value	Reason
Feb-17-2021 11:23:17 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: PREGNANCY	Initial Entry

3. Collection Date:

Date	Location	User	Value	Reason
Feb-17-2021 11:23:17 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: Feb/17/2021	Initial Entry

4. Laboratory Name and Address (Derived)

Date	Location	User	Value	Reason
Feb-17-2021 11:23:17 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: STUDY SITE	Initial Entry

5. Specimen Type:

Date	Location	User	Value	Reason
Feb-17-2021 11:23:17 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: URINE	Initial Entry

6.a

Date	Location	User	Value	Reason
Feb-17-2021 11:23:17 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sponsor-Defined 113 Identifier: Test:: Choriogonadotropin Beta_PX113 Result:: NEGATIVE	Initial Entry

090177e196ae3d55\Final\Final On: 01-Apr-2021 04:31 (GMT)

Header Text: c4591001

Visit: V101_VAX3

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

Form Version: 14-Jan-2021 02:21

Form Status: Data Complete, Frozen, Verified

Site No: 1135

Site Name: (1135) Anaheim Clinical Trials

Subject No: 11351563

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:34

			Not Done::	
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6.a Sponsor ID:

Date	Location	User	Value	Reason
Feb-17-2021 11:23:17 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 113	Initial Entry

6.a Test:

Date	Location	User	Value	Reason
Feb-17-2021 11:23:17 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: Choriogonadotropin Beta_PX113	Initial Entry

6.a Result:

Date	Location	User	Value	Reason
Feb-17-2021 11:23:17 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: NEGATIVE	Initial Entry

090177e196ae3d55\Final\Final On: 01-Apr-2021 04:31 (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: 1135

Site Name: (1135) Anaheim Clinical Trials

Subject No: 11351563

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:34

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1. Data Origin

Date	Location	User	Value	Reason
Feb-17-2021 11:23:38 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Feb-17-2021 11:23:38 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SERUM	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Feb-26-2021 03:02:09 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Feb-18-2021 05:05:58 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Feb-17-2021 11:23:38 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Feb-17-2021 11:23:38 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Collection: Feb/17/2021	Initial Entry

5.a

Date	Location	User	Value	Reason
Feb-26-2021 03:02:09 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: Sample ID: BRGVBK	Initial Entry

090177e196ae3d55\Final\Final On: 01-Apr-2021 04:31 (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: 1135

Site Name: (1135) Anaheim Clinical Trials

Subject No: 11351563

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:34

5.a Sample ID

Date	Location	User	Value	Reason
Feb-26-2021 03:02:09 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: BRGVBK	Initial Entry

5.b

Date	Location	User	Value	Reason
Feb-26-2021 03:02:36 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: Sample ID: BSG9YT	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Feb-26-2021 03:02:36 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: BSG9YT	Initial Entry

5.c

Date	Location	User	Value	Reason
Feb-26-2021 03:02:46 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: Sample ID: BSG9YV	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Feb-26-2021 03:02:46 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: BSG9YV	Initial Entry

090177e196ae3d55\Final\Final On: 01-Apr-2021 04:31 (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: 1135

Site Name: (1135) Anaheim Clinical Trials

Subject No: 11351563

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:34

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1. Data Origin

Date	Location	User	Value	Reason
Feb-17-2021 11:23:47 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Feb-17-2021 11:23:47 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: NASAL_SWAB	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Feb-26-2021 03:01:47 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Feb-18-2021 05:05:58 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Feb-17-2021 11:23:47 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Feb-17-2021 11:23:47 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Collection: Feb/17/2021	Initial Entry

5.a

Date	Location	User	Value	Reason
Feb-26-2021 03:01:47 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: Sample ID: BRGVBL	Initial Entry

090177e196ae3d55\Final\Final On: 01-Apr-2021 04:31 (GMT)

Header Text: c4591001

Visit: V101_VAX3

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

Form Version: 22-Apr-2020 21:03

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Site No: 1135

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Generated Time (GMT): 29-Mar-2021 11:34

5.a Sample ID

Date	Location	User	Value	Reason
Feb-26-2021 03:01:47 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	<u>Data Entry:</u> BRGVBL	Initial Entry

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: 1135

Site Name: (1135) Anaheim Clinical Trials

Subject No: 11351563

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:34

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1. Was there a temporary delay of vaccination?

Date	Location	User	Value	Reason
Feb-17-2021 11:23:56 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: NO	Initial Entry

2. Treatment Name

Date	Location	User	Value	Reason
Feb-18-2021 14:35:52 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: BNT162b2	Initial Entry

3. Formulation:

Date	Location	User	Value	Reason
Feb-18-2021 14:35:52 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INJECTION	Initial Entry

4. Dose Date Time:

Date	Location	User	Value	Reason
Feb-19-2021 00:31:26 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Feb-18-2021 14:35:52 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Initial Entry
Feb-18-2021 14:35:52 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b)(6)	Data Entry: Feb/17/2021 11:44	Initial Entry
Feb-17-2021 22:47:27 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	DM: The response for "Dose Date Time" is missing. Kindly review and update.

5. Anatomical Location:

Date	Location	User	Value	Reason
Feb-18-2021 14:35:52 (UTC-08:00) Pacific Time	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: DELTOID MUSCLE	Initial Entry

090177e196ae3d55\Final\Final On: 01-Apr-2021 04:31 (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: 1135

Site Name: (1135) Anaheim Clinical Trials

Subject No: 11351563

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:34

(US & Canada)

6. Body Side:

Date	Location	User	Value	Reason
Feb-19-2021 00:32:08 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Feb-18-2021 14:35:52 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Initial Entry
Feb-18-2021 14:35:52 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b)(6)	Data Entry: RIGHT	Initial Entry
Feb-17-2021 22:46:58 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	DM: The response for "Body Side" is missing. Kindly review and update.

7. Route:

Date	Location	User	Value	Reason
Feb-18-2021 14:35:52 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INTRAMUSCULAR	Initial Entry

8. Actual Dose:

Date	Location	User	Value	Reason
Feb-18-2021 14:35:52 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 30.0	Initial Entry

9. Unit:

Date	Location	User	Value	Reason
Feb-18-2021 14:35:52 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: ug	Initial Entry

10. Timeframe Subject Was Observed

Date	Location	User	Value	Reason
Feb-18-2021 14:35:52 (UTC-08:00) Pacific Time	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 30 MINUTES	Initial Entry

090177e196ae3d55\Final\Final On: 01-Apr-2021 04:31 (GMT)

Header Text: c4591001

Visit: V101_VAX3

Form Version: 10-Dec-2020 02:26

Site No: 1135

Subject No: 11351563

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1135) Anaheim Clinical Trials

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:34

(US & Canada)

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

Date	Location	User	Value	Reason
Feb-17-2021 11:23:56 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: YES	Initial Entry

Header Text: c4591001

Visit: V102_VAX4

Form Version: 22-Apr-2020 21:02

Site No: 1135

Subject No: 11351563

Generated By: (b) (4)

Form: DATE OF VISIT - eCRF Audit Trail History

Form Status: Data Complete, Verified

Site Name: (1135) Anaheim Clinical Trials

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:34

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1. Date of Visit

Date	Location	User	Value	Reason
Mar-10-2021 14:22:15 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Mar/10/2021	Initial Entry

Header Text: c4591001

Visit: V102_VAX4

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

Form Version: 14-Jan-2021 02:21

Form Status: Data Complete, Verified

Site No: 1135

Site Name: (1135) Anaheim Clinical Trials

Subject No: 11351563

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:34

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1. Lab Panel:

Date	Location	User	Value	Reason
Mar-10-2021 14:22:33 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: URINALYSIS	Initial Entry

2. Lab Sub-Panel:

Date	Location	User	Value	Reason
Mar-10-2021 14:22:33 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: PREGNANCY	Initial Entry

3. Collection Date:

Date	Location	User	Value	Reason
Mar-10-2021 14:22:33 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Mar/10/2021	Initial Entry

4. Laboratory Name and Address (Derived)

Date	Location	User	Value	Reason
Mar-10-2021 14:22:33 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: STUDY SITE	Initial Entry

5. Specimen Type:

Date	Location	User	Value	Reason
Mar-10-2021 14:22:33 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: URINE	Initial Entry

6.a

Date	Location	User	Value	Reason
Mar-10-2021 14:22:33 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sponsor-Defined 113 Identifier: Test:: Choriogonadotropin Beta_PX113 Result:: NEGATIVE	Initial Entry

090177e196ae3d55\Final\Final On: 01-Apr-2021 04:31 (GMT)

Header Text: c4591001

Visit: V102_VAX4

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

Form Version: 14-Jan-2021 02:21

Form Status: Data Complete, Verified

Site No: 1135

Site Name: (1135) Anaheim Clinical Trials

Subject No: 11351563

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:34

			Not Done::	
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6.a Sponsor ID:

Date	Location	User	Value	Reason
Mar-10-2021 14:22:33 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 113	Initial Entry

6.a Test:

Date	Location	User	Value	Reason
Mar-10-2021 14:22:33 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Choriogonadotropin Beta_PX113	Initial Entry

6.a Result:

Date	Location	User	Value	Reason
Mar-10-2021 14:22:33 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NEGATIVE	Initial Entry

090177e196ae3d55\Final\Final On: 01-Apr-2021 04:31 (GMT)

Header Text: c4591001

Visit: V102_VAX4

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Verified

Site No: 1135

Site Name: (1135) Anaheim Clinical Trials

Subject No: 11351563

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:34

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1. Data Origin

Date	Location	User	Value	Reason
Mar-10-2021 14:22:43 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Mar-10-2021 14:22:43 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: NASAL_SWAB	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Mar-10-2021 14:22:56 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Mar-10-2021 14:22:43 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Mar-10-2021 14:22:43 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Collection: Mar/10/2021	Initial Entry

5.a

Date	Location	User	Value	Reason
Mar-10-2021 14:22:56 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BR9MPM	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Mar-10-2021 14:22:56 (UTC-08:00) Pacific Time	ACV0PFEINFP6000	(b) (6)	Data Entry: BR9MPM	Initial Entry

090177e196ae3d55\Final\Final On: 01-Apr-2021 04:31 (GMT)

Header Text: c4591001

Visit: V102_VAX4

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Verified

Site No: 1135

Site Name: (1135) Anaheim Clinical Trials

Subject No: 11351563

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:34

(US & Canada)

(b) (4)

Header Text: c4591001

Visit: V102_VAX4

Form: VACCINATION - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:26

Form Status: Data Complete, Verified

Site No: 1135

Site Name: (1135) Anaheim Clinical Trials

Subject No: 11351563

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:34

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1. Was there a temporary delay of vaccination?

Date	Location	User	Value	Reason
Mar-10-2021 14:28:47 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

2. Treatment Name

Date	Location	User	Value	Reason
Mar-10-2021 14:28:47 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> BNT162b2	Initial Entry

3. Formulation:

Date	Location	User	Value	Reason
Mar-10-2021 14:28:47 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> INJECTION	Initial Entry

4. Dose Date Time:

Date	Location	User	Value	Reason
Mar-10-2021 14:28:47 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Mar/10/2021 10:11	Initial Entry

5. Anatomical Location:

Date	Location	User	Value	Reason
Mar-10-2021 14:28:47 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> DELTOID MUSCLE	Initial Entry

6. Body Side:

Date	Location	User	Value	Reason
Mar-10-2021 14:28:47 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> RIGHT	Initial Entry

7. Route:

090177e196ae3d55\Final\Final On: 01-Apr-2021 04:31 (GMT)

Header Text: c4591001

Visit: V102_VAX4

Form: VACCINATION - eCRF Audit Trail History

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Site No: 1135

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Subject No: 11351563

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:34

Date	Location	User	Value	Reason
Mar-10-2021 14:28:47 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> INTRAMUSCULAR	Initial Entry

8. Actual Dose:

Date	Location	User	Value	Reason
Mar-10-2021 14:28:47 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> 30.0	Initial Entry

9. Unit:

Date	Location	User	Value	Reason
Mar-10-2021 14:28:47 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> ug	Initial Entry

10. Timeframe Subject Was Observed

Date	Location	User	Value	Reason
Mar-10-2021 14:28:47 (UTC-08:00) Pacific Time (US & Canada)	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
Mar-10-2021 14:28:47 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> YES	Initial Entry

090177e196ae3d55\Final\Final On: 01-Apr-2021 04:31 (GMT)

Header Text: c4591001

Visit: Subject Status - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1135

Subject No: 11351563

Generated By: (b) (4)

Form: SUBJECT STATUS - eCRF Audit Trail History

Form Status: Data Complete, Verified

Site Name: (1135) Anaheim Clinical Trials

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:34

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1. Subject Status

Date	Location	User	Value	Reason
Dec-16-2020 16:17:59 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: FOLLOW-UP	Initial Entry
Oct-28-2020 10:20:16 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: ENROLLED/RANDOMIZED	Initial Entry
Oct-28-2020 10:13:23 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SCREENED	Initial Entry

2. Subject Status Date

Date	Location	User	Value	Reason
Dec-18-2020 04:13:20 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Dec-17-2020 09:10:51 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	data has been entered in EDC
Dec-17-2020 05:47:04 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	SAE RECON:AER#2020498809 acute pancreatitis was reported as serious in Safety database but missing in AE CRF. Please confirm and update CRF. If safety update is required, submit a follow-up SAE Form.
Dec-16-2020 16:17:59 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Dec/16/2020	Initial Entry
Oct-28-2020 10:20:16 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Oct/27/2020	Initial Entry
Oct-28-2020 10:13:23 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Oct/27/2020	Initial Entry

090177e196ae3d55\Final\Final On: 01-Apr-2021 04:31 (GMT)