

Header Text: c4591001

Visit: COHORT_SELECTION

Form Version: 30-Jul-2020 21:29

Site No: 1054

Subject No: 10541067

Generated By: (b) (4)

Form: COHORT_SELECTION

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1054) Collaborative Neuroscience Network, LLC.

Subject Initials: ---

Generated Time (GMT): 19-Apr-2021 21:04

[eCRF Audit Trail History](#)

Cohort Selection

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

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

Header Text: c4591001

Visit: COHORT_SELECTION

Form Version: 22-Apr-2020 21:02

Site No: 1054

Subject No: 10541067

Generated By: (b) (4)

Form: MAIN INFORMED CONSENT

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1054) Collaborative Neuroscience Network, LLC.

Subject Initials: ---

Generated Time (GMT): 19-Apr-2021 21:04

[eCRF Audit Trail History](#)

Informed Consent

1.	Consent Was:	OBTAINED Date Written Consent Obtained Aug/28/2020
----	--------------	--

Header Text: c4591001

Visit: COHORT_SELECTION

Form Version: 06-Jul-2020 21:55

Site No: 1054

Subject No: 10541067

Generated By: (b) (4)

Form: DEMOGRAPHY

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1054) Collaborative Neuroscience Network, LLC.

Subject Initials: ---

Generated Time (GMT): 19-Apr-2021 21:04

[eCRF Audit Trail History](#)

Demography

1.	Subject ID	[10541067]
2.	Birth Date:	(b) (6) /1984
3.	Sex:	FEMALE
4.	Ethnicity:	NOT HISPANIC OR LATINO(A) OR OF SPANISH ORIGIN
5.	Race: (Check X all that apply):	WHITE
6.	Racial Designation:	

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:02

Site No: 1054

Subject No: 10541067

Generated By: (b) (4)

Form: DATE OF VISIT

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1054) Collaborative Neuroscience Network, LLC.

Subject Initials: ---

Generated Time (GMT): 19-Apr-2021 21:04

eCRF Audit Trail History

Date of Visit

1.	Date of Visit	Aug/28/2020
2.	Erroneous Visit	

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 30-Jul-2020 21:29

Site No: 1054

Subject No: 10541067

Generated By: (b) (4)

Form: INCLUSION/EXCLUSION CRITERIA

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1054) Collaborative Neuroscience Network, LLC.

Subject Initials: ---

Generated Time (GMT): 19-Apr-2021 21:04

Form Comments

Inclusion Criteria Not Met

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

Exclusion Criteria Met

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

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1054

Subject No: 10541067

Generated By: (b) (4)

Form: DISPOSITION - SCREENING

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1054) Collaborative Neuroscience Network, LLC.

Subject Initials: ---

Generated Time (GMT): 19-Apr-2021 21:04

[eCRF Audit Trail History](#)

Disposition - Screening

1.	Date of Completion/Discontinuation/Death	Aug/28/2020
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: 1054

Subject No: 10541067

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1054) Collaborative Neuroscience Network, LLC.

Subject Initials: ---

Generated Time (GMT): 19-Apr-2021 21:04

[eCRF Audit Trail History](#)

Medical History Details

1.a	Line/MH Number:	[1]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[gallstones]
	Start Date:	UNK/UNK/2017
	Ongoing:	NO End Date: UNK/UNK/2017
1.b	Line/MH Number:	[2]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[cholecystectomy]
	Start Date:	UNK/UNK/2017
	Ongoing:	NO End Date: UNK/UNK/2017
1.c	Line/MH Number:	[3]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[environmental allergies]
	Start Date:	UNK/UNK/2014
	Ongoing:	YES
1.d	Line/MH Number:	[4]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[anxiety (intermittent)]
	Start Date:	UNK/UNK/2001
	Ongoing:	YES

090177e196d89027\Final\Final On: 22-Apr-2021 02:13 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1054

Subject No: 10541067

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1054) Collaborative Neuroscience Network, LLC.

Subject Initials: ---

Generated Time (GMT): 19-Apr-2021 21:04

1.e	Line/MH Number:	[5]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[salpingectomy, bilateral]
	Start Date:	UNK/UNK/2018
	Ongoing:	NO End Date: UNK/UNK/2018
1.f	Line/MH Number:	[6]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[asthma]
	Start Date:	UNK/UNK/1998
	Ongoing:	NO End Date: UNK/UNK/2010
1.g	Line/MH Number:	[7]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[scar in abdomen]
	Start Date:	UNK/UNK/2018
	Ongoing:	YES
1.h	Line/MH Number:	[8]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[TMJ dysfunction]
	Start Date:	UNK/UNK/2018
	Ongoing:	YES

090177e196d89027\Final\Final On: 22-Apr-2021 02:13 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 21-Aug-2020 02:51

Site No: 1054

Subject No: 10541067

Generated By: (b) (4)

Form: VITAL SIGNS - BASELINE

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1054) Collaborative Neuroscience Network, LLC.

Subject Initials: ---

Generated Time (GMT): 19-Apr-2021 21:04

[eCRF Audit Trail History](#)

Vital Signs

1.	Date:	Aug/28/2020
2.	Weight:	[77.0]
3.	Unit:	kg
4.	Height:	[159.0]
5.	Unit:	cm
6.	Body Mass Index:	[30.5]

Vital Signs Details

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

090177e196d89027\Final\Final On: 22-Apr-2021 02:13 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 21-Aug-2020 02:49

Site No: 1054

Subject No: 10541067

Generated By: (b) (4)

Form: LAB URINALYSIS - PREGNANCY TEST

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1054) Collaborative Neuroscience Network, LLC.

Subject Initials: ---

Generated Time (GMT): 19-Apr-2021 21:04

eCRF Audit Trail History

Lab Urinalysis

1.	Lab Panel:	URINALYSIS
2.	Lab Sub-Panel:	PREGNANCY
3.	Collection Date:	Aug/28/2020
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:	

090177e196d89027\Final\Final On: 22-Apr-2021 02:13 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1054

Subject No: 10541067

Generated By: (b) (4)

Form: RANDOMIZATION

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1054) Collaborative Neuroscience Network, LLC.

Subject Initials: ---

Generated Time (GMT): 19-Apr-2021 21:04

[eCRF Audit Trail History](#)

Disposition

1.	Randomization Date :	Aug/28/2020
2.	Randomization Number:	[71999]
3.	Randomization Group:	[]

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1054

Subject No: 10541067

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1054) Collaborative Neuroscience Network, LLC.

Subject Initials: ---

Generated Time (GMT): 19-Apr-2021 21:04

eCRF Audit Trail History

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	SERUM
3.	Sample Collected?	YES Date of Collection: Aug/28/2020
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[]

Aliquot

Please enter barcode for each aliquot.

5.a	Sample ID	[BPYWS8]
5.b	Sample ID	[BPYWS9]
5.c	Sample ID	[BPYWSB]

090177e196d89027\Final\Final On: 22-Apr-2021 02:13 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1054

Subject No: 10541067

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1054) Collaborative Neuroscience Network, LLC.

Subject Initials: ---

Generated Time (GMT): 19-Apr-2021 21:04

eCRF Audit Trail History

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Aug/28/2020
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[]

Aliquot

Please enter barcode for each aliquot.

5.a	Sample ID	[BPYWSC]
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090177e196d89027\Final\Final On: 22-Apr-2021 02:13 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:04

Site No: 1054

Subject No: 10541067

Generated By: (b) (4)

Form: VACCINATION

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1054) Collaborative Neuroscience Network, LLC.

Subject Initials: ---

Generated Time (GMT): 19-Apr-2021 21:04

eCRF Audit Trail History

Vaccination

1.	Was there a temporary delay of vaccination?	NO
2.	Treatment Name	[BLINDED THERAPY]
3.	Formulation:	INJECTION
4.	Dose Date Time:	Aug/28/2020 09:02
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

090177e196d89027\Final\Final On: 22-Apr-2021 02:13 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 06-Jul-2020 21:53

Site No: 1054

Subject No: 10541067

Generated By: (b) (4)

Form: REACTOGENICITY DIARY

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1054) Collaborative Neuroscience Network, LLC.

Subject Initials: ---

Generated Time (GMT): 19-Apr-2021 21:04

[eCRF Audit Trail History](#)

Reactogenicity Diary

1.	Select appropriate response - Reactogenicity diary collection	NO - REACTOGENICITY E-DIARY NOT COLLECTED FOR THIS SUBJECT
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Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 1054

Subject No: 10541067

Generated By: (b) (4)

Form: DATE OF VISIT

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1054) Collaborative Neuroscience Network, LLC.

Subject Initials: ---

Generated Time (GMT): 19-Apr-2021 21:04

eCRF Audit Trail History

Date of Visit

1.	Date of Visit	Sep/18/2020
2.	Erroneous Visit	

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 15-Sep-2020 21:54

Site No: 1054

Subject No: 10541067

Generated By: (b) (4)

Form: VITAL SIGNS - TEMP

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1054) Collaborative Neuroscience Network, LLC.

Subject Initials: ---

Generated Time (GMT): 19-Apr-2021 21:04

[eCRF Audit Trail History](#)

Vital Signs

1.	Date:	Sep/18/2020
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Vital Signs Details

2.a	Record Identifier:	1
	Temperature:	[98.4]
	Unit:	F
	Temperature Location:	ORAL CAVITY

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 21-Aug-2020 02:49

Site No: 1054

Subject No: 10541067

Generated By: (b) (4)

Form: LAB URINALYSIS - PREGNANCY TEST

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1054) Collaborative Neuroscience Network, LLC.

Subject Initials: ---

Generated Time (GMT): 19-Apr-2021 21:04

eCRF Audit Trail History

Lab Urinalysis

1.	Lab Panel:	URINALYSIS
2.	Lab Sub-Panel:	PREGNANCY
3.	Collection Date:	Sep/18/2020
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:	

090177e196d89027\Final\Final On: 22-Apr-2021 02:13 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:03

Site No: 1054

Subject No: 10541067

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1054) Collaborative Neuroscience Network, LLC.

Subject Initials: ---

Generated Time (GMT): 19-Apr-2021 21:04

eCRF Audit Trail History

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Sep/18/2020
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	[BM98TP]
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090177e196d89027\Final\Final On: 22-Apr-2021 02:13 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1054

Subject No: 10541067

Generated By: (b) (4)

Form: VACCINATION

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1054) Collaborative Neuroscience Network, LLC.

Subject Initials: ---

Generated Time (GMT): 19-Apr-2021 21:04

eCRF Audit Trail History

Vaccination

1.	Was there a temporary delay of vaccination?	NO
2.	Treatment Name	[BLINDED THERAPY]
3.	Formulation:	INJECTION
4.	Dose Date Time:	Sep/18/2020 08:33
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

090177e196d89027\Final\Final On: 22-Apr-2021 02:13 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 1054

Subject No: 10541067

Generated By: (b) (4)

Form: DATE OF VISIT

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1054) Collaborative Neuroscience Network, LLC.

Subject Initials: ---

Generated Time (GMT): 19-Apr-2021 21:04

eCRF Audit Trail History

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

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form Version: 22-Apr-2020 21:03

Site No: 1054

Subject No: 10541067

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1054) Collaborative Neuroscience Network, LLC.

Subject Initials: ---

Generated Time (GMT): 19-Apr-2021 21:04

eCRF Audit Trail History

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	SERUM
3.	Sample Collected?	YES Date of Collection: Oct/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	[BPYX50]
5.b	Sample ID	[BPYX51]

090177e196d89027\Final\Final On: 22-Apr-2021 02:13 (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: 1054

Site Name: (1054) Collaborative Neuroscience Network, LLC.

Subject No: 10541067

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 19-Apr-2021 21:04

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: 1054

Site Name: (1054) Collaborative Neuroscience Network, LLC.

Subject No: 10541067

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 19-Apr-2021 21:04

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: 1054

Site Name: (1054) Collaborative Neuroscience Network, LLC.

Subject No: 10541067

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 19-Apr-2021 21:04

Electronic Sample Tracking

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

Aliquot

Please enter barcode for each aliquot.

5.	Sample ID	[]
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Header Text: c4591001

Visit: POT_COVID_ILL - New Unscheduled Visit

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1054

Site Name: (1054) Collaborative Neuroscience Network, LLC.

Subject No: 10541067

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 19-Apr-2021 21:04

Electronic Sample Tracking

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

Aliquot

Please enter barcode for each aliquot.

5.	Sample ID	[]
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Header Text: c4591001

Visit: POT_COVID_ILL - New Unscheduled Visit

Form: HEALTH CARE UTILIZATION

Form Version: 20-Feb-2021 02:19

Form Status: Not Started

Site No: 1054

Site Name: (1054) Collaborative Neuroscience Network, LLC.

Subject No: 10541067

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 19-Apr-2021 21:04

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?	
----	--	--

090177e196d89027\Final\Final On: 22-Apr-2021 02:13 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL - New Unscheduled Visit **Form:** ILLNESS DETAILS

Form Version: 06-Jul-2020 21:52 **Form Status:** Not Started

Site No: 1054 **Site Name:** (1054) Collaborative Neuroscience Network, LLC.

Subject No: 10541067 **Subject Initials:** ---

Generated By: (b) (4) **Generated Time (GMT):** 19-Apr-2021 21:04

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: 1054

Site Name: (1054) Collaborative Neuroscience Network, LLC.

Subject No: 10541067

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 19-Apr-2021 21:04

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

COVID-19 Illness Visit

3.	COVID-19 Illness Visit:	
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Header Text: c4591001

Visit: POT_COVID_CONVA - New
Unscheduled Visit

Form Version: 22-Apr-2020 21:03

Site No: 1054

Subject No: 10541067

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Status: Not Started

Site Name: (1054) Collaborative Neuroscience Network, LLC.

Subject Initials: ---

Generated Time (GMT): 19-Apr-2021 21:04

Electronic Sample Tracking

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

Aliquot

Please enter barcode for each aliquot.

5.	Sample ID	[]
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Header Text: c4591001

Visit: Unplanned - New Unscheduled Visit

Form: DATE OF VISIT

Form Version: 22-Apr-2020 21:02

Form Status: Not Started

Site No: 1054

Site Name: (1054) Collaborative Neuroscience Network, LLC.

Subject No: 10541067

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 19-Apr-2021 21:04

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: 1054

Site Name: (1054) Collaborative Neuroscience Network, LLC.

Subject No: 10541067

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 19-Apr-2021 21:04

Unplanned Assessments

1.	Assessments	
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Header Text: c4591001

Visit: End of Treatment - Unscheduled

Form Version: 15-Sep-2020 21:55

Site No: 1054

Subject No: 10541067

Generated By: (b) (4)

Form: DISPOSITION - TREATMENT

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1054) Collaborative Neuroscience Network, LLC.

Subject Initials: ---

Generated Time (GMT): 19-Apr-2021 21:04

eCRF Audit Trail History

Disposition - Treatment

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

Header Text: c4591001

Visit: Follow-Up - Unscheduled

Form Version: 15-Sep-2020 21:53

Site No: 1054

Subject No: 10541067

Generated By: (b) (4)

Form: DISPOSITION - FOLLOW-UP

Form Status: Not Started

Site Name: (1054) Collaborative Neuroscience Network, LLC.

Subject Initials: ---

Generated Time (GMT): 19-Apr-2021 21:04

Disposition - Follow-Up

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

Header Text: c4591001

Visit: POT_COVID_REPEAT_SWAB - New
Unscheduled Visit

Form: DATE OF VISIT - REPEAT SWAB

Form Version: 10-Oct-2020 15:57

Form Status: Not Started

Site No: 1054

Site Name: (1054) Collaborative Neuroscience Network, LLC.

Subject No: 10541067

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 19-Apr-2021 21:04

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: 1054

Site Name: (1054) Collaborative Neuroscience Network, LLC.

Subject No: 10541067

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 19-Apr-2021 21:04

Electronic Sample Tracking

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

Aliquot

Please enter barcode for each aliquot.

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

Header Text: c4591001

Visit: Logs

Form: ADVERSE EVENT REPORT

Form Version: 22-Apr-2020 21:02

Site No: 1054

Site Name: (1054) Collaborative Neuroscience Network, LLC.

Subject No: 10541067

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 19-Apr-2021 21:04

#	Category	AE Identifier	Adverse Event	Start Date	Is the Adverse Event Still Ongoing	Form Instance
1.	ADVERSE EVENT	1	Headache	Aug/28/2020 17:30	NO End Date Time: Aug/29/2020 15:00	Repeating Pages
2.	ADVERSE EVENT	2	vertigo	Sep/20/2020 UNK:UNK	NO End Date Time: Sep/22/2020 UNK:UNK	Repeating Pages
3.	ADVERSE EVENT	3	fluid R ear	Sep/22/2020 UNK:UNK	NO End Date Time: Feb/13/2021 UNK:UNK	Repeating Pages
4.	ADVERSE EVENT	4	decreased hearing R ear	Sep/20/2020 UNK:UNK	YES	Repeating Pages
5.	ADVERSE EVENT	5	Tinnitus R ear	Sep/20/2020 UNK:UNK	YES	Repeating Pages
6.	ADVERSE EVENT	6	headache	Sep/18/2020 18:00	NO End Date Time: Sep/19/2020 10:00	Repeating Pages
7.	ADVERSE EVENT	7	worsening R TMJ dysfunction	Feb/12/2021 UNK:UNK	YES	Repeating Pages

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Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1054

Subject No: 10541067

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Locked, Frozen

Site Name: (1054) Collaborative Neuroscience Network, LLC.

Subject Initials: ---

Generated Time (GMT): 19-Apr-2021 21:04

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Adverse Event Report

1.	Category:	ADVERSE EVENT
2.	AE ID:	[1]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[Headache]
4.	Start Date Time:	Aug/28/2020 17:30
5.	Is the adverse event still ongoing?	NO End Date Time: Aug/29/2020 15:00
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).	NO
8.	Is this adverse event the result of a study Medication Error? If Yes, record the type of medication error on the Medication Error Log.	NO
9.	Is this event related to study treatment:	RELATED
10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE
11.	Was a Concomitant Medication given?	YES

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Header Text: c4591001

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Form Version: 22-Apr-2020 21:02

Site No: 1054

Subject No: 10541067

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Locked, Frozen

Site Name: (1054) Collaborative Neuroscience Network, LLC.

Subject Initials: ---

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

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Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1054

Subject No: 10541067

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Locked, Frozen

Site Name: (1054) Collaborative Neuroscience Network, LLC.

Subject Initials: ---

Generated Time (GMT): 19-Apr-2021 21:04

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Adverse Event Report

1.	Category:	ADVERSE EVENT
2.	AE ID:	[2]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[vertigo]
4.	Start Date Time:	Sep/20/2020 UNK:UNK
5.	Is the adverse event still ongoing?	NO End Date Time: Sep/22/2020 UNK:UNK
6.	Toxicity Grade:	1
7.	Is the adverse event serious? If Yes, NOTIFY PFIZER IMMEDIATELY. Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).	NO
8.	Is this adverse event the result of a study Medication Error? If Yes, record the type of medication error on the Medication Error Log.	NO
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: [unknown, possible allergy]

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Header Text: c4591001

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Site No: 1054

Subject No: 10541067

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Locked, Frozen

Site Name: (1054) Collaborative Neuroscience Network, LLC.

Subject Initials: ---

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

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Header Text: c4591001

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Form Version: 22-Apr-2020 21:02

Site No: 1054

Subject No: 10541067

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Frozen

Site Name: (1054) Collaborative Neuroscience Network, LLC.

Subject Initials: ---

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Adverse Event Report

1.	Category:	ADVERSE EVENT
2.	AE ID:	[3]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[fluid R ear]
4.	Start Date Time:	Sep/22/2020 UNK:UNK
5.	Is the adverse event still ongoing?	NO End Date Time: Feb/13/2021 UNK:UNK
6.	Toxicity Grade:	1
7.	Is the adverse event serious? If Yes, NOTIFY PFIZER IMMEDIATELY. Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).	NO
8.	Is this adverse event the result of a study Medication Error? If Yes, record the type of medication error on the Medication Error Log.	NO
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: [unknown, possible allergy]

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Header Text: c4591001

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Site No: 1054

Subject No: 10541067

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Frozen

Site Name: (1054) Collaborative Neuroscience Network, LLC.

Subject Initials: ---

Generated Time (GMT): 19-Apr-2021 21:04

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

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Subject No: 10541067

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete

Site Name: (1054) Collaborative Neuroscience Network, LLC.

Subject Initials: ---

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Adverse Event Report

1.	Category:	ADVERSE EVENT
2.	AE ID:	[4]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[decreased hearing R ear]
4.	Start Date Time:	Sep/20/2020 UNK:UNK
5.	Is the adverse event still ongoing?	YES
6.	Toxicity Grade:	2
7.	Is the adverse event serious? If Yes, NOTIFY PFIZER IMMEDIATELY. Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).	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: [unknown, possible allergy]
10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE

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Subject No: 10541067

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete

Site Name: (1054) Collaborative Neuroscience Network, LLC.

Subject Initials: ---

Generated Time (GMT): 19-Apr-2021 21:04

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

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Subject No: 10541067

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Form Status: Data Complete

Site Name: (1054) Collaborative Neuroscience Network, LLC.

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Adverse Event Report

1.	Category:	ADVERSE EVENT
2.	AE ID:	[5]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[Tinnitus R ear]
4.	Start Date Time:	Sep/20/2020 UNK:UNK
5.	Is the adverse event still ongoing?	YES
6.	Toxicity Grade:	2
7.	Is the adverse event serious? If Yes, NOTIFY PFIZER IMMEDIATELY. Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).	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: [unknown, possible allergy]
10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE

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Form: ADVERSE EVENT REPORT

Form Status: Data Complete

Site Name: (1054) Collaborative Neuroscience Network, LLC.

Subject Initials: ---

Generated Time (GMT): 19-Apr-2021 21:04

11.	Was a Concomitant Medication given?	YES
12.	Was a Non-Drug Treatment given?	NO
13.	What was the outcome of this adverse event?:	NOT RECOVERED/NOT RESOLVED
14.	Did the adverse event cause the subject to be discontinued from the study?	NO
15.	Serious Adverse Event Number: For Pfizer Use Only	[]

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Form Status: Data Complete, Locked, Frozen

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Subject Initials: ---

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Adverse Event Report

1.	Category:	ADVERSE EVENT
2.	AE ID:	[6]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[headache]
4.	Start Date Time:	Sep/18/2020 18:00
5.	Is the adverse event still ongoing?	NO End Date Time: Sep/19/2020 10:00
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).	NO
8.	Is this adverse event the result of a study Medication Error? If Yes, record the type of medication error on the Medication Error Log.	NO
9.	Is this event related to study treatment:	RELATED
10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE

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Form Version: 22-Apr-2020 21:02

Site No: 1054

Subject No: 10541067

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Locked, Frozen

Site Name: (1054) Collaborative Neuroscience Network, LLC.

Subject Initials: ---

Generated Time (GMT): 19-Apr-2021 21:04

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	[]

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Header Text: c4591001

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Site No: 1054

Subject No: 10541067

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete

Site Name: (1054) Collaborative Neuroscience Network, LLC.

Subject Initials: ---

Generated Time (GMT): 19-Apr-2021 21:04

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Adverse Event Report

1.	Category:	ADVERSE EVENT
2.	AE ID:	[7]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[worsening R TMJ dysfunction]
4.	Start Date Time:	Feb/12/2021 UNK:UNK
5.	Is the adverse event still ongoing?	YES
6.	Toxicity Grade:	1
7.	Is the adverse event serious? If Yes, NOTIFY PFIZER IMMEDIATELY. Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).	NO
8.	Is this adverse event the result of a study Medication Error? If Yes, record the type of medication error on the Medication Error Log.	NO
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: [TMJ 2/2 increased stress, has a h/o TMJ dysfunction]
10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE

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Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1054

Subject No: 10541067

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete

Site Name: (1054) Collaborative Neuroscience Network, LLC.

Subject Initials: ---

Generated Time (GMT): 19-Apr-2021 21:04

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

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Header Text: c4591001

Visit: Logs

Form: MEDICATION ERROR

Form Version: 17-Jul-2020 21:54

Site No: 1054

Site Name: (1054) Collaborative Neuroscience Network, LLC.

Subject No: 10541067

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 19-Apr-2021 21:04

#	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: 1054

Subject No: 10541067

Generated By: (b) (4)

Form: MEDICATION ERROR

Form Status: Not Started

Site Name: (1054) Collaborative Neuroscience Network, LLC.

Subject Initials: ---

Generated Time (GMT): 19-Apr-2021 21:04

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Medication Error

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

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Header Text: c4591001

Visit: Logs

Form: CONCOMITANT MEDICATIONS - NON STUDY VACCINATIONS

Form Version: 22-Apr-2020 21:03

Site No: 1054

Site Name: (1054) Collaborative Neuroscience Network, LLC.

Subject No: 10541067

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 19-Apr-2021 21:04

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

Header Text: c4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - NON STUDY
VACCINATIONS

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1054

Site Name: (1054) Collaborative Neuroscience Network, LLC.

Subject No: 10541067

Subject Initials: ---

Generated By: (b) (4)

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Concomitant Medications

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

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Header Text: c4591001

Visit: Logs

Form: CONCOMITANT MEDICATIONS - PROHIBITED

Form Version: 22-Apr-2020 21:03

Site No: 1054

Site Name: (1054) Collaborative Neuroscience Network, LLC.

Subject No: 10541067

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 19-Apr-2021 21:04

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

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1054

Subject No: 10541067

Generated By: (b) (4)

Form: CONCOMITANT MEDICATIONS - PROHIBITED

Form Status: Not Started

Site Name: (1054) Collaborative Neuroscience Network, LLC.

Subject Initials: ---

Generated Time (GMT): 19-Apr-2021 21:04

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Concomitant Medications

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

090177e196d89027\Final\Final On: 22-Apr-2021 02:13 (GMT)

Header Text: c4591001

Visit: Logs

Form: RADIATION TREATMENT

Form Version: 22-Apr-2020 21:02

Site No: 1054

Site Name: (1054) Collaborative Neuroscience Network, LLC.

Subject No: 10541067

Subject Initials: ---

Generated By: (b) (4)

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

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1054

Subject No: 10541067

Generated By: (b) (4)

Form: RADIATION TREATMENT

Form Status: Not Started

Site Name: (1054) Collaborative Neuroscience Network, LLC.

Subject Initials: ---

Generated Time (GMT): 19-Apr-2021 21:04

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Radiation Treatment

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

Header Text: c4591001

Visit: Logs

Form: TRANSFUSIONS

Form Version: 22-Apr-2020 21:03

Site No: 1054

Site Name: (1054) Collaborative Neuroscience Network, LLC.

Subject No: 10541067

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 19-Apr-2021 21:04

#	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: 1054

Subject No: 10541067

Generated By: (b) (4)

Form: TRANSFUSIONS

Form Status: Not Started

Site Name: (1054) Collaborative Neuroscience Network, LLC.

Subject Initials: ---

Generated Time (GMT): 19-Apr-2021 21:04

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

Header Text: c4591001

Visit: Unplanned Vaccination - Unscheduled

Form: DATE OF VISIT

Form Version: 22-Apr-2020 21:02

Form Status: Not Started

Site No: 1054

Site Name: (1054) Collaborative Neuroscience Network, LLC.

Subject No: 10541067

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 19-Apr-2021 21:04

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: 1054

Site Name: (1054) Collaborative Neuroscience Network, LLC.

Subject No: 10541067

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 19-Apr-2021 21:04

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: 1054

Site Name: (1054) Collaborative Neuroscience Network, LLC.

Subject No: 10541067

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 19-Apr-2021 21:04

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:	

090177e196d89027\Final\Final On: 22-Apr-2021 02:13 (GMT)

Header Text: c4591001

Visit: Unplanned Vaccination - Unscheduled

Form: VACCINATION

Form Version: 10-Dec-2020 02:26

Form Status: Not Started

Site No: 1054

Site Name: (1054) Collaborative Neuroscience Network, LLC.

Subject No: 10541067

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 19-Apr-2021 21:04

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?	

090177e196d89027\Final\Final On: 22-Apr-2021 02:13 (GMT)

Header Text: c4591001

Visit: Unplanned Vaccination - Unscheduled

Form: CONTACT OUTCOME - MONTH 1

Form Version: 10-Oct-2020 15:57

Form Status: Not Started

Site No: 1054

Site Name: (1054) Collaborative Neuroscience Network, LLC.

Subject No: 10541067

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 19-Apr-2021 21:04

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: 1054

Site Name: (1054) Collaborative Neuroscience Network, LLC.

Subject No: 10541067

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 19-Apr-2021 21:04

Contact Outcome

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

Header Text: c4591001

Visit: Potential ReVax Initial Contact -
Unscheduled

Form: DATE OF VISIT

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen, Verified

Site No: 1054

Site Name: (1054) Collaborative Neuroscience Network, LLC.

Subject No: 10541067

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 19-Apr-2021 21:04

[eCRF Audit Trail History](#)

Date of Visit

1.	Date of Visit	Feb/2/2021
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: 1054

Site Name: (1054) Collaborative Neuroscience Network, LLC.

Subject No: 10541067

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 19-Apr-2021 21:04

[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
----	---	---

090177e196d89027\Final\Final On: 22-Apr-2021 02:13 (GMT)

Header Text: c4591001

Visit: Disposition - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1054

Subject No: 10541067

Generated By: (b) (4)

Form: TREATMENT UNBLINDED

Form Status: Data Complete, Frozen, Verified

Site Name: (1054) Collaborative Neuroscience Network, LLC.

Subject Initials: ---

Generated Time (GMT): 19-Apr-2021 21:04

eCRF Audit Trail History

Treatment Unblinded

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

Header Text: c4591001

Visit: Disposition - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1054

Subject No: 10541067

Generated By: (b) (4)

Form: WITHDRAWAL OF CONSENT

Form Status: Not Started

Site Name: (1054) Collaborative Neuroscience Network, LLC.

Subject Initials: ---

Generated Time (GMT): 19-Apr-2021 21:04

Withdrawal Of Consent

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

090177e196d89027\Final\Final On: 22-Apr-2021 02:13 (GMT)

Header Text: c4591001

Visit: Disposition - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1054

Subject No: 10541067

Generated By: (b) (4)

Form: DEATH DETAILS CODED

Form Status: Not Started

Site Name: (1054) Collaborative Neuroscience Network, LLC.

Subject Initials: ---

Generated Time (GMT): 19-Apr-2021 21:04

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: 1054

Subject No: 10541067

Generated By: (b) (4)

Form: DATE OF VISIT

Form Status: Data Complete, Frozen, Verified

Site Name: (1054) Collaborative Neuroscience Network, LLC.

Subject Initials: ---

Generated Time (GMT): 19-Apr-2021 21:04

eCRF Audit Trail History

Date of Visit

1.	Date of Visit	Feb/3/2021
2.	Erroneous Visit	

Header Text: c4591001

Visit: V101_VAX3

Form Version: 10-Dec-2020 02:31

Site No: 1054

Subject No: 10541067

Generated By: (b) (4)

Form: INFORMED CONSENT - FURTHER VACCINATION

Form Status: Data Complete, Frozen, Verified

Site Name: (1054) Collaborative Neuroscience Network, LLC.

Subject Initials: ---

Generated Time (GMT): 19-Apr-2021 21:04

[eCRF Audit Trail History](#)

Informed Consent - Further Vaccination

1.	Consent Was:	OBTAINED Date Written Consent Obtained Feb/3/2021
----	--------------	---

Header Text: c4591001

Visit: V101_VAX3

Form: INCLUSION/EXCLUSION CRITERIA - FURTHER VACCINATION

Form Version: 10-Dec-2020 02:30

Form Status: Data Complete, Frozen, Verified

Site No: 1054

Site Name: (1054) Collaborative Neuroscience Network, LLC.

Subject No: 10541067

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 19-Apr-2021 21:04

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: 1054

Subject No: 10541067

Generated By: (b) (4)

Form: DISPOSITION - SCREENING FOR FURTHER VACCINATION

Form Status: Data Complete, Frozen, Verified

Site Name: (1054) Collaborative Neuroscience Network, LLC.

Subject Initials: ---

Generated Time (GMT): 19-Apr-2021 21:04

[eCRF Audit Trail History](#)

Disposition - Screening for Further Vaccination

1.	Date of Completion/Discontinuation/Death :	Feb/3/2021
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: 1054

Subject No: 10541067

Generated By: (b) (4)

Form: LAB URINALYSIS - PREGNANCY TEST

Form Status: Data Complete, Frozen, Verified

Site Name: (1054) Collaborative Neuroscience Network, LLC.

Subject Initials: ---

Generated Time (GMT): 19-Apr-2021 21:04

eCRF Audit Trail History

Lab Urinalysis

1.	Lab Panel:	URINALYSIS
2.	Lab Sub-Panel:	PREGNANCY
3.	Collection Date:	Feb/3/2021
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:	

090177e196d89027\Final\Final On: 22-Apr-2021 02:13 (GMT)

Header Text: c4591001

Visit: V101_VAX3

Form Version: 22-Apr-2020 21:03

Site No: 1054

Subject No: 10541067

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Status: Data Complete, Frozen, Verified

Site Name: (1054) Collaborative Neuroscience Network, LLC.

Subject Initials: ---

Generated Time (GMT): 19-Apr-2021 21:04

eCRF Audit Trail History

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	SERUM
3.	Sample Collected?	YES Date of Collection: Feb/3/2021
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	[BR54YF]
5.b	Sample ID	[BR54YG]
5.c	Sample ID	[BR54YH]

090177e196d89027\Final\Final On: 22-Apr-2021 02:13 (GMT)

Header Text: c4591001

Visit: V101_VAX3

Form Version: 22-Apr-2020 21:03

Site No: 1054

Subject No: 10541067

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB

Form Status: Data Complete, Frozen, Verified

Site Name: (1054) Collaborative Neuroscience Network, LLC.

Subject Initials: ---

Generated Time (GMT): 19-Apr-2021 21:04

eCRF Audit Trail History

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Feb/3/2021
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	[BR54YJ]
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090177e196d89027\Final\Final On: 22-Apr-2021 02:13 (GMT)

Header Text: c4591001

Visit: V101_VAX3

Form Version: 10-Dec-2020 02:26

Site No: 1054

Subject No: 10541067

Generated By: (b) (4)

Form: VACCINATION

Form Status: Data Complete, Frozen, Verified

Site Name: (1054) Collaborative Neuroscience Network, LLC.

Subject Initials: ---

Generated Time (GMT): 19-Apr-2021 21:04

[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/3/2021 09:50
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

090177e196d89027\Final\Final On: 22-Apr-2021 02:13 (GMT)

Header Text: c4591001

Visit: V102_VAX4

Form Version: 22-Apr-2020 21:02

Site No: 1054

Subject No: 10541067

Generated By: (b) (4)

Form: DATE OF VISIT

Form Status: Data Complete, Frozen, Verified

Site Name: (1054) Collaborative Neuroscience Network, LLC.

Subject Initials: ---

Generated Time (GMT): 19-Apr-2021 21:04

eCRF Audit Trail History

Date of Visit

1.	Date of Visit	Feb/26/2021
2.	Erroneous Visit	

Header Text: c4591001

Visit: V102_VAX4

Form Version: 14-Jan-2021 02:21

Site No: 1054

Subject No: 10541067

Generated By: (b) (4)

Form: LAB URINALYSIS - PREGNANCY TEST

Form Status: Data Complete, Frozen, Verified

Site Name: (1054) Collaborative Neuroscience Network, LLC.

Subject Initials: ---

Generated Time (GMT): 19-Apr-2021 21:04

eCRF Audit Trail History

Lab Urinalysis

1.	Lab Panel:	URINALYSIS
2.	Lab Sub-Panel:	PREGNANCY
3.	Collection Date:	Feb/26/2021
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:	

090177e196d89027\Final\Final On: 22-Apr-2021 02:13 (GMT)

Header Text: c4591001

Visit: V102_VAX4

Form Version: 22-Apr-2020 21:03

Site No: 1054

Subject No: 10541067

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB

Form Status: Data Complete, Frozen, Verified

Site Name: (1054) Collaborative Neuroscience Network, LLC.

Subject Initials: ---

Generated Time (GMT): 19-Apr-2021 21:04

eCRF Audit Trail History

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Feb/26/2021
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	[BRMTLT]
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090177e196d89027\Final\Final On: 22-Apr-2021 02:13 (GMT)

Header Text: c4591001

Visit: V102_VAX4

Form Version: 10-Dec-2020 02:26

Site No: 1054

Subject No: 10541067

Generated By: (b) (4)

Form: VACCINATION

Form Status: Data Complete, Frozen, Verified

Site Name: (1054) Collaborative Neuroscience Network, LLC.

Subject Initials: ---

Generated Time (GMT): 19-Apr-2021 21:04

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/26/2021 08:48
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

090177e196d89027\Final\Final On: 22-Apr-2021 02:13 (GMT)

Header Text: c4591001

Visit: V103_MONTH1

Form Version: 22-Apr-2020 21:02

Site No: 1054

Subject No: 10541067

Generated By: (b) (4)

Form: DATE OF VISIT

Form Status: Not Started

Site Name: (1054) Collaborative Neuroscience Network, LLC.

Subject Initials: ---

Generated Time (GMT): 19-Apr-2021 21:04

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: 1054

Subject No: 10541067

Generated By: (b) (4)

Form: CONTACT OUTCOME

Form Status: Not Started

Site Name: (1054) Collaborative Neuroscience Network, LLC.

Subject Initials: ---

Generated Time (GMT): 19-Apr-2021 21:04

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: 1054

Subject No: 10541067

Generated By: (b) (4)

Form: DATE OF VISIT

Form Status: Not Started

Site Name: (1054) Collaborative Neuroscience Network, LLC.

Subject Initials: ---

Generated Time (GMT): 19-Apr-2021 21:04

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: 1054

Subject No: 10541067

Generated By: (b) (4)

Form: CONTACT OUTCOME

Form Status: Not Started

Site Name: (1054) Collaborative Neuroscience Network, LLC.

Subject Initials: ---

Generated Time (GMT): 19-Apr-2021 21:04

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: 1054

Subject No: 10541067

Generated By: (b) (4)

Form: DATE OF VISIT

Form Status: Not Started

Site Name: (1054) Collaborative Neuroscience Network, LLC.

Subject Initials: ---

Generated Time (GMT): 19-Apr-2021 21:04

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: 1054

Subject No: 10541067

Generated By: (b) (4)

Form: CONTACT OUTCOME

Form Status: Not Started

Site Name: (1054) Collaborative Neuroscience Network, LLC.

Subject Initials: ---

Generated Time (GMT): 19-Apr-2021 21:04

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: 1054

Site Name: (1054) Collaborative Neuroscience Network, LLC.

Subject No: 10541067

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 19-Apr-2021 21:04

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: 1054

Subject No: 10541067

Generated By: (b) (4)

Form: SUBJECT STATUS

Form Status: Data Complete, Verified

Site Name: (1054) Collaborative Neuroscience Network, LLC.

Subject Initials: ---

Generated Time (GMT): 19-Apr-2021 21:04

[eCRF Audit Trail History](#)

Subject Status

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

Header Text: c4591001

Visit: Investigator Signature - Unscheduled

Form: CASEBOOK SIGNATURE FORM

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Verified

Site No: 1054

Site Name: (1054) Collaborative Neuroscience Network, LLC.

Subject No: 10541067

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 19-Apr-2021 21:04

[eCRF Audit Trail History](#)

Casebook Signature Form

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

Header Text: c4591001

Visit: Investigator Signature - Unscheduled

Form: CASEBOOK SIGNATURE FORM

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Verified

Site No: 1054

Site Name: (1054) Collaborative Neuroscience Network, LLC.

Subject No: 10541067

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 19-Apr-2021 21:04

[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: 30-Jul-2020 21:29

Site No: 1054

Subject No: 10541067

Generated By: (b) (4)

Form: INCLUSION/EXCLUSION CRITERIA - Comments

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1054) Collaborative Neuroscience Network, LLC.

Subject Initials: ---

Generated Time (GMT): 19-Apr-2021 21:04

[Back to Form](#)

Item	Date	User	Comment
Form	Aug-28-2020 10:27:07 (UTC-08:00) Pacific Time (US & Canada)	Steven Choi (b) (4)	Not Applicable

Header Text: c4591001

Visit: V101_VAX3

Form: INCLUSION/EXCLUSION CRITERIA - FURTHER
VACCINATION - Comments

Form Version: 10-Dec-2020 02:30

Form Status: Data Complete, Frozen, Verified

Site No: 1054

Site Name: (1054) Collaborative Neuroscience Network, LLC.

Subject No: 10541067

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 19-Apr-2021 21:04

[Back to Form](#)

Item	Date	User	Comment
Form	Feb-04-2021 09:34:03 (UTC-08:00) Pacific Time (US & Canada)	Steven Choi (b) (4)	Not Applicable

Header Text: c4591001

Visit: Investigator Signature - Unscheduled

Form: CASEBOOK SIGNATURE FORM - Signature History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Verified

Site No: 1054

Site Name: (1054) Collaborative Neuroscience Network, LLC.

Subject No: 10541067

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 19-Apr-2021 21:04

[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
Steven Choi	N/A	Feb-04-2021 09:30:31 (UTC-08:00) Pacific Time (US & Canada)		Edit - All signatures invalidated

Affidavit:

N/A

Mark Leibowitz	Approved	Oct-21-2020 09:12:22 (UTC-08:00) Pacific Time (US & Canada)	BOOK	Signed
----------------	----------	---	------	--------

Affidavit:

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

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

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

090177e196d89027\Final\Final On: 22-Apr-2021 02:13 (GMT)

Header Text: c4591001

Visit: COHORT_SELECTION

Form Version: 30-Jul-2020 21:29

Site No: 1054

Subject No: 10541067

Generated By: (b) (4)

Form: COHORT SELECTION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1054) Collaborative Neuroscience Network, LLC.

Subject Initials: ---

Generated Time (GMT): 19-Apr-2021 21:04

[Back to Form](#)

1. Select appropriate response - Protocol version

Date	Location	User	Value	Reason
Aug-28-2020 10:24:57 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: 24 JUL 2020	Initial Entry

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

Date	Location	User	Value	Reason
Aug-28-2020 10:24:57 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: STAGE 3 COHORTS	Initial Entry

Header Text: c4591001

Visit: COHORT_SELECTION

Form Version: 22-Apr-2020 21:02

Site No: 1054

Subject No: 10541067

Generated By: (b) (4)

Form: MAIN INFORMED CONSENT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1054) Collaborative Neuroscience Network, LLC.

Subject Initials: ---

Generated Time (GMT): 19-Apr-2021 21:04

[Back to Form](#)

I. Consent Was:

Date	Location	User	Value	Reason
Aug-28-2020 10:25:12 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: OBTAINED Date Written Consent Obtained Aug/28/2020	Initial Entry

Header Text: c4591001

Visit: COHORT_SELECTION

Form Version: 06-Jul-2020 21:55

Site No: 1054

Subject No: 10541067

Generated By: (b) (4)

Form: DEMOGRAPHY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1054) Collaborative Neuroscience Network, LLC.

Subject Initials: ---

Generated Time (GMT): 19-Apr-2021 21:04

[Back to Form](#)

1. Subject ID

Date	Location	User	Value	Reason
Aug-28-2020 10:24:41 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 10541067	Item copied from previous form

2. Birth Date:

Date	Location	User	Value	Reason
Aug-28-2020 10:24:06 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: (b) (6)/1984	Enrollment Entry

3. Sex:

Date	Location	User	Value	Reason
Aug-28-2020 10:25:27 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: FEMALE	Initial Entry

4. Ethnicity:

Date	Location	User	Value	Reason
Aug-28-2020 10:25:27 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: NOT HISPANIC OR LATINO(A) OR OF SPANISH ORIGIN	Initial Entry

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

Date	Location	User	Value	Reason
Aug-28-2020 10:25:27 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: WHITE	Initial Entry

090177e196d89027\Final\Final On: 22-Apr-2021 02:13 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:02

Site No: 1054

Subject No: 10541067

Generated By: (b) (4)

Form: DATE OF VISIT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1054) Collaborative Neuroscience Network, LLC.

Subject Initials: ---

Generated Time (GMT): 19-Apr-2021 21:04

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1. Date of Visit

Date	Location	User	Value	Reason
Aug-28-2020 10:26:08 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: Aug/28/2020	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1054

Subject No: 10541067

Generated By: (b) (4)

Form: DISPOSITION - SCREENING - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1054) Collaborative Neuroscience Network, LLC.

Subject Initials: ---

Generated Time (GMT): 19-Apr-2021 21:04

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1. Date of Completion/Discontinuation/Death

Date	Location	User	Value	Reason
Aug-28-2020 10:27:26 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: Aug/28/2020	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Aug-28-2020 10:27:26 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SCREENING	Initial Entry

3. Status:

Date	Location	User	Value	Reason
Aug-28-2020 10:27:26 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: COMPLETED	Initial Entry

090177e196d89027\Final\Final On: 22-Apr-2021 02:13 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1054

Subject No: 10541067

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1054) Collaborative Neuroscience Network, LLC.

Subject Initials: ---

Generated Time (GMT): 19-Apr-2021 21:04

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1.a

Date	Location	User	Value	Reason
Aug-28-2020 10:29:21 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: r: Medical History gallstones Term: Start Date: UNK/UNK/2017 Ongoing: NO End Date: UNK/UNK/ 2017	Initial Entry

1.a Line/MH Number:

Date	Location	User	Value	Reason
Aug-28-2020 10:29:21 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 1	Initial Entry

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

Date	Location	User	Value	Reason
Aug-28-2020 10:29:21 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: gallstones	Initial Entry

1.a Start Date:

Date	Location	User	Value	Reason
Aug-28-2020 10:29:21 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: UNK/UNK/2017	Initial Entry

1.a Ongoing:

Date	Location	User	Value	Reason
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090177e196d89027\Final\Final On: 22-Apr-2021 02:13 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1054

Subject No: 10541067

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1054) Collaborative Neuroscience Network, LLC.

Subject Initials: ---

Generated Time (GMT): 19-Apr-2021 21:04

Aug-28-2020 10:29:21 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: NO End Date: UNK/UNK/2017	Initial Entry
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I.b

Date	Location	User	Value	Reason
Aug-28-2020 10:30:31 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Numbe 2 r: Medical History cholecystectom Term: y Start Date: UNK/UNK/201 7 Ongoing: NO End Date: UNK/UNK/ 2017	Initial Entry

090177e196d89027\Final\Final On: 22-Apr-2021 02:13 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1054

Subject No: 10541067

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1054) Collaborative Neuroscience Network, LLC.

Subject Initials: ---

Generated Time (GMT): 19-Apr-2021 21:04

1.b Line/MH Number:

Date	Location	User	Value	Reason
Aug-28-2020 10:30:31 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 2	Initial Entry

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

Date	Location	User	Value	Reason
Aug-28-2020 10:30:31 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: cholecystectomy	Initial Entry

1.b Start Date:

Date	Location	User	Value	Reason
Aug-28-2020 10:30:31 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: UNK/UNK/2017	Initial Entry

1.b Ongoing:

Date	Location	User	Value	Reason
Aug-28-2020 10:30:31 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: NO End Date: UNK/UNK/2017	Initial Entry

1.c

Date	Location	User	Value	Reason
Aug-28-2020 10:31:48 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 3 Medical History Term: environmental allergies Start Date: UNK/UNK/2014 Ongoing: YES	Initial Entry

090177e196d89027\Final\Final On: 22-Apr-2021 02:13 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1054

Subject No: 10541067

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1054) Collaborative Neuroscience Network, LLC.

Subject Initials: ---

Generated Time (GMT): 19-Apr-2021 21:04

I.c Line/MH Number:

Date	Location	User	Value	Reason
Aug-28-2020 10:31:48 (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
Aug-28-2020 10:31:48 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: environmental allergies	Initial Entry

I.c Start Date:

Date	Location	User	Value	Reason
Aug-28-2020 10:31:48 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: UNK/UNK/2014	Initial Entry

I.c Ongoing:

Date	Location	User	Value	Reason
Aug-28-2020 10:31:48 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: YES	Initial Entry

I.d

Date	Location	User	Value	Reason
Aug-28-2020 10:32:13 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 4 Medical History Term: anxiety (intermittent) Start Date: UNK/UNK/2001 Ongoing: YES	Initial Entry

090177e196d89027\Final\Final On: 22-Apr-2021 02:13 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1054

Subject No: 10541067

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1054) Collaborative Neuroscience Network, LLC.

Subject Initials: ---

Generated Time (GMT): 19-Apr-2021 21:04

I.d Line/MH Number:

Date	Location	User	Value	Reason
Aug-28-2020 10:32:13 (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
Aug-28-2020 10:32:13 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: anxiety (intermittent)	Initial Entry

I.d Start Date:

Date	Location	User	Value	Reason
Aug-28-2020 10:32:13 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: UNK/UNK/2001	Initial Entry

I.d Ongoing:

Date	Location	User	Value	Reason
Aug-28-2020 10:32:13 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: YES	Initial Entry

I.e

Date	Location	User	Value	Reason
Aug-28-2020 10:32:42 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 5 Medical History Term: salpingectomy, bilateral Start Date: UNK/UNK/2018 Ongoing: NO End Date: UNK/UNK/2018	Initial Entry

090177e196d89027\Final\Final On: 22-Apr-2021 02:13 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1054

Subject No: 10541067

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1054) Collaborative Neuroscience Network, LLC.

Subject Initials: ---

Generated Time (GMT): 19-Apr-2021 21:04

I.e Line/MH Number:

Date	Location	User	Value	Reason
Aug-28-2020 10:32:42 (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
Aug-28-2020 10:32:42 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: salpingectomy, bilateral	Initial Entry

I.e Start Date:

Date	Location	User	Value	Reason
Aug-28-2020 10:32:42 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: UNK/UNK/2018	Initial Entry

I.e Ongoing:

Date	Location	User	Value	Reason
Aug-28-2020 10:32:42 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: NO End Date: UNK/UNK/2018	Initial Entry

I.f

Date	Location	User	Value	Reason
Aug-28-2020 10:33:02 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 6 Medical History asthma Term: Start Date: UNK/UNK/199 8	Initial Entry

090177e196d89027\Final\Final On: 22-Apr-2021 02:13 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1054

Subject No: 10541067

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1054) Collaborative Neuroscience Network, LLC.

Subject Initials: ---

Generated Time (GMT): 19-Apr-2021 21:04

			Ongoing:	NO	
				End Date:	
				UNK/UNK/2010	

1.f Line/MH Number:

Date	Location	User	Value	Reason
Aug-28-2020 10:33:02 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 6	Initial Entry

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

Date	Location	User	Value	Reason
Aug-28-2020 10:33:02 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: asthma	Initial Entry

1.f Start Date:

Date	Location	User	Value	Reason
Aug-28-2020 10:33:02 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: UNK/UNK/1998	Initial Entry

1.f Ongoing:

Date	Location	User	Value	Reason
Aug-28-2020 10:33:02 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: NO End Date: UNK/UNK/2010	Initial Entry

1.g

Date	Location	User	Value	Reason
Aug-28-2020 10:33:22 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number 7 :	Initial Entry

090177e196d89027\Final\Final On: 22-Apr-2021 02:13 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1054

Subject No: 10541067

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1054) Collaborative Neuroscience Network, LLC.

Subject Initials: ---

Generated Time (GMT): 19-Apr-2021 21:04

			Medical History Term: scar in abdomen Start Date: UNK/UNK/2018 Ongoing: YES	
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I.g Line/MH Number:

Date	Location	User	Value	Reason
Aug-28-2020 10:33:22 (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
Aug-28-2020 10:33:22 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: scar in abdomen	Initial Entry

I.g Start Date:

Date	Location	User	Value	Reason
Aug-28-2020 10:33:22 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: UNK/UNK/2018	Initial Entry

I.g Ongoing:

Date	Location	User	Value	Reason
Aug-28-2020 10:33:22 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: YES	Initial Entry

I.h

Date	Location	User	Value	Reason
Oct-16-2020 11:18:26 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number 8 Medical History Term: TMJ dysfunction	Initial Entry

090177e196d89027\Final\Final On: 22-Apr-2021 02:13 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1054

Subject No: 10541067

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1054) Collaborative Neuroscience Network, LLC.

Subject Initials: ---

Generated Time (GMT): 19-Apr-2021 21:04

			Start Date:	UNK/UNK/2018
			Ongoing:	YES

1.h Line/MH Number:

Date	Location	User	Value	Reason
Oct-16-2020 11:18:26 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 8	Initial Entry

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

Date	Location	User	Value	Reason
Oct-16-2020 11:18:26 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: TMJ dysfunction	Initial Entry

1.h Start Date:

Date	Location	User	Value	Reason
Oct-16-2020 11:18:26 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: UNK/UNK/2018	Initial Entry

1.h Ongoing:

Date	Location	User	Value	Reason
Oct-16-2020 11:18:26 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: YES	Initial Entry

090177e196d89027\Final\Final On: 22-Apr-2021 02:13 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 21-Aug-2020 02:51

Site No: 1054

Subject No: 10541067

Generated By: (b) (4)

Form: VITAL SIGNS - BASELINE - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1054) Collaborative Neuroscience Network, LLC.

Subject Initials: ---

Generated Time (GMT): 19-Apr-2021 21:04

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1. Date:

Date	Location	User	Value	Reason
Aug-28-2020 10:35:02 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: Aug/28/2020	Initial Entry

2. Weight:

Date	Location	User	Value	Reason
Aug-28-2020 10:35:02 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: 77.0	Initial Entry

3. Unit:

Date	Location	User	Value	Reason
Aug-28-2020 10:35:02 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: kg	Initial Entry

4. Height:

Date	Location	User	Value	Reason
Aug-28-2020 10:35:02 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: 159.0	Initial Entry

5. Unit:

Date	Location	User	Value	Reason
Aug-28-2020 10:35:02 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: cm	Initial Entry

6. Body Mass Index:

Date	Location	User	Value	Reason
Aug-28-2020 10:35:02 (UTC-08:00) Pacific	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 30.5	Initial Entry

090177e196d89027\Final\Final On: 22-Apr-2021 02:13 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 21-Aug-2020 02:51

Site No: 1054

Subject No: 10541067

Generated By: (b) (4)

Form: VITAL SIGNS - BASELINE - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1054) Collaborative Neuroscience Network, LLC.

Subject Initials: ---

Generated Time (GMT): 19-Apr-2021 21:04

Time (US & Canada)

7.a

Date	Location	User	Value	Reason
Aug-28-2020 10:35:02 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: Record Identifier: 1 : Temperature: 98.3 Temperature Unit: F Temperature Location: ORAL CAVITY	Initial Entry

7.a Record Identifier:

Date	Location	User	Value	Reason
Aug-28-2020 10:35:02 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: 1	Initial Entry

7.a Temperature:

Date	Location	User	Value	Reason
Aug-28-2020 10:35:02 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: 98.3	Initial Entry

7.a Unit:

Date	Location	User	Value	Reason
Aug-28-2020 10:35:02 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: F	Initial Entry

7.a Temperature Location:

Date	Location	User	Value	Reason
Aug-28-2020 10:35:02 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: ORAL CAVITY	Initial Entry

090177e196d89027\Final\Final On: 22-Apr-2021 02:13 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

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

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1054

Site Name: (1054) Collaborative Neuroscience Network, LLC.

Subject No: 10541067

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 19-Apr-2021 21:04

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1. Lab Panel:

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

3. Collection Date:

Date	Location	User	Value	Reason
Aug-28-2020 10:35:15 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: Aug/28/2020	Initial Entry

4. Laboratory Name and Address (Derived)

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

6.a

Date	Location	User	Value	Reason
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090177e196d89027\Final\Final On: 22-Apr-2021 02:13 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

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

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1054

Site Name: (1054) Collaborative Neuroscience Network, LLC.

Subject No: 10541067

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 19-Apr-2021 21:04

Aug-28-2020 10:35:15 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sponsor-Defined Identifier: 113 Test:: Choriogonadotropin Beta_PX113 Result:: NEGATIVE Not Done::	Initial Entry
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6.a Sponsor ID:

Date	Location	User	Value	Reason
Aug-28-2020 10:35:15 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 113	Initial Entry

6.a Test:

Date	Location	User	Value	Reason
Aug-28-2020 10:35:15 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: Choriogonadotropin Beta_PX113	Initial Entry

6.a Result:

Date	Location	User	Value	Reason
Aug-28-2020 10:35:15 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: NEGATIVE	Initial Entry

090177e196d89027\Final\Final On: 22-Apr-2021 02:13 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1054

Subject No: 10541067

Generated By: (b) (4)

Form: RANDOMIZATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1054) Collaborative Neuroscience Network, LLC.

Subject Initials: ---

Generated Time (GMT): 19-Apr-2021 21:04

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1. Randomization Date :

Date	Location	User	Value	Reason
Aug-28-2020 10:35:30 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: Aug/28/2020	Initial Entry

2. Randomization Number:

Date	Location	User	Value	Reason
Aug-28-2020 10:35:30 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: 71999	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, Locked, Frozen, Verified

Site No: 1054

Site Name: (1054) Collaborative Neuroscience Network, LLC.

Subject No: 10541067

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 19-Apr-2021 21:04

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1. Data Origin

Date	Location	User	Value	Reason
Aug-28-2020 10:36:07 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Aug-28-2020 10:36:07 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SERUM	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Aug-28-2020 18:46:42 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Aug-28-2020 10:36:07 (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.
Aug-28-2020 10:36:07 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: YES Date of Collection: Aug/28/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Aug-28-2020 18:46:42 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: Sample ID: BPYWS8	Initial Entry

090177e196d89027\Final\Final On: 22-Apr-2021 02:13 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1054

Site Name: (1054) Collaborative Neuroscience Network, LLC.

Subject No: 10541067

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 19-Apr-2021 21:04

5.a Sample ID

Date	Location	User	Value	Reason
Aug-28-2020 18:46:42 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: BPYWS8	Initial Entry

5.b

Date	Location	User	Value	Reason
Aug-28-2020 18:46:50 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: Sample ID: BPYWS9	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Aug-28-2020 18:46:50 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: BPYWS9	Initial Entry

5.c

Date	Location	User	Value	Reason
Aug-28-2020 18:47:04 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: Sample ID: BPYWSB	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Aug-28-2020 18:47:04 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: BPYWSB	Initial Entry

090177e196d89027\Final\Final On: 22-Apr-2021 02:13 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1054

Site Name: (1054) Collaborative Neuroscience Network, LLC.

Subject No: 10541067

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 19-Apr-2021 21:04

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1. Data Origin

Date	Location	User	Value	Reason
Aug-28-2020 10:36:23 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Aug-28-2020 10:36:23 (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
Aug-28-2020 18:47:46 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Aug-28-2020 10:36:23 (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.
Aug-28-2020 10:36:23 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: YES Date of Collection: Aug/28/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Aug-28-2020 18:47:46 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: Sample ID: BPYWSC	Initial Entry

090177e196d89027\Final\Final On: 22-Apr-2021 02:13 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1054

Site Name: (1054) Collaborative Neuroscience Network, LLC.

Subject No: 10541067

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 19-Apr-2021 21:04

5.a Sample ID

Date	Location	User	Value	Reason
Aug-28-2020 18:47:46 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: BPYWSC	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:04

Site No: 1054

Subject No: 10541067

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1054) Collaborative Neuroscience Network, LLC.

Subject Initials: ---

Generated Time (GMT): 19-Apr-2021 21:04

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1. Was there a temporary delay of vaccination?

Date	Location	User	Value	Reason
Aug-28-2020 10:36:47 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: NO	Initial Entry

2. Treatment Name

Date	Location	User	Value	Reason
Aug-28-2020 10:36:47 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: BLINDED THERAPY	Initial Entry

3. Formulation:

Date	Location	User	Value	Reason
Aug-28-2020 10:36:47 (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
Aug-28-2020 10:36:47 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: Aug/28/2020 09:02	Initial Entry

5. Anatomical Location:

Date	Location	User	Value	Reason
Aug-28-2020 10:36:47 (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
Aug-28-2020 10:36:47 (UTC-08:00) Pacific	ACV0PFEINFP6000	Steven Choi	Data Entry: RIGHT	Initial Entry

090177e196d89027\Final\Final On: 22-Apr-2021 02:13 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:04

Site No: 1054

Subject No: 10541067

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1054) Collaborative Neuroscience Network, LLC.

Subject Initials: ---

Generated Time (GMT): 19-Apr-2021 21:04

Time (US & Canada)	(b) (4)
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7. Route:

Date	Location	User	Value	Reason
Aug-28-2020 10:36:47 (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
Aug-28-2020 10:36:47 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: THE PROTOCOL SPECIFIED O BSERVATION PERIOD	Initial Entry

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

Date	Location	User	Value	Reason
Aug-28-2020 10:36:47 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: YES	Initial Entry

090177e196d89027\Final\Final On: 22-Apr-2021 02:13 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 06-Jul-2020 21:53

Site No: 1054

Subject No: 10541067

Generated By: (b) (4)

Form: REACTOGENICITY DIARY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1054) Collaborative Neuroscience Network, LLC.

Subject Initials: ---

Generated Time (GMT): 19-Apr-2021 21:04

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1. Select appropriate response - Reactogenicity diary collection

Date	Location	User	Value	Reason
Aug-28-2020 10:36:55 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: NO - REACTOGENICITY E-DI ARY NOT COLLECTED FOR T HIS SUBJECT	Initial Entry

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 1054

Subject No: 10541067

Generated By: (b) (4)

Form: DATE OF VISIT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1054) Collaborative Neuroscience Network, LLC.

Subject Initials: ---

Generated Time (GMT): 19-Apr-2021 21:04

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1. Date of Visit

Date	Location	User	Value	Reason
Sep-18-2020 09:16:27 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: Sep/18/2020	Initial Entry

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 15-Sep-2020 21:54

Site No: 1054

Subject No: 10541067

Generated By: (b) (4)

Form: VITAL SIGNS - TEMP - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1054) Collaborative Neuroscience Network, LLC.

Subject Initials: ---

Generated Time (GMT): 19-Apr-2021 21:04

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1. Date:

Date	Location	User	Value	Reason
Sep-18-2020 09:17:29 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: Sep/18/2020	Initial Entry

2.a

Date	Location	User	Value	Reason
Sep-18-2020 09:17:29 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: Record Identifier: 1 : Temperature: 98.4 Temperature Unit: F Temperature Location: ORAL CAVITY	Initial Entry

2.a Record Identifier:

Date	Location	User	Value	Reason
Sep-18-2020 09:17:29 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: 1	Initial Entry

2.a Temperature:

Date	Location	User	Value	Reason
Sep-18-2020 09:17:29 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: 98.4	Initial Entry

2.a Unit:

Date	Location	User	Value	Reason
Sep-18-2020 09:17:29 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: F	Initial Entry

090177e196d89027\Final\Final On: 22-Apr-2021 02:13 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 15-Sep-2020 21:54

Site No: 1054

Subject No: 10541067

Generated By: (b) (4)

Form: VITAL SIGNS - TEMP - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1054) Collaborative Neuroscience Network, LLC.

Subject Initials: ---

Generated Time (GMT): 19-Apr-2021 21:04

2.a Temperature Location:

Date	Location	User	Value	Reason
Sep-18-2020 09:17:29 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: ORAL CAVITY	Initial Entry

Header Text: c4591001

Visit: V2_VAX2_L

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

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1054

Site Name: (1054) Collaborative Neuroscience Network, LLC.

Subject No: 10541067

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 19-Apr-2021 21:04

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1. Lab Panel:

Date	Location	User	Value	Reason
Sep-18-2020 09:17:48 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: URINALYSIS	Initial Entry

2. Lab Sub-Panel:

Date	Location	User	Value	Reason
Sep-18-2020 09:17:48 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: PREGNANCY	Initial Entry

3. Collection Date:

Date	Location	User	Value	Reason
Sep-18-2020 09:17:48 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: Sep/18/2020	Initial Entry

4. Laboratory Name and Address (Derived)

Date	Location	User	Value	Reason
Sep-18-2020 09:17:48 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: STUDY SITE	Initial Entry

5. Specimen Type:

Date	Location	User	Value	Reason
Sep-18-2020 09:17:48 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: URINE	Initial Entry

6.a

Date	Location	User	Value	Reason
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090177e196d89027\Final\Final On: 22-Apr-2021 02:13 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

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

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1054

Site Name: (1054) Collaborative Neuroscience Network, LLC.

Subject No: 10541067

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 19-Apr-2021 21:04

Sep-18-2020 09:17:48 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sponsor-Defined Identifier: 113 Test:: Choriogonadotropin Beta_PX113 Result:: NEGATIVE Not Done::	Initial Entry
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6.a Sponsor ID:

Date	Location	User	Value	Reason
Sep-18-2020 09:17:48 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 113	Initial Entry

6.a Test:

Date	Location	User	Value	Reason
Sep-18-2020 09:17:48 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: Choriogonadotropin Beta_PX113	Initial Entry

6.a Result:

Date	Location	User	Value	Reason
Sep-18-2020 09:17:48 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: NEGATIVE	Initial Entry

090177e196d89027\Final\Final On: 22-Apr-2021 02:13 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1054

Site Name: (1054) Collaborative Neuroscience Network, LLC.

Subject No: 10541067

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 19-Apr-2021 21:04

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1. Data Origin

Date	Location	User	Value	Reason
Sep-18-2020 09:17:57 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Sep-18-2020 09:17:57 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: NASAL_SWAB	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Sep-18-2020 09:29:40 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Sep-18-2020 09:17:57 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Sep-18-2020 09:17:57 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: YES Date of Collection: Sep/18/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Sep-18-2020 09:29:40 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: Sample ID: BM98TP	Initial Entry

090177e196d89027\Final\Final On: 22-Apr-2021 02:13 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1054

Site Name: (1054) Collaborative Neuroscience Network, LLC.

Subject No: 10541067

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 19-Apr-2021 21:04

5.a Sample ID

Date	Location	User	Value	Reason
Sep-18-2020 09:29:40 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: BM98TP	Initial Entry

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1054

Subject No: 10541067

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1054) Collaborative Neuroscience Network, LLC.

Subject Initials: ---

Generated Time (GMT): 19-Apr-2021 21:04

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1. Was there a temporary delay of vaccination?

Date	Location	User	Value	Reason
Sep-18-2020 09:18:13 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: NO	Initial Entry

2. Treatment Name

Date	Location	User	Value	Reason
Sep-18-2020 09:18:13 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: BLINDED THERAPY	Initial Entry

3. Formulation:

Date	Location	User	Value	Reason
Sep-18-2020 09:18:13 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INJECTION	Initial Entry

4. Dose Date Time:

Date	Location	User	Value	Reason
Sep-21-2020 08:26:13 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: Sep/18/2020 08:33	Transcription Error
Sep-18-2020 09:18:13 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: Sep/18/2020 08:31	Initial Entry

5. Anatomical Location:

Date	Location	User	Value	Reason
Sep-18-2020 09:18:13 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: DELTOID MUSCLE	Initial Entry

6. Body Side:

090177e196d89027\Final\Final On: 22-Apr-2021 02:13 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1054

Subject No: 10541067

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1054) Collaborative Neuroscience Network, LLC.

Subject Initials: ---

Generated Time (GMT): 19-Apr-2021 21:04

Date	Location	User	Value	Reason
Sep-18-2020 09:18:13 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: RIGHT	Initial Entry

7. Route:

Date	Location	User	Value	Reason
Sep-18-2020 09:18:13 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INTRAMUSCULAR	Initial Entry

10. Timeframe Subject Was Observed

Date	Location	User	Value	Reason
Sep-18-2020 09:18:13 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: THE PROTOCOL SPECIFIED O BSERVATION PERIOD	Initial Entry

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

Date	Location	User	Value	Reason
Sep-18-2020 09:18:13 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: YES	Initial Entry

090177e196d89027\Final\Final On: 22-Apr-2021 02:13 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 1054

Subject No: 10541067

Generated By: (b) (4)

Form: DATE OF VISIT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1054) Collaborative Neuroscience Network, LLC.

Subject Initials: ---

Generated Time (GMT): 19-Apr-2021 21:04

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1. Date of Visit

Date	Location	User	Value	Reason
Oct-16-2020 10:13:51 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: Oct/16/2020	Initial Entry

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1054

Site Name: (1054) Collaborative Neuroscience Network, LLC.

Subject No: 10541067

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 19-Apr-2021 21:04

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1. Data Origin

Date	Location	User	Value	Reason
Oct-16-2020 10:13:57 (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-16-2020 10:13:57 (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-16-2020 14:04:06 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Oct-16-2020 10:13:57 (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-16-2020 10:13:57 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: YES Date of Collection: Oct/16/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Oct-16-2020 14:04:06 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: Sample ID: BPYX50	Initial Entry

090177e196d89027\Final\Final On: 22-Apr-2021 02:13 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1054

Site Name: (1054) Collaborative Neuroscience Network, LLC.

Subject No: 10541067

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 19-Apr-2021 21:04

5.a Sample ID

Date	Location	User	Value	Reason
Oct-16-2020 14:04:06 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: BPYX50	Initial Entry

5.b

Date	Location	User	Value	Reason
Oct-16-2020 14:04:16 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: Sample ID: BPYX51	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Oct-16-2020 14:04:16 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: BPYX51	Initial Entry

090177e196d89027\Final\Final On: 22-Apr-2021 02:13 (GMT)

Header Text: c4591001

Visit: End of Treatment - Unscheduled

Form Version: 15-Sep-2020 21:55

Site No: 1054

Subject No: 10541067

Generated By: (b) (4)

Form: DISPOSITION - TREATMENT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1054) Collaborative Neuroscience Network, LLC.

Subject Initials: ---

Generated Time (GMT): 19-Apr-2021 21:04

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1. Date of Completion/Discontinuation/Death :

Date	Location	User	Value	Reason
Oct-16-2020 10:15:46 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: Oct/16/2020	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Oct-16-2020 10:15:46 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: VACCINATION	Initial Entry

3. Status:

Date	Location	User	Value	Reason
Oct-16-2020 10:15:46 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: COMPLETED	Initial Entry

090177e196d89027\Final\Final On: 22-Apr-2021 02:13 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1054

Subject No: 10541067

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - Audit Trail

Form Status:

Site Name: (1054) Collaborative Neuroscience Network, LLC.

Subject Initials: ---

Generated Time (GMT): 19-Apr-2021 21:04

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Date	Location	User	Value	Reason
Sep-03-2020 11:02:13 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Form Created	

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1054

Subject No: 10541067

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - Audit Trail

Form Status:

Site Name: (1054) Collaborative Neuroscience Network, LLC.

Subject Initials: ---

Generated Time (GMT): 19-Apr-2021 21:04

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Date	Location	User	Value	Reason
Oct-16-2020 10:18:01 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Form Created	

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1054

Subject No: 10541067

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - Audit Trail

Form Status:

Site Name: (1054) Collaborative Neuroscience Network, LLC.

Subject Initials: ---

Generated Time (GMT): 19-Apr-2021 21:04

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Date	Location	User	Value	Reason
Oct-16-2020 10:18:48 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Form Created	

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1054

Subject No: 10541067

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - Audit Trail

Form Status:

Site Name: (1054) Collaborative Neuroscience Network, LLC.

Subject Initials: ---

Generated Time (GMT): 19-Apr-2021 21:04

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Date	Location	User	Value	Reason
Oct-16-2020 10:24:27 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Form Created	

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1054

Subject No: 10541067

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - Audit Trail

Form Status:

Site Name: (1054) Collaborative Neuroscience Network, LLC.

Subject Initials: ---

Generated Time (GMT): 19-Apr-2021 21:04

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Date	Location	User	Value	Reason
Oct-16-2020 10:25:39 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Form Created	

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1054

Subject No: 10541067

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - Audit Trail

Form Status:

Site Name: (1054) Collaborative Neuroscience Network, LLC.

Subject Initials: ---

Generated Time (GMT): 19-Apr-2021 21:04

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Date	Location	User	Value	Reason
Oct-16-2020 10:29:41 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Form Created	

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1054

Subject No: 10541067

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - Audit Trail

Form Status:

Site Name: (1054) Collaborative Neuroscience Network, LLC.

Subject Initials: ---

Generated Time (GMT): 19-Apr-2021 21:04

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Date	Location	User	Value	Reason
Mar-04-2021 12:02:46 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Form Created	

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1054

Subject No: 10541067

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen

Site Name: (1054) Collaborative Neuroscience Network, LLC.

Subject Initials: ---

Generated Time (GMT): 19-Apr-2021 21:04

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1. Category:

Date	Location	User	Value	Reason
Sep-03-2020 11:02:13 (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
Sep-03-2020 11:02:13 (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
Sep-03-2020 11:02:13 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: Headache	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason
Sep-03-2020 11:02:13 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: Aug/28/2020 17:30	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Sep-03-2020 11:02:13 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: NO End Date Time: Aug/29/2020 15:00	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
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090177e196d89027\Final\Final On: 22-Apr-2021 02:13 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1054

Subject No: 10541067

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen

Site Name: (1054) Collaborative Neuroscience Network, LLC.

Subject Initials: ---

Generated Time (GMT): 19-Apr-2021 21:04

Sep-03-2020 11:02:13 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: 2	Initial Entry
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7. Is the adverse event serious?

If Yes, NOTIFY PFIZER IMMEDIATELY.

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

Date	Location	User	Value	Reason
Sep-03-2020 11:02:13 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: NO	Initial Entry

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

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

Date	Location	User	Value	Reason
Sep-03-2020 11:02:13 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: NO	Initial Entry

9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Sep-03-2020 11:02:13 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: RELATED	Initial Entry

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Sep-03-2020 11:02:13 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: NOT APPLICABLE	Initial Entry

11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
Sep-03-2020 12:45:52	ACV0PFEINFP6000	Steven	Data Entry:	Transcription Error

090177e196d89027\Final\Final On: 22-Apr-2021 02:13 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

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Site No: 1054

Subject No: 10541067

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen

Site Name: (1054) Collaborative Neuroscience Network, LLC.

Subject Initials: ---

Generated Time (GMT): 19-Apr-2021 21:04

(UTC-08:00) Pacific Time (US & Canada)		Choi (b) (4)	YES	
Sep-03-2020 11:02:13 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: NO	Initial Entry

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Sep-03-2020 11:02:13 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: YES	Initial Entry

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

Date	Location	User	Value	Reason
Sep-03-2020 11:02:13 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: RECOVERED/RESOLVED	Initial Entry

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

Date	Location	User	Value	Reason
Sep-03-2020 11:02:13 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: NO	Initial Entry

090177e196d89027\Final\Final On: 22-Apr-2021 02:13 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1054

Subject No: 10541067

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen

Site Name: (1054) Collaborative Neuroscience Network, LLC.

Subject Initials: ---

Generated Time (GMT): 19-Apr-2021 21:04

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1. Category:

Date	Location	User	Value	Reason
Oct-16-2020 10:18:01 (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
Oct-16-2020 10:18:01 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 2	Initial Entry

3. Adverse Event:

(If possible specify diagnosis, not individual symptoms)

Date	Location	User	Value	Reason
Oct-16-2020 10:18:01 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: vertigo	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason
Oct-16-2020 10:18:01 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: Sep/20/2020 UNK:UNK	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Oct-16-2020 10:18:01 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: NO End Date Time: Sep/22/2020 UNK:UNK	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
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090177e196d89027\Final\Final On: 22-Apr-2021 02:13 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1054

Subject No: 10541067

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen

Site Name: (1054) Collaborative Neuroscience Network, LLC.

Subject Initials: ---

Generated Time (GMT): 19-Apr-2021 21:04

Oct-16-2020 10:18:01 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: 1	Initial Entry
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7. Is the adverse event serious?

If Yes, NOTIFY PFIZER IMMEDIATELY.

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

Date	Location	User	Value	Reason
Oct-16-2020 10:18:01 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: NO	Initial Entry

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

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

Date	Location	User	Value	Reason
Oct-16-2020 10:18:01 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: NO	Initial Entry

9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Oct-16-2020 10:18:01 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: NOT RELATED If Not Related to study treatment (s), this event is due to: OTHER If Other, specify: unknown, possible allergy	Initial Entry

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Oct-16-2020 10:18:01 (UTC-08:00) Pacific	ACV0PFEINFP6000	Steven Choi	Data Entry: NOT APPLICABLE	Initial Entry

090177e196d89027\Final\Final On: 22-Apr-2021 02:13 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

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Site No: 1054

Subject No: 10541067

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen

Site Name: (1054) Collaborative Neuroscience Network, LLC.

Subject Initials: ---

Generated Time (GMT): 19-Apr-2021 21:04

Time (US & Canada)		(b) (4)	
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11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
Oct-16-2020 10:18:01 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: NO	Initial Entry

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Oct-16-2020 10:18:01 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: NO	Initial Entry

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

Date	Location	User	Value	Reason
Oct-16-2020 10:18:01 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: RECOVERED/RESOLVED	Initial Entry

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

Date	Location	User	Value	Reason
Oct-16-2020 10:18:01 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: NO	Initial Entry

090177e196d89027\Final\Final On: 22-Apr-2021 02:13 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

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Site No: 1054

Subject No: 10541067

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Frozen

Site Name: (1054) Collaborative Neuroscience Network, LLC.

Subject Initials: ---

Generated Time (GMT): 19-Apr-2021 21:04

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1. Category:

Date	Location	User	Value	Reason
Oct-16-2020 10:18:48 (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
Oct-16-2020 10:18:48 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 3	Initial Entry

3. Adverse Event:

(If possible specify diagnosis, not individual symptoms)

Date	Location	User	Value	Reason
Oct-16-2020 10:18:48 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: fluid R ear	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason
Oct-16-2020 10:18:48 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: Sep/22/2020 UNK:UNK	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Mar-05-2021 01:34:38 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Mar-04-2021 11:49:56 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Changed Information
Mar-04-2021 11:49:56	ACV0PFEINFP6000	Steven Choi	Data Entry:	Changed

090177e196d89027\Final\Final On: 22-Apr-2021 02:13 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1054

Subject No: 10541067

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Frozen

Site Name: (1054) Collaborative Neuroscience Network, LLC.

Subject Initials: ---

Generated Time (GMT): 19-Apr-2021 21:04

(UTC-08:00) Pacific Time (US & Canada)		(b) (4)	NO End Date Time: Feb/13/2021 UNK:UNK	Information
Mar-03-2021 10:03:56 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	GPD CLINQUERY: Please confirm if AE is ongoing and without change to severity.
Oct-16-2020 10:18:48 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: YES	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
Oct-16-2020 10:18:48 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: 1	Initial Entry

7. Is the adverse event serious?

If Yes, NOTIFY PFIZER IMMEDIATELY.

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

Date	Location	User	Value	Reason
Oct-16-2020 10:18:48 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: NO	Initial Entry

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

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

Date	Location	User	Value	Reason
Oct-16-2020 10:18:48 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: NO	Initial Entry

9. Is this event related to study treatment:

090177e196d89027\Final\Final On: 22-Apr-2021 02:13 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1054

Subject No: 10541067

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Frozen

Site Name: (1054) Collaborative Neuroscience Network, LLC.

Subject Initials: ---

Generated Time (GMT): 19-Apr-2021 21:04

Date	Location	User	Value	Reason
Oct-16-2020 10:18:48 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: NOT RELATED If Not Related to study treatment (s), this event is due to: OTHER <i>If Other, specify:</i> unknown, possible allergy	Initial Entry

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Oct-16-2020 10:18:48 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: NOT APPLICABLE	Initial Entry

11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
Oct-16-2020 10:18:48 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: YES	Initial Entry

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Oct-16-2020 10:18:48 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: NO	Initial Entry

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

Date	Location	User	Value	Reason
Mar-04-2021 11:55:55 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Mar-04-2021 11:55:55 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: RECOVERED/RESOLVED	Changed Information

090177e196d89027\Final\Final On: 22-Apr-2021 02:13 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen

Site No: 1054

Site Name: (1054) Collaborative Neuroscience Network, LLC.

Subject No: 10541067

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 19-Apr-2021 21:04

Mar-04-2021 11:49:56 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	For AE fluid R ear: Response to "What was the outcome of this adverse event?" is 'Recovering/Resolving' but AE End Date/Time is present.
Oct-16-2020 10:18:48 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: RECOVERING/RESOLVING	Initial Entry

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

Date	Location	User	Value	Reason
Oct-16-2020 10:18:48 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: NO	Initial Entry

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Subject No: 10541067

Generated By: (b) (4)

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Form Status: Data Complete

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Subject Initials: ---

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1. Category:

Date	Location	User	Value	Reason
Oct-16-2020 10:24:27 (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
Oct-16-2020 10:24:27 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 4	Initial Entry

3. Adverse Event:

(If possible specify diagnosis, not individual symptoms)

Date	Location	User	Value	Reason
Oct-16-2020 10:24:27 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: decreased hearing R ear	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason
Oct-16-2020 10:24:27 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: Sep/20/2020 UNK:UNK	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Mar-05-2021 01:37:59 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Closed	Response satisfies query
Mar-04-2021 11:57:26 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Query 2: Answered	Per phone call on 04Mar21, this AE is still recovering / resolving.

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Header Text: c4591001

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Site No: 1054

Subject No: 10541067

Generated By: (b) (4)

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Mar-03-2021 09:59:43 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Opened	GPD CLINQUERY: Please confirm if AE is still ongoing and without change to severity or identification of cause.
Nov-11-2020 14:56:17 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Nov-11-2020 14:23:19 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Query 1: Answered	AE Lines 3-5 are still ongoing; pt plans on seeing an ear specialist within the next month or so, as soon as their new insurance kicks in.
Nov-09-2020 14:33:40 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	CLINQUERY: Grade 2 DECREASED HEARING and TINNITUS of RIGHT EAR are both reported as ONGOING since 20SEP2020. Please clarify if these AEs remain ONGOING. If RESOLVED, please provide STOP DATES and update OUTCOMES accordingly.
Oct-16-2020 10:24:27 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: YES	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
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Header Text: c4591001

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Oct-16-2020 10:24:27 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: 2	Initial Entry
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7. Is the adverse event serious?

If Yes, NOTIFY PFIZER IMMEDIATELY.

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

Date	Location	User	Value	Reason
Oct-16-2020 10:24:27 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: NO	Initial Entry

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

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

Date	Location	User	Value	Reason
Oct-16-2020 10:24:27 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: NO	Initial Entry

9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Oct-16-2020 10:24:27 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: NOT RELATED If Not Related to study treatment (s), this event is due to: OTHER If Other, specify: unknown, possible allergy	Initial Entry

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Oct-16-2020 10:24:27 (UTC-08:00) Pacific	ACV0PFEINFP6000	Steven Choi	Data Entry: NOT APPLICABLE	Initial Entry

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Header Text: c4591001

Visit: Logs - Unscheduled

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Site No: 1054

Subject No: 10541067

Generated By: (b) (4)

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Time (US & Canada)

(b) (4)

11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
Oct-16-2020 10:24:27 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: YES	Initial Entry

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Oct-16-2020 10:24:27 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: NO	Initial Entry

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

Date	Location	User	Value	Reason
Oct-16-2020 10:24:27 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: RECOVERING/RESOLVING	Initial Entry

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

Date	Location	User	Value	Reason
Oct-16-2020 10:24:27 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: NO	Initial Entry

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Generated By: (b) (4)

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1. Category:

Date	Location	User	Value	Reason
Oct-16-2020 10:25:39 (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
Oct-16-2020 10:25:39 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 5	Initial Entry

3. Adverse Event:

(If possible specify diagnosis, not individual symptoms)

Date	Location	User	Value	Reason
Oct-16-2020 10:31:21 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: Tinnitus R ear	Transcription Error
Oct-16-2020 10:25:39 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: decreased hearing R ear	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason
Oct-16-2020 10:25:39 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: Sep/20/2020 UNK:UNK	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Mar-05-2021 01:39:00 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Mar-04-2021 11:58:16	ACV0PFEINFP6000	Steven Choi	Query 1: Answered	Per phone call on

090177e196d89027\Final\Final On: 22-Apr-2021 02:13 (GMT)

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(UTC-08:00) Pacific Time (US & Canada)		(b) (4)		04Mar21, this AE is still ongoing w/o change in severity.
Mar-03-2021 09:55:34 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	GPD CLINQUERY: Please confirm if AE is still ongoing and without change in severity.
Oct-16-2020 10:25:39 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: YES	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
Oct-16-2020 10:25:39 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	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
Oct-16-2020 10:25:39 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: NO	Initial Entry

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

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

Date	Location	User	Value	Reason
Oct-16-2020 10:25:39 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: NO	Initial Entry

9. Is this event related to study treatment:

Date	Location	User	Value	Reason
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Oct-16-2020 10:25:39 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: NOT RELATED If Not Related to study treatment (s), this event is due to: OTHER <i>If Other, specify:</i> unknown, possible allergy	Initial Entry
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10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Oct-16-2020 10:25:39 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: NOT APPLICABLE	Initial Entry

11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
Oct-16-2020 10:25:39 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: YES	Initial Entry

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Oct-16-2020 10:25:39 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: NO	Initial Entry

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

Date	Location	User	Value	Reason
Oct-16-2020 10:31:45 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: NOT RECOVERED/NOT RESOLVED	Transcription Error
Oct-16-2020 10:25:39 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: RECOVERING/RESOLVING	Initial Entry

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

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Generated Time (GMT): 19-Apr-2021 21:04

Date	Location	User	Value	Reason
Oct-16-2020 10:25:39 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: NO	Initial Entry

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Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen

Site Name: (1054) Collaborative Neuroscience Network, LLC.

Subject Initials: ---

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1. Category:

Date	Location	User	Value	Reason
Oct-16-2020 10:29:41 (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
Oct-16-2020 10:29:41 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 6	Initial Entry

3. Adverse Event:

(If possible specify diagnosis, not individual symptoms)

Date	Location	User	Value	Reason
Oct-16-2020 10:31:58 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: headache	Transcription Error
Oct-16-2020 10:29:41 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: tinnitus R ear	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason
Oct-16-2020 10:33:02 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: Sep/18/2020 18:00	Transcription Error
Oct-16-2020 10:29:41 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: Sep/20/2020 UNK:UNK	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Oct-16-2020 10:33:40	ACV0PFEINFP6000	Steven	Data Entry:	Transcription Error

090177e196d89027\Final\Final On: 22-Apr-2021 02:13 (GMT)

Header Text: c4591001

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Generated By: (b) (4)

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(UTC-08:00) Pacific Time (US & Canada)		Choi (b) (4)	NO End Date Time: Sep/19/2020 10:00	
Oct-16-2020 10:29:41 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: YES	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
Oct-16-2020 10:29:41 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	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
Oct-16-2020 10:29:41 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: NO	Initial Entry

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

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

Date	Location	User	Value	Reason
Oct-16-2020 10:29:41 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: NO	Initial Entry

9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Oct-16-2020 10:33:57 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: RELATED	Transcription Error

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Oct-16-2020 10:29:41 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: NOT RELATED If Not Related to study treatment(s), this event is due to: OTHER If Other, specify: unknown, possible allergy	Initial Entry
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10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Oct-16-2020 10:29:41 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: NOT APPLICABLE	Initial Entry

11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
Oct-16-2020 10:29:41 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: YES	Initial Entry

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Oct-16-2020 10:29:41 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: NO	Initial Entry

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

Date	Location	User	Value	Reason
Oct-16-2020 10:34:39 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Oct-16-2020 10:34:39 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: RECOVERED/RESOLVED	Transcription Error
Oct-16-2020 10:33:40	ACV0PFEINFP6000	auto query	Query 1: Opened	For AE headache:

090177e196d89027\Final\Final On: 22-Apr-2021 02:13 (GMT)

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(UTC-08:00) Pacific Time (US & Canada)		(autoquery)		Response to "What was the outcome of this adverse event?" is 'Recovering/Resolving' but AE End Date/Time is present.
Oct-16-2020 10:29:41 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: RECOVERING/RESOLVING	Initial Entry

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

Date	Location	User	Value	Reason
Oct-16-2020 10:29:41 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: NO	Initial Entry

090177e196d89027\Final\Final On: 22-Apr-2021 02:13 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

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Site Name: (1054) Collaborative Neuroscience Network, LLC.

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Generated By: (b) (4)

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1. Category:

Date	Location	User	Value	Reason
Mar-04-2021 12:02:46 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: ADVERSE EVENT	Initial Entry

2. AE ID:

Date	Location	User	Value	Reason
Mar-04-2021 12:02:46 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 7	Initial Entry

3. Adverse Event:

(If possible specify diagnosis, not individual symptoms)

Date	Location	User	Value	Reason
Mar-05-2021 10:14:04 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	PFETMS Oracle (b) (4)	Query 1: Clo sed	Discrepancy has been closed.
Mar-05-2021 08:25:21 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: An swere d	Changed Information
Mar-05-2021 08:25:21 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry : worse ning R TM J dysf unctio n	Changed Information

090177e196d89027\Final\Final On: 22-Apr-2021 02:13 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1054

Subject No: 10541067

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete

Site Name: (1054) Collaborative Neuroscience Network, LLC.

Subject Initials: ---

Generated Time (GMT): 19-Apr-2021 21:04

Mar-05-2021 00:45:35 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	PFETMS Oracle (b) (4)	Query 1: Op ened	Clarify WORSENING R TMJ as follows...The term appears incomplete. Are you reporting WORSENING R TMJ SYNDROME? OSTEOARTHRITIS? DISLOCATION? If so, update the verbatim term as such. Otherwise please specify the corresponding symptom or diagnosis being reported for TEMPOROMANDIBULAR JOINT and update the verbatim term accordingly. Thank you.
Mar-04-2021 12:02:46 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry : worse ning R TM J	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason
Mar-04-2021 12:02:46 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: Feb/12/2021 UNK:UNK	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Mar-04-2021 12:02:46 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: YES	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
Mar-04-2021 12:02:46 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: 1	Initial Entry

090177e196d89027\Final\Final On: 22-Apr-2021 02:13 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1054

Subject No: 10541067

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete

Site Name: (1054) Collaborative Neuroscience Network, LLC.

Subject Initials: ---

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7. Is the adverse event serious?

If Yes, NOTIFY PFIZER IMMEDIATELY.

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

Date	Location	User	Value	Reason
Mar-04-2021 12:02:46 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: NO	Initial Entry

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

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

Date	Location	User	Value	Reason
Mar-04-2021 12:02:46 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: NO	Initial Entry

9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Mar-04-2021 12:02:46 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: NOT RELATED If Not Related to study treatment (s), this event is due to: OTHER If Other, specify: TMJ 2/2 increased stress, has a h/o TMJ dysfunction	Initial Entry

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Mar-04-2021 12:02:46 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: NOT APPLICABLE	Initial Entry

11. Was a Concomitant Medication given?

090177e196d89027\Final\Final On: 22-Apr-2021 02:13 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1054

Subject No: 10541067

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete

Site Name: (1054) Collaborative Neuroscience Network, LLC.

Subject Initials: ---

Generated Time (GMT): 19-Apr-2021 21:04

Date	Location	User	Value	Reason
Mar-04-2021 12:02:46 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: NO	Initial Entry

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Mar-04-2021 12:02:46 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: NO	Initial Entry

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

Date	Location	User	Value	Reason
Mar-04-2021 12:02:46 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: RECOVERING/RESOLVING	Initial Entry

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

Date	Location	User	Value	Reason
Mar-04-2021 12:02:46 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: NO	Initial Entry

090177e196d89027\Final\Final On: 22-Apr-2021 02:13 (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: 1054

Site Name: (1054) Collaborative Neuroscience Network, LLC.

Subject No: 10541067

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 19-Apr-2021 21:04

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1. Date of Visit

Date	Location	User	Value	Reason
Feb-04-2021 09:30:31 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: Feb/2/2021	Initial Entry

Header Text: c4591001

Visit: Potential ReVax Initial Contact -
Unscheduled

Form Version: 10-Dec-2020 02:25

Site No: 1054

Subject No: 10541067

Generated By: (b) (4)

Form: FURTHER VACCINATION CONFIRMATION - eCRF Audit
Trail History

Form Status: Data Complete, Frozen

Site Name: (1054) Collaborative Neuroscience Network, LLC.

Subject Initials: ---

Generated Time (GMT): 19-Apr-2021 21:04

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

Date	Location	User	Value	Reason
Feb-04-2021 12:16:53 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Feb-04-2021 11:00:58 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	The response indicates participant was unblinded, however the TREATMENT UNBLINDED date is missing in the DISP visit. Please complete this date.
Feb-04-2021 09:30:48 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	The response indicates participant was unblinded, however the TREATMENT UNBLINDED date is missing in the DISP visit. Please complete this date.
Feb-04-2021 09:30:48 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	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

090177e196d89027\Final\Final On: 22-Apr-2021 02:13 (GMT)

Header Text: c4591001

Visit: Disposition - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1054

Subject No: 10541067

Generated By: (b) (4)

Form: TREATMENT UNBLINDED - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1054) Collaborative Neuroscience Network, LLC.

Subject Initials: ---

Generated Time (GMT): 19-Apr-2021 21:04

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1. Date Treatment Unblinded :

Date	Location	User	Value	Reason
Feb-04-2021 12:16:53 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: Feb/2/2021	Initial Entry

2. Primary Reason for Unblinding:

Date	Location	User	Value	Reason
Feb-04-2021 12:16:53 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: ASSESS ELIGIBILITY FOR AD DITIONAL VACCINATION	Initial Entry

Header Text: c4591001

Visit: V101_VAX3

Form Version: 22-Apr-2020 21:02

Site No: 1054

Subject No: 10541067

Generated By: (b) (4)

Form: DATE OF VISIT - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1054) Collaborative Neuroscience Network, LLC.

Subject Initials: ---

Generated Time (GMT): 19-Apr-2021 21:04

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1. Date of Visit

Date	Location	User	Value	Reason
Feb-04-2021 09:31:29 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: Feb/3/2021	Initial Entry

Header Text: c4591001

Visit: V101_VAX3

Form Version: 10-Dec-2020 02:31

Site No: 1054

Subject No: 10541067

Generated By: (b) (4)

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

Form Status: Data Complete, Frozen, Verified

Site Name: (1054) Collaborative Neuroscience Network, LLC.

Subject Initials: ---

Generated Time (GMT): 19-Apr-2021 21:04

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I. Consent Was:

Date	Location	User	Value	Reason
Feb-04-2021 09:32:30 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: OBTAINED Date Written Consent Obtained Feb/3/2021	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: 1054

Site Name: (1054) Collaborative Neuroscience Network, LLC.

Subject No: 10541067

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 19-Apr-2021 21:04

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1. Date of Completion/Discontinuation/Death :

Date	Location	User	Value	Reason
Feb-04-2021 09:34:17 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: Feb/3/2021	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Feb-04-2021 09:34:17 (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-04-2021 09:34:17 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: COMPLETED	Initial Entry

090177e196d89027\Final\Final On: 22-Apr-2021 02:13 (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: 1054

Site Name: (1054) Collaborative Neuroscience Network, LLC.

Subject No: 10541067

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 19-Apr-2021 21:04

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1. Lab Panel:

Date	Location	User	Value	Reason
Feb-04-2021 09:34:36 (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-04-2021 09:34:36 (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-04-2021 09:34:36 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: Feb/3/2021	Initial Entry

4. Laboratory Name and Address (Derived)

Date	Location	User	Value	Reason
Feb-04-2021 09:34:36 (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-04-2021 09:34:36 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: URINE	Initial Entry

6.a

Date	Location	User	Value	Reason
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090177e196d89027\Final\Final On: 22-Apr-2021 02:13 (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: 1054

Site Name: (1054) Collaborative Neuroscience Network, LLC.

Subject No: 10541067

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 19-Apr-2021 21:04

Feb-04-2021 09:34:36 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sponsor-Defined Identifier: 113 Test:: Choriogonadotropin Beta_PX113 Result:: NEGATIVE Not Done::	Initial Entry
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6.a Sponsor ID:

Date	Location	User	Value	Reason
Feb-04-2021 09:34:36 (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-04-2021 09:34:36 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: Choriogonadotropin Beta_PX113	Initial Entry

6.a Result:

Date	Location	User	Value	Reason
Feb-04-2021 09:34:36 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: NEGATIVE	Initial Entry

090177e196d89027\Final\Final On: 22-Apr-2021 02:13 (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: 1054

Site Name: (1054) Collaborative Neuroscience Network, LLC.

Subject No: 10541067

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 19-Apr-2021 21:04

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1. Data Origin

Date	Location	User	Value	Reason
Feb-04-2021 09:34:45 (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-04-2021 09:34:45 (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-04-2021 09:37:03 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Feb-04-2021 09:34:45 (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-04-2021 09:34:45 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: YES Date of Collection: Feb/3/2021	Initial Entry

5.a

Date	Location	User	Value	Reason
Feb-04-2021 09:37:03 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: Sample ID: BR54YF	Initial Entry

090177e196d89027\Final\Final On: 22-Apr-2021 02:13 (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: 1054

Site Name: (1054) Collaborative Neuroscience Network, LLC.

Subject No: 10541067

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 19-Apr-2021 21:04

5.a Sample ID

Date	Location	User	Value	Reason
Feb-04-2021 09:37:03 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: BR54YF	Initial Entry

5.b

Date	Location	User	Value	Reason
Feb-04-2021 09:37:12 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: Sample ID: BR54YG	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Feb-04-2021 09:37:12 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: BR54YG	Initial Entry

5.c

Date	Location	User	Value	Reason
Feb-04-2021 09:37:22 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: Sample ID: BR54YH	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Feb-04-2021 09:37:22 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: BR54YH	Initial Entry

090177e196d89027\Final\Final On: 22-Apr-2021 02:13 (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: 1054

Site Name: (1054) Collaborative Neuroscience Network, LLC.

Subject No: 10541067

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 19-Apr-2021 21:04

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1. Data Origin

Date	Location	User	Value	Reason
Feb-04-2021 09:35:09 (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-04-2021 09:35:09 (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-04-2021 09:37:38 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Feb-04-2021 09:35:09 (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-04-2021 09:35:09 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: YES Date of Collection: Feb/3/2021	Initial Entry

5.a

Date	Location	User	Value	Reason
Feb-04-2021 09:37:38 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: Sample ID: BR54YJ	Initial Entry

090177e196d89027\Final\Final On: 22-Apr-2021 02:13 (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: 1054

Site Name: (1054) Collaborative Neuroscience Network, LLC.

Subject No: 10541067

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 19-Apr-2021 21:04

5.a Sample ID

Date	Location	User	Value	Reason
Feb-04-2021 09:37:38 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: BR54YJ	Initial Entry

Header Text: c4591001

Visit: V101_VAX3

Form Version: 10-Dec-2020 02:26

Site No: 1054

Subject No: 10541067

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1054) Collaborative Neuroscience Network, LLC.

Subject Initials: ---

Generated Time (GMT): 19-Apr-2021 21:04

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1. Was there a temporary delay of vaccination?

Date	Location	User	Value	Reason
Feb-04-2021 09:35:40 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: NO	Initial Entry

2. Treatment Name

Date	Location	User	Value	Reason
Feb-04-2021 09:35:40 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: BNT162b2	Initial Entry

3. Formulation:

Date	Location	User	Value	Reason
Feb-04-2021 09:35:40 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INJECTION	Initial Entry

4. Dose Date Time:

Date	Location	User	Value	Reason
Feb-04-2021 09:35:40 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: Feb/3/2021 09:50	Initial Entry

5. Anatomical Location:

Date	Location	User	Value	Reason
Feb-04-2021 09:35:40 (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
Feb-04-2021 09:35:40 (UTC-08:00) Pacific	ACV0PFEINFP6000	Steven Choi	Data Entry: RIGHT	Initial Entry

090177e196d89027\Final\Final On: 22-Apr-2021 02:13 (GMT)

Header Text: c4591001

Visit: V101_VAX3

Form Version: 10-Dec-2020 02:26

Site No: 1054

Subject No: 10541067

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1054) Collaborative Neuroscience Network, LLC.

Subject Initials: ---

Generated Time (GMT): 19-Apr-2021 21:04

Time (US & Canada)

(b) (4)

7. Route:

Date	Location	User	Value	Reason
Feb-04-2021 09:35:40 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> INTRAMUSCULAR	Initial Entry

8. Actual Dose:

Date	Location	User	Value	Reason
Feb-04-2021 09:35:40 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> 30.0	Initial Entry

9. Unit:

Date	Location	User	Value	Reason
Feb-04-2021 09:35:40 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> ug	Initial Entry

10. Timeframe Subject Was Observed

Date	Location	User	Value	Reason
Feb-04-2021 09:35:40 (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
Feb-04-2021 09:35:40 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	<u>Data Entry:</u> YES	Initial Entry

090177e196d89027\Final\Final On: 22-Apr-2021 02:13 (GMT)

Header Text: c4591001

Visit: V102_VAX4

Form Version: 22-Apr-2020 21:02

Site No: 1054

Subject No: 10541067

Generated By: (b) (4)

Form: DATE OF VISIT - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1054) Collaborative Neuroscience Network, LLC.

Subject Initials: ---

Generated Time (GMT): 19-Apr-2021 21:04

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1. Date of Visit

Date	Location	User	Value	Reason
Feb-26-2021 12:23:43 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: Feb/26/2021	Initial Entry

Header Text: c4591001

Visit: V102_VAX4

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

Form Version: 14-Jan-2021 02:21

Form Status: Data Complete, Frozen, Verified

Site No: 1054

Site Name: (1054) Collaborative Neuroscience Network, LLC.

Subject No: 10541067

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 19-Apr-2021 21:04

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1. Lab Panel:

Date	Location	User	Value	Reason
Feb-26-2021 12:23:57 (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-26-2021 12:23:57 (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-26-2021 12:23:57 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: Feb/26/2021	Initial Entry

4. Laboratory Name and Address (Derived)

Date	Location	User	Value	Reason
Feb-26-2021 12:23:57 (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-26-2021 12:23:57 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: URINE	Initial Entry

6.a

Date	Location	User	Value	Reason
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090177e196d89027\Final\Final On: 22-Apr-2021 02:13 (GMT)

Header Text: c4591001

Visit: V102_VAX4

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

Form Version: 14-Jan-2021 02:21

Form Status: Data Complete, Frozen, Verified

Site No: 1054

Site Name: (1054) Collaborative Neuroscience Network, LLC.

Subject No: 10541067

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 19-Apr-2021 21:04

Feb-26-2021 12:23:57 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sponsor-Defined Identifier: 113 Test:: Choriogonadotropin Beta_PX113 Result:: NEGATIVE Not Done::	Initial Entry
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6.a Sponsor ID:

Date	Location	User	Value	Reason
Feb-26-2021 12:23:57 (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-26-2021 12:23:57 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: Choriogonadotropin Beta_PX113	Initial Entry

6.a Result:

Date	Location	User	Value	Reason
Feb-26-2021 12:23:57 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: NEGATIVE	Initial Entry

090177e196d89027\Final\Final On: 22-Apr-2021 02:13 (GMT)

Header Text: c4591001

Visit: V102_VAX4

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1054

Site Name: (1054) Collaborative Neuroscience Network, LLC.

Subject No: 10541067

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 19-Apr-2021 21:04

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1. Data Origin

Date	Location	User	Value	Reason
Feb-26-2021 12:24:28 (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-26-2021 12:24:28 (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 16:16:16 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Feb-26-2021 12:24:28 (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-26-2021 12:24:28 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: YES Date of Collection: Feb/26/2021	Initial Entry

5.a

Date	Location	User	Value	Reason
Feb-26-2021 16:16:16 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: Sample ID: BRMTLT	Initial Entry

090177e196d89027\Final\Final On: 22-Apr-2021 02:13 (GMT)

Header Text: c4591001

Visit: V102_VAX4

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1054

Site Name: (1054) Collaborative Neuroscience Network, LLC.

Subject No: 10541067

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 19-Apr-2021 21:04

5.a Sample ID

Date	Location	User	Value	Reason
Feb-26-2021 16:16:16 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: BRMTLT	Initial Entry

Header Text: c4591001

Visit: V102_VAX4

Form Version: 10-Dec-2020 02:26

Site No: 1054

Subject No: 10541067

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1054) Collaborative Neuroscience Network, LLC.

Subject Initials: ---

Generated Time (GMT): 19-Apr-2021 21:04

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1. Was there a temporary delay of vaccination?

Date	Location	User	Value	Reason
Feb-26-2021 12:25:00 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: NO	Initial Entry

2. Treatment Name

Date	Location	User	Value	Reason
Feb-26-2021 12:25:00 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: BNT162b2	Initial Entry

3. Formulation:

Date	Location	User	Value	Reason
Feb-26-2021 12:25:00 (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-26-2021 12:25:00 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: Feb/26/2021 08:48	Initial Entry

5. Anatomical Location:

Date	Location	User	Value	Reason
Feb-26-2021 12:25:00 (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
Feb-26-2021 12:25:00 (UTC-08:00) Pacific	ACV0PFEINFP6000	Steven Choi	Data Entry: RIGHT	Initial Entry

090177e196d89027\Final\Final On: 22-Apr-2021 02:13 (GMT)

Header Text: c4591001

Visit: V102_VAX4

Form Version: 10-Dec-2020 02:26

Site No: 1054

Subject No: 10541067

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1054) Collaborative Neuroscience Network, LLC.

Subject Initials: ---

Generated Time (GMT): 19-Apr-2021 21:04

Time (US & Canada)		(b) (4)	
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7. Route:

Date	Location	User	Value	Reason
Feb-26-2021 12:25:00 (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
Feb-26-2021 12:25:00 (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
Feb-26-2021 12:25:00 (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
Feb-26-2021 12:25:00 (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
Feb-26-2021 12:25:00 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	<u>Data Entry:</u> YES	Initial Entry

090177e196d89027\Final\Final On: 22-Apr-2021 02:13 (GMT)

Header Text: c4591001

Visit: Subject Status - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1054

Subject No: 10541067

Generated By: (b) (4)

Form: SUBJECT STATUS - eCRF Audit Trail History

Form Status: Data Complete, Verified

Site Name: (1054) Collaborative Neuroscience Network, LLC.

Subject Initials: ---

Generated Time (GMT): 19-Apr-2021 21:04

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1. Subject Status

Date	Location	User	Value	Reason
Oct-16-2020 10:15:46 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: FOLLOW-UP	Initial Entry
Aug-28-2020 10:35:30 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: ENROLLED/RANDOMIZED	Initial Entry
Aug-28-2020 10:27:26 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SCREENED	Initial Entry

2. Subject Status Date

Date	Location	User	Value	Reason
Oct-16-2020 10:15:46 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Oct/16/2020	Initial Entry
Aug-28-2020 10:35:30 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Aug/28/2020	Initial Entry
Aug-28-2020 10:27:26 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Aug/28/2020	Initial Entry

090177e196d89027\Final\Final On: 22-Apr-2021 02:13 (GMT)

Header Text: c4591001

Visit: Investigator Signature - Unscheduled

Form Version: 22-Apr-2020 21:04

Site No: 1054

Subject No: 10541067

Generated By: (b) (4)

Form: CASEBOOK SIGNATURE FORM - eCRF Audit Trail History

Form Status: Data Complete, Verified

Site Name: (1054) Collaborative Neuroscience Network, LLC.

Subject Initials: ---

Generated Time (GMT): 19-Apr-2021 21:04

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1. Casebook Signature

Date	Location	User	Value	Reason
Sep-22-2020 11:58:22 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: Click Here to Enable	Initial Entry