

Header Text: c4591001

Visit: COHORT_SELECTION

Form: COHORT SELECTION

Form Version: 15-Sep-2020 21:55

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1054

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

Subject No: 10541168

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

[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	08 SEP 2020
2.	Select appropriate response - What cohort does the subject belong to?	STAGE 3 COHORTS

090177e196ae30e4\Final\Final On: 01-Apr-2021 04:18 (GMT)

Header Text: c4591001

Visit: COHORT_SELECTION

Form: MAIN INFORMED CONSENT

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1054

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

Subject No: 10541168

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

[eCRF Audit Trail History](#)

Informed Consent

1.	Consent Was:	OBTAINED Date Written Consent Obtained Sep/17/2020
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Header Text: c4591001

Visit: COHORT_SELECTION

Form: DEMOGRAPHY

Form Version: 15-Sep-2020 21:54

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1054

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

Subject No: 10541168

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

[eCRF Audit Trail History](#)

Demography

1.	Subject ID	[10541168]
2.	Birth Date:	(b) (6)/1956
3.	Sex:	FEMALE
4.	Ethnicity:	HISPANIC OR LATINO(A) OR OF SPANISH ORIGIN
5.	Race: (Check X all that apply):	WHITE
6.	Racial Designation:	

090177e196ae30e4\Final\Final On: 01-Apr-2021 04:18 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:02

Site No: 1054

Subject No: 10541168

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): 29-Mar-2021 04:44

[eCRF Audit Trail History](#)

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

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 15-Sep-2020 21:53

Site No: 1054

Subject No: 10541168

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): 29-Mar-2021 04:44

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 _____
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090177e196ae30e4\Final\Final On: 01-Apr-2021 04:18 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 15-Sep-2020 21:52

Site No: 1054

Subject No: 10541168

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): 29-Mar-2021 04:44

[eCRF Audit Trail History](#)

Disposition - Screening

1.	Date of Completion/Discontinuation/Death	Sep/17/2020
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: 10541168

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): 29-Mar-2021 04:44

[eCRF Audit Trail History](#)

Medical History Details

1.a	Line/MH Number:	[1]
	Disease/Syndrome /Surgery/Non-Drug Allergies/Drug Allergies:	[Cesarean section]
	Start Date:	Mar/22/1976
	Ongoing:	NO End Date: Mar/22/1976
1.b	Line/MH Number:	[2]
	Disease/Syndrome /Surgery/Non-Drug Allergies/Drug Allergies:	[abdominal surgical scar]
	Start Date:	Mar/22/1976
	Ongoing:	YES
1.c	Line/MH Number:	[3]
	Disease/Syndrome /Surgery/Non-Drug Allergies/Drug Allergies:	[obesity]
	Start Date:	UNK/UNK/1995
	Ongoing:	YES

090177e196ae30e4\Final\Final On: 01-Apr-2021 04:18 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1054

Subject No: 10541168

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): 29-Mar-2021 04:44

1.d	Line/MH Number:	[4]
	Disease/Syndrome /Surgery/Non-Drug Allergies/Drug Allergies:	[mild intermittent headacheq]
	Start Date:	UNK/UNK/2018
	Ongoing:	YES
1.e	Line/MH Number:	[5]
	Disease/Syndrome /Surgery/Non-Drug Allergies/Drug Allergies:	[post-menopause]
	Start Date:	UNK/UNK/1990
	Ongoing:	YES
1.f	Line/MH Number:	[6]
	Disease/Syndrome /Surgery/Non-Drug Allergies/Drug Allergies:	[Cesarean section]
	Start Date:	Oct/26/1979
	Ongoing:	NO End Date: Oct/26/1979

090177e196ae30e4\Final\Final On: 01-Apr-2021 04:18 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 15-Sep-2020 21:57

Site No: 1054

Subject No: 10541168

Generated By: (b) (4)

Form: HIV STATUS

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

[eCRF Audit Trail History](#)

HIV Status

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

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: VITAL SIGNS - BASELINE

Form Version: 15-Sep-2020 21:56

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1054

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

Subject No: 10541168

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

[eCRF Audit Trail History](#)

Vital Signs

1.	Date:	Sep/17/2020
2.	Weight:	[82.73]
3.	Unit:	kg
4.	Height:	[144.78]
5.	Unit:	cm
6.	Body Mass Index:	[39.5]

Vital Signs Details

7.a	Record Identifier:	1
	Temperature:	[99.0]
	Unit:	F
	Temperature Location:	ORAL CAVITY

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 15-Sep-2020 21:51

Site No: 1054

Subject No: 10541168

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): 29-Mar-2021 04:44

[eCRF Audit Trail History](#)

Lab Urinalysis

1.	Lab Panel:	URINALYSIS
2.	Lab Sub-Panel:	PREGNANCY
3.	Collection Date:	Sep/17/2020
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:	

090177e196ae30e4\Final\Final On: 01-Apr-2021 04:18 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1054

Subject No: 10541168

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): 29-Mar-2021 04:44

[eCRF Audit Trail History](#)

Disposition

1.	Randomization Date :	Sep/17/2020
2.	Randomization Number:	[261401]
3.	Randomization Group:	[]

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1054

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

Subject No: 10541168

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

[eCRF Audit Trail History](#)

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	SERUM
3.	Sample Collected?	YES Date of Collection: Sep/17/2020
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	[BM98TH]
5.b	Sample ID	[BM98TJ]
5.c	Sample ID	[BM98TK]

090177e196ae30e4\Final\Final On: 01-Apr-2021 04:18 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1054

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

Subject No: 10541168

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

[eCRF Audit Trail History](#)

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Sep/17/2020
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	[BM98TL]
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Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:04

Site No: 1054

Subject No: 10541168

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): 29-Mar-2021 04:44

[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/17/2020 12:59
5.	Anatomical Location:	DELTOID MUSCLE
6.	Body Side:	LEFT
7.	Route:	INTRAMUSCULAR
8.	Actual Dose:	[]
9.	Unit:	
10.	Timeframe Subject Was Observed	THE PROTOCOL SPECIFIED OBSERVATION PERIOD
11.	Was the subject observed for at least the protocol specified observation period after investigational product administration?	YES

090177e196ae30e4\Final\Final On: 01-Apr-2021 04:18 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 06-Jul-2020 21:53

Site No: 1054

Subject No: 10541168

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): 29-Mar-2021 04:44

[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: 10541168

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): 29-Mar-2021 04:44

[eCRF Audit Trail History](#)

Date of Visit		
1.	Date of Visit	Oct/8/2020
2.	Erroneous Visit	

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 15-Sep-2020 21:54

Site No: 1054

Subject No: 10541168

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): 29-Mar-2021 04:44

[eCRF Audit Trail History](#)

Vital Signs

1.	Date:	Oct/8/2020
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Vital Signs Details

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

090177e196ae30e4\Final\Final On: 01-Apr-2021 04:18 (GMT)

Header Text: c4591001**Visit:** V2_VAX2_L**Form Version:** 15-Sep-2020 21:51**Site No:** 1054**Subject No:** 10541168**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):** 29-Mar-2021 04:44[Form Comments](#)[eCRF Audit Trail History](#)**Lab Urinalysis**

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

Lab Result

6.a	Sponsor ID:	Not Applicable _____ []	Comments
	Test:	Not Applicable _____ Choriogonadotropin Beta_PX113	
	Result:	Not Applicable _____	Comments
	Not Done:	Not Applicable _____	Comments

Header Text: c4591001

Visit: V2_VAX2_L

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1054

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

Subject No: 10541168

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

[eCRF Audit Trail History](#)

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Oct/8/2020
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	[BPYX0M]
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Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1054

Subject No: 10541168

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): 29-Mar-2021 04:44

[eCRF Audit Trail History](#)

Vaccination

1.	Was there a temporary delay of vaccination?	NO
2.	Treatment Name	[BLINDED THERAPY]
3.	Formulation:	INJECTION
4.	Dose Date Time:	Oct/8/2020 08:33
5.	Anatomical Location:	DELTOID MUSCLE
6.	Body Side:	LEFT
7.	Route:	INTRAMUSCULAR
8.	Actual Dose:	[]
9.	Unit:	
10.	Timeframe Subject Was Observed	THE PROTOCOL SPECIFIED OBSERVATION PERIOD
11.	Was the subject observed for at least the protocol specified observation period after investigational product administration?	YES

090177e196ae30e4\Final\Final On: 01-Apr-2021 04:18 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L **Form:** DATE OF VISIT

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

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

Subject No: 10541168 **Subject Initials:** ---

Generated By: (b) (4) **Generated Time (GMT):** 29-Mar-2021 04:44

[eCRF Audit Trail History](#)

Date of Visit		
1.	Date of Visit	Nov/5/2020
2.	Erroneous Visit	

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L **Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

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

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

Subject No: 10541168 **Subject Initials:** ---

Generated By: (b) (4) **Generated Time (GMT):** 29-Mar-2021 04:44

[eCRF Audit Trail History](#)

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	SERUM
3.	Sample Collected?	YES Date of Collection: Nov/5/2020
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	[BM98BK]
5.b	Sample ID	[BM98BL]

090177e196ae30e4\Final\Final On: 01-Apr-2021 04:18 (GMT)

Header Text: c4591001

Visit: V4_MONTH6_L

Form Version: 22-Apr-2020 21:02

Site No: 1054

Subject No: 10541168

Generated By: (b) (4)

Form: DATE OF VISIT

Form Status: Not Started

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

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

Header Text: c4591001

Visit: V4_MONTH6_L

Form Version: 22-Apr-2020 21:03

Site No: 1054

Subject No: 10541168

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): 29-Mar-2021 04:44

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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090177e196ae30e4\Final\Final On: 01-Apr-2021 04:18 (GMT)

Header Text: c4591001

Visit: V5_MONTH12_L

Form Version: 22-Apr-2020 21:02

Site No: 1054

Subject No: 10541168

Generated By: (b) (4)

Form: DATE OF VISIT

Form Status: Not Started

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

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

Header Text: c4591001

Visit: V5_MONTH12_L

Form Version: 22-Apr-2020 21:03

Site No: 1054

Subject No: 10541168

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): 29-Mar-2021 04:44

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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090177e196ae30e4\Final\Final On: 01-Apr-2021 04:18 (GMT)

Header Text: c4591001

Visit: V6_MONTH24_L

Form Version: 22-Apr-2020 21:02

Site No: 1054

Subject No: 10541168

Generated By: (b) (4)

Form: DATE OF VISIT

Form Status: Not Started

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

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

Header Text: c4591001

Visit: V6_MONTH24_L

Form Version: 22-Apr-2020 21:03

Site No: 1054

Subject No: 10541168

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): 29-Mar-2021 04:44

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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090177e196ae30e4\Final\Final On: 01-Apr-2021 04:18 (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: 10541168

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

COVID-19 Illness Visit

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

Visit: POT_COVID_ILL - New
Unscheduled Visit

Form Version: 20-Feb-2021 02:17

Site No: 1054

Subject No: 10541168

Generated By: (b) (4)

Form: SIGNS AND SYMPTOMS OF POTENTIAL
COVID-19

Form Status: Not Started

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

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

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

090177e196ae30e4\Final\Final On: 01-Apr-2021 04:18 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL - New
Unscheduled Visit

Form Version: 22-Apr-2020 21:03

Site No: 1054

Subject No: 10541168

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - NASAL
SWAB SELF

Form Status: Not Started

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

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

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 Version: 22-Apr-2020 21:03

Site No: 1054

Subject No: 10541168

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - NASAL
SWAB

Form Status: Not Started

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

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

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	[]
----	-----------	-----

090177e196ae30e4\Final\Final On: 01-Apr-2021 04:18 (GMT)

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: 10541168

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

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?	
----	--	--

090177e196ae30e4\Final\Final On: 01-Apr-2021 04:18 (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: 10541168

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

Illness Details

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

090177e196ae30e4\Final\Final On: 01-Apr-2021 04:18 (GMT)

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: 10541168

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

COVID-19 Illness Visit

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

Header Text: c4591001

Visit: POT_COVID_CONVA - New
Unscheduled Visit

Form: ELECTRONIC SAMPLE TRACKING -
IMMUNOGENICITY

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1054

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

Subject No: 10541168

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

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	[]
----	-----------	-----

090177e196ae30e4\Final\Final On: 01-Apr-2021 04:18 (GMT)

Header Text: c4591001

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

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

Site No: 1054

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

Subject No: 10541168

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

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: 10541168 **Subject Initials:** ---

Generated By: (b) (4) **Generated Time (GMT):** 29-Mar-2021 04:44

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	[]
----	-----------	-----

090177e196ae30e4\Final\Final On: 01-Apr-2021 04:18 (GMT)

Header Text: c4591001

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

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

Site No: 1054

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

Subject No: 10541168

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

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: 10541168 **Subject Initials:** ---

Generated By: (b) (4) **Generated Time (GMT):** 29-Mar-2021 04:44

Unplanned Assessments

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

090177e196ae30e4\Final\Final On: 01-Apr-2021 04:18 (GMT)

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: 10541168

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

#	Category	AE Identifier	Adverse Event	Start Date	Is the Adverse Event Still Ongoing	Form Instance
1.	ADVERSE EVENT	1	closed fracture, transverse process of lumbar vertebra	Dec/3/2020 UNK:UNK	YES	Repeating Pages

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete

Site No: 1054

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

Subject No: 10541168

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

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[eCRF Audit Trail History](#)

[Form Audit Trail](#)

Adverse Event Report

1.	Category:	ADVERSE EVENT
2.	AE ID:	[1]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[closed fracture, transverse process of lumbar vertebra]
4.	Start Date Time:	Dec/3/2020 UNK:UNK
5.	Is the adverse event still ongoing?	YES
6.	Toxicity Grade:	3

090177e196ae30e4\Final\Final On: 01-Apr-2021 04:18 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1054

Subject No: 10541168

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete

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

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

7.	<p>Is the adverse event serious?</p> <p>If Yes, NOTIFY PFIZER IMMEDIATELY.</p> <p>Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).</p>	<p>YES</p> <p>Is this serious event associated with congenital anomaly or birth defect? NO</p> <p>Did this serious event result in death? NO</p> <p>Did this serious event require or prolong hospitalization? YES</p> <p>Did this serious event result in persistent or significant disability/incapacity? NO</p> <p>Is this serious event life threatening? NO</p> <p>Other medically important serious event NO</p>
8.	<p>Is this adverse event the result of a study Medication Error?</p> <p>If Yes, record the type of medication error on the Medication Error Log.</p>	<p>NO</p>
9.	<p>Is this event related to study treatment:</p>	<p>NOT RELATED</p> <p>If Not Related to study treatment(s), this event is due to: OTHER</p> <p>If Other, specify: [pedestrian vs motor vehicle accident]</p>

090177e196ae30e4\Final\Final On: 01-Apr-2021 04:18 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete

Site No: 1054

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

Subject No: 10541168

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE
11.	Was a Concomitant Medication given?	YES
12.	Was a Non-Drug Treatment given?	YES
13.	What was the outcome of this adverse event?:	RECOVERING/RESOLVING
14.	Did the adverse event cause the subject to be discontinued from the study?	NO
15.	Serious Adverse Event Number: For Pfizer Use Only	[2021067301]

090177e196ae30e4\Final\Final On: 01-Apr-2021 04:18 (GMT)

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: 10541168

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

#	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: 10541168

Generated By: (b) (4)

Form: MEDICATION ERROR

Form Status: Not Started

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

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

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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	[]

090177e196ae30e4\Final\Final On: 01-Apr-2021 04:18 (GMT)

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: 10541168

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

#	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: 10541168

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

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Concomitant Medications

1.	What is the medication identifier?	[]
2.	Category:	
3.	Concomitant Medications Pre-specified:	
4.	<p>Medication:</p> <p>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).</p>	[]
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: 10541168

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

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

Header Text: c4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - PROHIBITED

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1054

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

Subject No: 10541168

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

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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?	

090177e196ae30e4\Final\Final On: 01-Apr-2021 04:18 (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: 10541168

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

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

Header Text: c4591001

Visit: Logs - Unscheduled

Form: RADIATION TREATMENT

Form Version: 22-Apr-2020 21:02

Form Status: Not Started

Site No: 1054

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

Subject No: 10541168

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

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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?	

090177e196ae30e4\Final\Final On: 01-Apr-2021 04:18 (GMT)

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: 10541168

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

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

Header Text: c4591001

Visit: Logs - Unscheduled

Form: TRANSFUSIONS

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1054

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

Subject No: 10541168

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

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

Header Text: c4591001

Visit: End of Treatment - Unscheduled **Form:** DISPOSITION - TREATMENT

Form Version: 15-Sep-2020 21:55

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1054

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

Subject No: 10541168

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

[eCRF Audit Trail History](#)

Disposition - Treatment

1.	Date of Completion/Discontinuation /Death :	Nov/5/2020
2.	Phase of Disposition:	VACCINATION
3.	Status:	COMPLETED
4.	Specify Status:	[]

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: 10541168

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

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: 10541168

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

Vital Signs

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

Vital Signs Details

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

090177e196ae30e4\Final\Final On: 01-Apr-2021 04:18 (GMT)

Header Text: c4591001**Visit:** Unplanned Vaccination -
Unscheduled**Form:** LAB URINALYSIS - PREGNANCY TEST**Form Version:** 20-Feb-2021 02:14**Form Status:** Not Started**Site No:** 1054**Site Name:** (1054) Collaborative Neuroscience Network,
LLC.**Subject No:** 10541168**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 04:44**Lab Urinalysis**

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

Lab Result

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

Header Text: c4591001

Visit: Unplanned Vaccination -
Unscheduled

Form: VACCINATION

Form Version: 10-Dec-2020 02:26

Form Status: Not Started

Site No: 1054

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

Subject No: 10541168

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

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?	

090177e196ae30e4\Final\Final On: 01-Apr-2021 04:18 (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: 10541168

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

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: 10541168

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

Contact Outcome

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

Header Text: c4591001

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

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

Site No: 1054

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

Subject No: 10541168

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

Header Text: c4591001

Visit: V201_SURVEIL_CONSENT -
Unscheduled

Form: INFORMED CONSENT - ASYMPTOMATIC
SURVEILLANCE

Form Version: 14-Jan-2021 02:29

Form Status: Not Started

Site No: 1054

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

Subject No: 10541168

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

Informed Consent - Asymptomatic Surveillance

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

Header Text: c4591001**Visit:** V201_SURVEIL_CONSENT -
Unscheduled**Form:** ELECTRONIC SAMPLE TRACKING -
IMMUNOGENICITY**Form Version:** 22-Apr-2020 21:03**Form Status:** Not Started**Site No:** 1054**Site Name:** (1054) Collaborative Neuroscience Network,
LLC.**Subject No:** 10541168**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 04:44**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:** V201_SURVEIL_CONSENT -
Unscheduled**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:** 10541168**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 04:44**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: Follow-Up - Unscheduled

Form: DISPOSITION - FOLLOW-UP

Form Version: 15-Sep-2020 21:53

Form Status: Not Started

Site No: 1054

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

Subject No: 10541168

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

Disposition - Follow-Up

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

090177e196ae30e4\Final\Final On: 01-Apr-2021 04:18 (GMT)

Header Text: c4591001

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

Unscheduled

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen, Verified

Site No: 1054

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

Subject No: 10541168

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

[eCRF Audit Trail History](#)

Date of Visit

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

Header Text: c4591001

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

Form Version: 10-Dec-2020 02:25 **Form Status:** Data Complete, Frozen

Site No: 1054

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

Subject No: 10541168

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

[eCRF Audit Trail History](#)

Further Vaccination Confirmation

1.	Select appropriate response - Is participant willing to return for Vaccination 3?	Participant is willing to return for Vaccination 3 Participant is: eligible and NOT confirmed to have received only placebo at Vaccination 1/2
----	--	--

090177e196ae30e4\Final\Final On: 01-Apr-2021 04:18 (GMT)

Header Text: c4591001

Visit: Disposition - Unscheduled

Form: TREATMENT UNBLINDED

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: 10541168

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

[eCRF Audit Trail History](#)

Treatment Unblinded

1.	Date Treatment Unblinded :	Feb/4/2021
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: 10541168

Generated By: (b) (4)

Form: WITHDRAWAL OF CONSENT

Form Status: Not Started

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

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

Withdrawal Of Consent

1.	Withdrawal of Consent Date :	//
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Header Text: c4591001

Visit: Disposition - Unscheduled

Form: DEATH DETAILS CODED

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1054

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

Subject No: 10541168

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

Death Details

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

Cause of Death

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

090177e196ae30e4\Final\Final On: 01-Apr-2021 04:18 (GMT)

Header Text: c4591001

Visit: Subject Status - Unscheduled

Form: SUBJECT STATUS

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Verified

Site No: 1054

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

Subject No: 10541168

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

[eCRF Audit Trail History](#)

Subject Status

1.	Subject Status	FOLLOW-UP
2.	Subject Status Date	Nov/5/2020

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: 10541168

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

[eCRF Audit Trail History](#)

Casebook Signature Form

1.	Casebook Signature	Click Here to Enable
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Header Text: c4591001

Visit: Investigator Signature -
Unscheduled

Form: CASEBOOK SIGNATURE FORM

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Verified

Site No: 1054

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

Subject No: 10541168

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

[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: INCLUSION/EXCLUSION CRITERIA -
Comments

Form Version: 15-Sep-2020 21:53

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1054

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

Subject No: 10541168

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

[Back to Form](#)

Item	Date	User	Comment
Form	Sep-17-2020 13:50:23 (UTC-08:00) Pacific Time (US & Canada)	Steven Choi (b) (4)	Not Applicable

Header Text: c4591001

Visit: V2_VAX2_L

Form: LAB URINALYSIS - PREGNANCY TEST -
Comments

Form Version: 15-Sep-2020 21:51

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1054

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

Subject No: 10541168

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

[Back to Form](#)

Item	Date	User	Comment
Form	Oct-08-2020 11:23:28 (UTC-08:00) Pacific Time (US & Canada)	Steven Choi (b) (4)	Not Applicable

090177e196ae30e4\Final\Final On: 01-Apr-2021 04:18 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form: LAB URINALYSIS - PREGNANCY TEST -
Comments

Form Version: 15-Sep-2020 21:51

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1054

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

Subject No: 10541168

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

[Back to Form](#)

Item	Date	User	Comment
1	Oct-08-2020 11:23:28 (UTC-08:00) Pacific Time (US & Canada)	Steven Choi (b) (4)	Not Applicable

Header Text: c4591001

Visit: V2_VAX2_L

Form: LAB URINALYSIS - PREGNANCY TEST -
Comments

Form Version: 15-Sep-2020 21:51

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1054

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

Subject No: 10541168

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

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Item	Date	User	Comment
2	Oct-08-2020 11:23:28 (UTC-08:00) Pacific Time (US & Canada)	Steven Choi (b) (4)	Not Applicable

Header Text: c4591001

Visit: V2_VAX2_L

Form: LAB URINALYSIS - PREGNANCY TEST -
Comments

Form Version: 15-Sep-2020 21:51

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1054

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

Subject No: 10541168

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

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Item	Date	User	Comment
3	Oct-08-2020 11:23:28 (UTC-08:00) Pacific Time (US & Canada)	Steven Choi (b) (4)	Not Applicable

Header Text: c4591001

Visit: V2_VAX2_L

Form: LAB URINALYSIS - PREGNANCY TEST -
Comments

Form Version: 15-Sep-2020 21:51

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1054

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

Subject No: 10541168

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

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Item	Date	User	Comment
4	Oct-08-2020 11:23:28 (UTC-08:00) Pacific Time (US & Canada)	Steven Choi (b) (4)	Not Applicable

Header Text: c4591001

Visit: V2_VAX2_L

Form: LAB URINALYSIS - PREGNANCY TEST -
Comments

Form Version: 15-Sep-2020 21:51

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1054

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

Subject No: 10541168

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

[Back to Form](#)

Item	Date	User	Comment
5	Oct-08-2020 11:23:28 (UTC-08:00) Pacific Time (US & Canada)	Steven Choi (b) (4)	Not Applicable

Header Text: c4591001

Visit: V2_VAX2_L

Form: LAB URINALYSIS - PREGNANCY TEST -
Comments

Form Version: 15-Sep-2020 21:51

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1054

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

Subject No: 10541168

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

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Item	Date	User	Comment
6.a	Oct-08-2020 11:23:28 (UTC-08:00) Pacific Time (US & Canada)	Steven Choi (b) (4)	Not Applicable

Header Text: c4591001

Visit: V2_VAX2_L

Form: LAB URINALYSIS - PREGNANCY TEST -
Comments

Form Version: 15-Sep-2020 21:51

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1054

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

Subject No: 10541168

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

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Item	Date	User	Comment
6.a	Oct-08-2020 11:23:28 (UTC-08:00) Pacific Time (US & Canada)	Steven Choi (b) (4)	Not Applicable

Header Text: c4591001

Visit: V2_VAX2_L

Form: LAB URINALYSIS - PREGNANCY TEST -
Comments

Form Version: 15-Sep-2020 21:51

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1054

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

Subject No: 10541168

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

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Item	Date	User	Comment
6.a	Oct-08-2020 11:23:28 (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: 10541168

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

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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
(b) (6)	N/A	Jan-26-2021 06:36:49 (UTC-08:00) Pacific Time (US & Canada)		Edit - All signatures invalidated

Affidavit:
N/A

Mark Leibowitz	Approved	Jan-25-2021 10:03:19 (UTC-08:00) Pacific Time (US & Canada)	BOOK	Signed
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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.

Steven Choi	N/A	Jan-22-2021 14:55:30 (UTC-08:00) Pacific Time (US & Canada)		Edit - All signatures invalidated
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090177e196ae30e4\Final\Final On: 01-Apr-2021 04:18 (GMT)

Header Text: c4591001

Visit: Investigator Signature -
Unscheduled

Form: CASEBOOK SIGNATURE FORM - Signature
History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Verified

Site No: 1054

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

Subject No: 10541168

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

Affidavit:

N/A

Mark Leibowitz	Approved	Nov-11-2020 10:06:28 (UTC-08:00) Pacific Time (US & Canada)	BOOK	Signed
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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.

090177e196ae30e4\Final\Final On: 01-Apr-2021 04:18 (GMT)

Header Text: c4591001

Visit: COHORT_SELECTION

Form: COHORT SELECTION - eCRF Audit Trail History

Form Version: 15-Sep-2020 21:55

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1054

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

Subject No: 10541168

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

[Back to Form](#)

1. Select appropriate response - Protocol version

Date	Location	User	Value	Reason
Sep-17-2020 13:48:53 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: 08 SEP 2020	Initial Entry

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

Date	Location	User	Value	Reason
Sep-17-2020 13:48:53 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: STAGE 3 COHORTS	Initial Entry

090177e196ae30e4\Final\Final On: 01-Apr-2021 04:18 (GMT)

Header Text: c4591001

Visit: COHORT_SELECTION

Form Version: 22-Apr-2020 21:02

Site No: 1054

Subject No: 10541168

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): 29-Mar-2021 04:44

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1. Consent Was:

Date	Location	User	Value	Reason
Sep-17-2020 13:49:01 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: OBTAINED Date Written Consen t Obtained Sep/17/2020	Initial Entry

090177e196ae30e4\Final\Final On: 01-Apr-2021 04:18 (GMT)

Header Text: c4591001

Visit: COHORT_SELECTION

Form Version: 15-Sep-2020 21:54

Site No: 1054

Subject No: 10541168

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): 29-Mar-2021 04:44

[Back to Form](#)

1. Subject ID

Date	Location	User	Value	Reason
Sep-17-2020 13:48:42 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 10541168	Item copied from previous form

2. Birth Date:

Date	Location	User	Value	Reason
Sep-17-2020 13:48:36 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: (b) (6)/1956	Enrollment Entry

3. Sex:

Date	Location	User	Value	Reason
Sep-17-2020 13:49:23 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: FEMALE	Initial Entry

4. Ethnicity:

Date	Location	User	Value	Reason
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090177e196ae30e4\Final\Final On: 01-Apr-2021 04:18 (GMT)

Header Text: c4591001

Visit: COHORT_SELECTION

Form: DEMOGRAPHY - eCRF Audit Trail History

Form Version: 15-Sep-2020 21:54

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1054

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

Subject No: 10541168

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

Sep-17-2020 13:49:23 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: HISPANIC OR LATI NO(A) OR OF SPANI SH ORIGIN	Initial Entry
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5. Race: (Check X all that apply):

Date	Location	User	Value	Reason
Sep-17-2020 13:49:23 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: WHITE	Initial Entry

090177e196ae30e4\Final\Final On: 01-Apr-2021 04:18 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:02

Site No: 1054

Subject No: 10541168

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): 29-Mar-2021 04:44

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1. Date of Visit

Date	Location	User	Value	Reason
Sep-17-2020 13:50:05 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: Sep/17/2020	Initial Entry

090177e196ae30e4\Final\Final On: 01-Apr-2021 04:18 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: DISPOSITION - SCREENING - eCRF Audit Trail History

Form Version: 15-Sep-2020 21:52

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1054

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

Subject No: 10541168

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

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1. Date of Completion/Discontinuation/Death

Date	Location	User	Value	Reason
Sep-17-2020 13:51:05 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: Sep/17/2020	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Sep-17-2020 13:51:05 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SCREENING	Initial Entry

3. Status:

Date	Location	User	Value	Reason
Sep-17-2020 13:51:05 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: COMPLETED	Initial Entry

090177e196ae30e4\Final\Final On: 01-Apr-2021 04:18 (GMT)

Header Text: c4591001**Visit:** V1_DAY1_VAX1_L**Form Version:** 22-Apr-2020 21:03**Site No:** 1054**Subject No:** 10541168**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):** 29-Mar-2021 04:44[Back to Form](#)*1.a*

Date	Location	User	Value	Reason
Sep-17-2020 13:53:33 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH 1 Number: Medical Hi Cesarean story Term section : Start Date: Mar/22/1 976 Ongoing: NO End Dat e: Mar/22 /1976	Initial Entry

1.a Line/MH Number:

Date	Location	User	Value	Reason
Sep-17-2020 13:53:33 (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:

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1054

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

Subject No: 10541168

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

Date	Location	User	Value	Reason
Sep-17-2020 13:53:33 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: Cesarean section	Initial Entry

1.a Start Date:

Date	Location	User	Value	Reason
Sep-17-2020 13:53:33 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: Mar/22/1976	Initial Entry

1.a Ongoing:

Date	Location	User	Value	Reason
Sep-17-2020 13:53:33 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: NO End Date: Mar/22/1976	Initial Entry

1.b

Date	Location	User	Value	Reason
Sep-17-2020 13:53:59 (UTC-08:00)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH 2	Initial Entry

090177e196ae30e4\Final\Final On: 01-Apr-2021 04:18 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1054

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

Subject No: 10541168

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

Pacific Time (US & Canada)			Number: Medical History Term: abdominal surgical scar Start Date: Mar/22/1976 Ongoing: YES	
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Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1054

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

Subject No: 10541168

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

1.b Line/MH Number:

Date	Location	User	Value	Reason
Sep-17-2020 13:53:59 (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
Sep-17-2020 13:53:59 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: abdominal surgical scar	Initial Entry

1.b Start Date:

Date	Location	User	Value	Reason
Sep-17-2020 13:53:59 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: Mar/22/1976	Initial Entry

1.b Ongoing:

Date	Location	User	Value	Reason
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090177e196ae30e4\Final\Final On: 01-Apr-2021 04:18 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1054

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

Subject No: 10541168

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

Sep-17-2020 13:53:59 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: YES	Initial Entry
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I.c

Date	Location	User	Value	Reason
Sep-17-2020 13:54:13 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH N 3 umber: Medical His obesity tory Term: Start Date: UNK/U NK/199 5 Ongoing: YES	Initial Entry

090177e196ae30e4\Final\Final On: 01-Apr-2021 04:18 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1054

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

Subject No: 10541168

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

I.c Line/MH Number:

Date	Location	User	Value	Reason
Sep-17-2020 13:54:13 (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
Sep-17-2020 13:54:13 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: obesity	Initial Entry

I.c Start Date:

Date	Location	User	Value	Reason
Sep-17-2020 13:54:13 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: UNK/UNK/1995	Initial Entry

I.c Ongoing:

Date	Location	User	Value	Reason
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090177e196ae30e4\Final\Final On: 01-Apr-2021 04:18 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1054

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

Subject No: 10541168

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

Sep-17-2020 13:54:13 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: YES	Initial Entry
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1.d

Date	Location	User	Value	Reason
Sep-17-2020 13:54:27 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH 4 Number: Medical mild inter History T mittent hea erm: dacheq Start Dat UNK/UNK e: /2018 Ongoing: YES	Initial Entry

090177e196ae30e4\Final\Final On: 01-Apr-2021 04:18 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1054

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

Subject No: 10541168

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

1.d Line/MH Number:

Date	Location	User	Value	Reason
Sep-17-2020 13:54:27 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 4	Initial Entry

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

Date	Location	User	Value	Reason
Sep-17-2020 13:54:27 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: mild intermittent head acheq	Initial Entry

1.d Start Date:

Date	Location	User	Value	Reason
Sep-17-2020 13:54:27 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: UNK/UNK/2018	Initial Entry

1.d Ongoing:

Date	Location	User	Value	Reason
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090177e196ae30e4\Final\Final On: 01-Apr-2021 04:18 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1054

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

Subject No: 10541168

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

Sep-17-2020 13:54:27 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: YES	Initial Entry
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I.e

Date	Location	User	Value	Reason
Sep-17-2020 13:55:01 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH N 5 umber: Medical His post-me tory Term: nopause Start Date: UNK/U NK/199 0 Ongoing: YES	Initial Entry

090177e196ae30e4\Final\Final On: 01-Apr-2021 04:18 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1054

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

Subject No: 10541168

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

1.e Line/MH Number:

Date	Location	User	Value	Reason
Sep-17-2020 13:55:01 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 5	Initial Entry

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

Date	Location	User	Value	Reason
Sep-17-2020 13:55:01 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: post-menopause	Initial Entry

1.e Start Date:

Date	Location	User	Value	Reason
Sep-17-2020 13:55:01 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: UNK/UNK/1990	Initial Entry

1.e Ongoing:

Date	Location	User	Value	Reason
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090177e196ae30e4\Final\Final On: 01-Apr-2021 04:18 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1054

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

Subject No: 10541168

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

Sep-17-2020 13:55:01 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: YES	Initial Entry
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If

Date	Location	User	Value	Reason
Sep-17-2020 14:21:53 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH N 6 umber: Medical Hi Cesarean story Term section : Start Date: Oct/26/19 79 Ongoing: NO End Dat e: Oct/26 /1979	Initial Entry

090177e196ae30e4\Final\Final On: 01-Apr-2021 04:18 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1054

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

Subject No: 10541168

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

1.f Line/MH Number:

Date	Location	User	Value	Reason
Sep-17-2020 14:21:53 (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
Sep-17-2020 14:21:53 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: Cesarean section	Initial Entry

1.f Start Date:

Date	Location	User	Value	Reason
Sep-17-2020 14:21:53 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: Oct/26/1979	Initial Entry

1.f Ongoing:

Date	Location	User	Value	Reason
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090177e196ae30e4\Final\Final On: 01-Apr-2021 04:18 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1054

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

Subject No: 10541168

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

Sep-17-2020 14:21:53 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: NO End Date: Oct/26/1979	Initial Entry
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Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 15-Sep-2020 21:57

Site No: 1054

Subject No: 10541168

Generated By: (b) (4)

Form: HIV STATUS - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

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

Date	Location	User	Value	Reason
Sep-17-2020 13:55:55 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: The subject is NOT k nown to be HIV POSI TIVE	Initial Entry

090177e196ae30e4\Final\Final On: 01-Apr-2021 04:18 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: VITAL SIGNS - BASELINE - eCRF Audit Trail History

Form Version: 15-Sep-2020 21:56

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1054

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

Subject No: 10541168

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

[Back to Form](#)

1. Date:

Date	Location	User	Value	Reason
Sep-17-2020 13:56:37 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: Sep/17/2020	Initial Entry

2. Weight:

Date	Location	User	Value	Reason
Sep-17-2020 13:56:37 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: 82.73	Initial Entry

3. Unit:

Date	Location	User	Value	Reason
Sep-17-2020 13:56:37 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: kg	Initial Entry

4. Height:

090177e196ae30e4\Final\Final On: 01-Apr-2021 04:18 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: VITAL SIGNS - BASELINE - eCRF Audit Trail History

Form Version: 15-Sep-2020 21:56

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1054

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

Subject No: 10541168

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

Date	Location	User	Value	Reason
Sep-17-2020 13:56:37 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: 144.78	Initial Entry

5. Unit:

Date	Location	User	Value	Reason
Sep-17-2020 13:56:37 (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
Sep-17-2020 13:56:37 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 39.5	Initial Entry

7.a

Date	Location	User	Value	Reason
Sep-17-2020 13:56:37 (UTC-08:00)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: Record Ide 1	Initial Entry

090177e196ae30e4\Final\Final On: 01-Apr-2021 04:18 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: VITAL SIGNS - BASELINE - eCRF Audit Trail History

Form Version: 15-Sep-2020 21:56

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1054

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

Subject No: 10541168

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

Pacific Time (US & Canada)			ntifier:: Temperatu 99.0 re: Temperatu F re Unit: Temperatu ORAL re Location CAVIT :: Y
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7.a Record Identifier:

Date	Location	User	Value	Reason
Sep-17-2020 13:56:37 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	<u>Data Entry:</u> 1	Initial Entry

7.a Temperature:

Date	Location	User	Value	Reason
Sep-17-2020 13:56:37 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	<u>Data Entry:</u> 99.0	Initial Entry

7.a Unit:

Date	Location	User	Value	Reason
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090177e196ae30e4\Final\Final On: 01-Apr-2021 04:18 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: VITAL SIGNS - BASELINE - eCRF Audit Trail History

Form Version: 15-Sep-2020 21:56

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1054

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

Subject No: 10541168

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

Sep-17-2020 13:56:37 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: F	Initial Entry
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7.a Temperature Location:

Date	Location	User	Value	Reason
Sep-17-2020 13:56:37 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: ORAL CAVITY	Initial Entry

090177e196ae30e4\Final\Final On: 01-Apr-2021 04:18 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 15-Sep-2020 21:51

Site No: 1054

Subject No: 10541168

Generated By: (b) (4)

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

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

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1. Lab Panel:

Date	Location	User	Value	Reason
Sep-17-2020 13:56:45 (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-17-2020 13:56:45 (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-17-2020 13:56:45 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: Sep/17/2020	Initial Entry

4. Laboratory Name and Address (Derived)

090177e196ae30e4\Final\Final On: 01-Apr-2021 04:18 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

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

Form Version: 15-Sep-2020 21:51

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1054

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

Subject No: 10541168

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

Date	Location	User	Value	Reason
Sep-17-2020 13:56:45 (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-17-2020 13:56:45 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: URINE	Initial Entry

6.a

Date	Location	User	Value	Reason
Sep-17-2020 13:56:45 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sponsor- 113 Defined I dentifier: Test:: Choriogon adotropin Beta_PX11 3 Result:: NEGATIV E	Initial Entry

090177e196ae30e4\Final\Final On: 01-Apr-2021 04:18 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

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

Form Version: 15-Sep-2020 21:51

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1054

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

Subject No: 10541168

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

			Not Done ::	
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6.a Sponsor ID:

Date	Location	User	Value	Reason
Sep-17-2020 13:56:45 (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-17-2020 13:56:45 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: Choriogonadotropin B eta_PX113	Initial Entry

6.a Result:

Date	Location	User	Value	Reason
Sep-17-2020 13:56:45 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: NEGATIVE	Initial Entry

090177e196ae30e4\Final\Final On: 01-Apr-2021 04:18 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1054

Subject No: 10541168

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): 29-Mar-2021 04:44

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1. Randomization Date :

Date	Location	User	Value	Reason
Sep-17-2020 13:57:12 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: Sep/17/2020	Initial Entry

2. Randomization Number:

Date	Location	User	Value	Reason
Sep-17-2020 13:57:12 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: 261401	Initial Entry

090177e196ae30e4\Final\Final On: 01-Apr-2021 04:18 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1054

Subject No: 10541168

Generated By: (b) (4)

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

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

[Back to Form](#)

1. Data Origin

Date	Location	User	Value	Reason
Sep-17-2020 13:57:18 (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-17-2020 13:57:18 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SERUM	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Sep-17-2020 15:13:14 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Sep-17-2020 13:57:18	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is

090177e196ae30e4\Final\Final On: 01-Apr-2021 04:18 (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: 10541168

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

(UTC-08:00) Pacific Time (US & Canada)				Yes, however no barcodes are entered. Please review and correct as appropriate.
Sep-17-2020 13:57:18 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: YES Date of Collection: Sep/17/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Sep-17-2020 15:13:14 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: Sample ID BM98T : H	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Sep-17-2020 15:13:14 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: BM98TH	Initial Entry

5.b

090177e196ae30e4\Final\Final On: 01-Apr-2021 04:18 (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: 10541168

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

Date	Location	User	Value	Reason
Sep-17-2020 15:13:30 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: Sample ID: BM98TJ	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Sep-17-2020 15:13:30 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: BM98TJ	Initial Entry

5.c

Date	Location	User	Value	Reason
Sep-17-2020 15:13:41 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: Sample ID BM98T : K	Initial Entry

090177e196ae30e4\Final\Final On: 01-Apr-2021 04:18 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1054

Subject No: 10541168

Generated By: (b) (4)

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

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

5.c Sample ID

Date	Location	User	Value	Reason
Sep-17-2020 15:13:41 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: BM98TK	Initial Entry

090177e196ae30e4\Final\Final On: 01-Apr-2021 04:18 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1054

Subject No: 10541168

Generated By: (b) (4)

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

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

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1. Data Origin

Date	Location	User	Value	Reason
Sep-17-2020 13:57:25 (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-17-2020 13:57:25 (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-17-2020 15:13:55 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Sep-17-2020 13:57:25	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is

090177e196ae30e4\Final\Final On: 01-Apr-2021 04:18 (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: 10541168

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

(UTC-08:00) Pacific Time (US & Canada)				Yes, however no barcodes are entered. Please review and correct as appropriate.
Sep-17-2020 13:57:25 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: YES Date of Collection: Sep/17/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Sep-17-2020 15:13:55 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: Sample ID BM98T : L	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Sep-17-2020 15:13:55 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: BM98TL	Initial Entry

090177e196ae30e4\Final\Final On: 01-Apr-2021 04:18 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:04

Site No: 1054

Subject No: 10541168

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): 29-Mar-2021 04:44

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1. Was there a temporary delay of vaccination?

Date	Location	User	Value	Reason
Sep-17-2020 13:58:01 (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-17-2020 13:58:01 (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-17-2020 13:58:01 (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
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090177e196ae30e4\Final\Final On: 01-Apr-2021 04:18 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: VACCINATION - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1054

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

Subject No: 10541168

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

Sep-17-2020 13:58:01 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: Sep/17/2020 12:59	Initial Entry
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5. Anatomical Location:

Date	Location	User	Value	Reason
Sep-17-2020 13:58:01 (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
Sep-17-2020 13:58:01 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: LEFT	Initial Entry

7. Route:

Date	Location	User	Value	Reason
Sep-17-2020 13:58:01 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INTRAMUSCULAR	Initial Entry

090177e196ae30e4\Final\Final On: 01-Apr-2021 04:18 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:04

Site No: 1054

Subject No: 10541168

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): 29-Mar-2021 04:44

10. Timeframe Subject Was Observed

Date	Location	User	Value	Reason
Sep-17-2020 13:58:01 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: THE PROTOCOL SPE CIFIED OBSERVATIO N 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-17-2020 13:58:01 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: YES	Initial Entry

090177e196ae30e4\Final\Final On: 01-Apr-2021 04:18 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 06-Jul-2020 21:53

Site No: 1054

Subject No: 10541168

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): 29-Mar-2021 04:44

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1. Select appropriate response - Reactogenicity diary collection

Date	Location	User	Value	Reason
Sep-17-2020 13:58:13 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: NO - REACTOGENI CITY E-DIARY NOT COLLECTED FOR T HIS SUBJECT	Initial Entry

090177e196ae30e4\Final\Final On: 01-Apr-2021 04:18 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 1054

Subject No: 10541168

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): 29-Mar-2021 04:44

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1. Date of Visit

Date	Location	User	Value	Reason
Oct-08-2020 11:21:48 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: Oct/8/2020	Initial Entry

090177e196ae30e4\Final\Final On: 01-Apr-2021 04:18 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 15-Sep-2020 21:54

Site No: 1054

Subject No: 10541168

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): 29-Mar-2021 04:44

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1. Date:

Date	Location	User	Value	Reason
Oct-08-2020 11:22:08 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: Oct/8/2020	Initial Entry

2.a

Date	Location	User	Value	Reason
Oct-08-2020 11:22:08 (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 CAVIT :: Y	Initial Entry

2.a Record Identifier:

Date	Location	User	Value	Reason
Oct-08-2020 11:22:08 (UTC-08:00)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: 1	Initial Entry

090177e196ae30e4\Final\Final On: 01-Apr-2021 04:18 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form: VITAL SIGNS - TEMP - eCRF Audit Trail History

Form Version: 15-Sep-2020 21:54

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1054

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

Subject No: 10541168

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

Pacific Time (US & Canada)				
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2.a Temperature:

Date	Location	User	Value	Reason
Oct-08-2020 11:22:08 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: 98.3	Initial Entry

2.a Unit:

Date	Location	User	Value	Reason
Oct-08-2020 11:22:08 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: F	Initial Entry

2.a Temperature Location:

Date	Location	User	Value	Reason
Oct-08-2020 11:22:08 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: ORAL CAVITY	Initial Entry

090177e196ae30e4\Final\Final On: 01-Apr-2021 04:18 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

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

Form Version: 15-Sep-2020 21:51

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1054

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

Subject No: 10541168

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

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1. Lab Panel:

Date	Location	User	Value	Reason
Oct-08-2020 11:23:28 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Not Applicable	Initial Entry
Oct-08-2020 11:22:50 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry:	Transcription Error
Oct-08-2020 11:22:21 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: URINALYSIS	Initial Entry

2. Lab Sub-Panel:

Date	Location	User	Value	Reason
Oct-08-2020 11:23:28 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Not Applicable	Initial Entry

090177e196ae30e4\Final\Final On: 01-Apr-2021 04:18 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

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

Form Version: 15-Sep-2020 21:51

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1054

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

Subject No: 10541168

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

Oct-08-2020 11:22:50 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry:	Transcription Error
Oct-08-2020 11:22:21 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: PREGNANCY	Initial Entry

3. Collection Date:

Date	Location	User	Value	Reason
Oct-08-2020 11:23:28 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: Not Applicable	Initial Entry
Oct-08-2020 11:22:50 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry:	Transcription Error
Oct-08-2020 11:22:21 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: Oct/8/2020	Initial Entry

090177e196ae30e4\Final\Final On: 01-Apr-2021 04:18 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

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

Form Version: 15-Sep-2020 21:51

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1054

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

Subject No: 10541168

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

4. Laboratory Name and Address (Derived)

Date	Location	User	Value	Reason
Oct-08-2020 11:23:28 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Not Applicable	Initial Entry
Oct-08-2020 11:22:50 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry:	Transcription Error
Oct-08-2020 11:22:21 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: STUDY SITE	Initial Entry

5. Specimen Type:

Date	Location	User	Value	Reason
Oct-08-2020 11:23:28 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Not Applicable	Initial Entry
Oct-08-2020 11:22:50 (UTC-08:00)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry:	Transcription Error

090177e196ae30e4\Final\Final On: 01-Apr-2021 04:18 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

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

Form Version: 15-Sep-2020 21:51

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1054

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

Subject No: 10541168

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

Pacific Time (US & Canada)				
Oct-08-2020 11:22:21 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: URINE	Initial Entry

6.a

Date	Location	User	Value	Reason
Oct-08-2020 11:23:28 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sponsor- Defined Identifier: Not Applicable Test:: Choriogon adotropin Beta_PX1 13 Result:: Not Applicable Not Done:: Not Applicable	Initial Entry
Oct-08-2020 11:23:09 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sponsor- Defined Identifier:	Transcription Error

090177e196ae30e4\Final\Final On: 01-Apr-2021 04:18 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

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

Form Version: 15-Sep-2020 21:51

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1054

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

Subject No: 10541168

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

			Test:: Choriogon adotropin Beta_PX1 13 Result:: Not Done::	
Oct-08-2020 11:22:21 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sponsor- 113 Defined Identifier: Test:: Choriogon adotropin Beta_PX1 13 Result:: NEGATIVE Not Done::	Initial Entry

6.a Sponsor ID:

Date	Location	User	Value	Reason
Oct-08-2020 11:23:28 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Not Applicable	Initial Entry

090177e196ae30e4\Final\Final On: 01-Apr-2021 04:18 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

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

Form Version: 15-Sep-2020 21:51

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1054

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

Subject No: 10541168

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

Oct-08-2020 11:23:09 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry:	Transcription Error
Oct-08-2020 11:22:21 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 113	Initial Entry

6.a Test:

Date	Location	User	Value	Reason
Oct-08-2020 11:22:21 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: Choriogonadotropin B eta_PX113	Initial Entry

6.a Result:

Date	Location	User	Value	Reason
Oct-08-2020 11:23:28 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: Not Applicable	Initial Entry
Oct-08-2020 11:23:09 (UTC-08:00)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry:	Transcription Error

090177e196ae30e4\Final\Final On: 01-Apr-2021 04:18 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

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

Form Version: 15-Sep-2020 21:51

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1054

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

Subject No: 10541168

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

Pacific Time (US & Canada)				
Oct-08-2020 11:22:21 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: NEGATIVE	Initial Entry

6.a Not Done:

Date	Location	User	Value	Reason
Oct-08-2020 11:23:28 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: Not Applicable	Initial Entry

090177e196ae30e4\Final\Final On: 01-Apr-2021 04:18 (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: 10541168

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

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1. Data Origin

Date	Location	User	Value	Reason
Oct-08-2020 11:23:47 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Oct-08-2020 11:23:47 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: NASAL_SWAB	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Oct-08-2020 14:54:28 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Oct-08-2020 11:23:47	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is

090177e196ae30e4\Final\Final On: 01-Apr-2021 04:18 (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: 10541168

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

(UTC-08:00) Pacific Time (US & Canada)				Yes, however no barcodes are entered. Please review and correct as appropriate.
Oct-08-2020 11:23:47 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: YES Date of Collection: Oct/8/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Oct-08-2020 14:54:28 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: Sample ID BPYX0 : M	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Oct-08-2020 14:54:28 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: BPYX0M	Initial Entry

090177e196ae30e4\Final\Final On: 01-Apr-2021 04:18 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1054

Subject No: 10541168

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): 29-Mar-2021 04:44

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1. Was there a temporary delay of vaccination?

Date	Location	User	Value	Reason
Oct-08-2020 11:24:00 (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
Oct-08-2020 11:24:00 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: BLINDED THERAPY	Initial Entry

3. Formulation:

Date	Location	User	Value	Reason
Oct-08-2020 11:24:00 (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
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090177e196ae30e4\Final\Final On: 01-Apr-2021 04:18 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1054

Subject No: 10541168

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): 29-Mar-2021 04:44

Oct-08-2020 11:24:00 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: Oct/8/2020 08:33	Initial Entry
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5. Anatomical Location:

Date	Location	User	Value	Reason
Oct-08-2020 11:24:00 (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
Oct-08-2020 11:24:00 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: LEFT	Initial Entry

7. Route:

Date	Location	User	Value	Reason
Oct-08-2020 11:24:00 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INTRAMUSCULAR	Initial Entry

090177e196ae30e4\Final\Final On: 01-Apr-2021 04:18 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form: VACCINATION - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1054

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

Subject No: 10541168

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

10. Timeframe Subject Was Observed

Date	Location	User	Value	Reason
Oct-08-2020 11:24:00 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: THE PROTOCOL SPE CIFIED OBSERVATIO N PERIOD	Initial Entry

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

Date	Location	User	Value	Reason
Oct-08-2020 11:24:00 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: YES	Initial Entry

090177e196ae30e4\Final\Final On: 01-Apr-2021 04:18 (GMT)

Header Text: c4591001

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

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

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

Subject No: 10541168 **Subject Initials:** ---

Generated By: (b) (4) **Generated Time (GMT):** 29-Mar-2021 04:44

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1. Date of Visit

Date	Location	User	Value	Reason
Nov-05-2020 08:42:49 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: Nov/5/2020	Initial Entry

090177e196ae30e4\Final\Final On: 01-Apr-2021 04:18 (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: 10541168 **Subject Initials:** ---

Generated By: (b) (4) **Generated Time (GMT):** 29-Mar-2021 04:44

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1. Data Origin

Date	Location	User	Value	Reason
Nov-05-2020 08:43:02 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Nov-05-2020 08:43:02 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SERUM	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Nov-05-2020 13:53:59 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Nov-05-2020 08:43:02	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is

090177e196ae30e4\Final\Final On: 01-Apr-2021 04:18 (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: 10541168 **Subject Initials:** ---

Generated By: (b) (4) **Generated Time (GMT):** 29-Mar-2021 04:44

(UTC-08:00) Pacific Time (US & Canada)				Yes, however no barcodes are entered. Please review and correct as appropriate.
Nov-05-2020 08:43:02 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: YES Date of Collection: Nov/5/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Nov-05-2020 13:53:59 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: Sample ID BM98B : K	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Nov-05-2020 13:53:59 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: BM98BK	Initial Entry

5.b

090177e196ae30e4\Final\Final On: 01-Apr-2021 04:18 (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: 10541168 **Subject Initials:** ---

Generated By: (b) (4) **Generated Time (GMT):** 29-Mar-2021 04:44

Date	Location	User	Value	Reason
Nov-05-2020 13:54:11 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: Sample ID BM98B : L	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Nov-05-2020 13:54:11 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: BM98BL	Initial Entry

090177e196ae30e4\Final\Final On: 01-Apr-2021 04:18 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1054

Subject No: 10541168

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - Audit Trail

Form Status:

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

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

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Date	Location	User	Value	Reason
Jan-22-2021 14:55:30 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Form Created	

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete

Site No: 1054

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

Subject No: 10541168

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

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1. Category:

Date	Location	User	Value	Reason
Jan-22-2021 14:55:30 (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
Jan-22-2021 14:55:30 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 1	Initial Entry

3. Adverse Event:

(If possible specify diagnosis, not individual symptoms)

Date	Location	User	Value	Reason
Mar-09-2021 10:24:16 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: closed fracture, transverse process of 1 umbar vertebra	Changed Information
Feb-25-2021 20:38:29	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Query closed; will follow for

090177e196ae30e4\Final\Final On: 01-Apr-2021 04:18 (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

Site No: 1054

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

Subject No: 10541168

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

(UTC-08:00) Pacific Time (US & Canada)		(b) (4), (b) (6)		requested vertebral body # information.
Feb-25-2021 14:15:20 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Query 1: Answered	Per latest SAE f/u submission on 25Feb21, specifics on lumbar vertebral fx still unknown, as med recs from pt's hospital stay are still pending.
Jan-26-2021 06:02:38 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	Clinical Please specify which lumbar vertebral body was fractured, in both AE and in SAE safety update
Jan-22-2021 14:55:30 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: lumbar vertebral fr acture	Initial Entry

4. Start Date Time:

090177e196ae30e4\Final\Final On: 01-Apr-2021 04:18 (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

Site No: 1054

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

Subject No: 10541168

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

Date	Location	User	Value	Reason
Jan-22-2021 14:55:30 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: Dec/3/2020 UNK:UNK	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Jan-22-2021 14:55:30 (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
Jan-22-2021 14:55:30 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: 3	Initial Entry

7. Is the adverse event serious?

If Yes, NOTIFY PFIZER IMMEDIATELY.

Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important

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Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete

Site No: 1054

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

Subject No: 10541168

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).

Date	Location	User	Value	Reason
Feb-28-2021 17:44:08 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Closed	Query closed; will follow for requested COVID test information.
Feb-26-2021 08:17:50 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Query 3: Answered	The SAE f/u submitted yesterday on 25-Feb-21 has that information. If submission is inadequate, please indicate why to us (site #1054) it is so.
Feb-25-2021 20:38:56 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Reissued: Opened	Clinical – Thank you. If NO hospital COVID test was performed is known, please submit this information on a follow-up SAE form, as pertinent information for

090177e196ae30e4\Final\Final On: 01-Apr-2021 04:18 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

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Form Status: Data Complete

Site No: 1054

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

Subject No: 10541168

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

				this trial.
Feb-25-2021 14:16:42 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Query 3: Answered	Per latest SAE f/u submission on 25Feb21, pt did not get a COVID test during their hospitalization.
Jan-26-2021 06:37:17 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Closed	Response satisfies query
Jan-26-2021 06:03:24 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Opened	Clinical COVID test status (yes/no) during Hosp and Rehab stay was not reported in the SAE. Please submit a follow-up SAE form [#2021067301] to document if COVID testing was performed (YES/NO or info not available) and if yes, the date and results.

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Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete

Site No: 1054

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

Subject No: 10541168

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

Jan-25-2021 08:22:18 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Query 2: Answered	As written; this SAE report was confirmed as sent on 22Jan2021 @ 12:57:07 pm PST from site's fax number (local ID = 12133534642).
Jan-25-2021 05:18:43 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Opened	SAE RECON: lumbar vertebral fracture(Onset date:03Dec2020) is not reported to Safety database but marked serious on AE CRF. Confirm seriousness and report to Pfizer immediately. If this event is not serious, downgrade the event on AE CRF
Jan-25-2021 05:17:50 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Deleted	Query can be addressed internally

090177e196ae30e4\Final\Final On: 01-Apr-2021 04:18 (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

Site No: 1054

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

Subject No: 10541168

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

<p>Jan-22-2021 14:55:30 (UTC-08:00) Pacific Time (US & Canada)</p>	<p>ACV0PFEINFP6000</p>	<p>auto query (autoquery)</p>	<p>Query 1: Candidate</p>	<p>For AE lumbar vertebral fracture: Response to "Is the adverse event serious?" is 'Yes' but "Serious Adverse Event Number" is blank.</p>
<p>Jan-22-2021 14:55:30 (UTC-08:00) Pacific Time (US & Canada)</p>	<p>ACV0PFEINFP6000</p>	<p>Steven Choi (b) (4)</p>	<p>Data Entry: YES Is this serious event associated with congenital anomaly or birth defect? NO Did this serious event result in death? NO Did this serious event require or prolong hospitalization? YES</p>	<p>Initial Entry</p>

090177e196ae30e4\Final\Final On: 01-Apr-2021 04:18 (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

Site No: 1054

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

Subject No: 10541168

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

			<p>Did this serious event result in persistent or significant disability/incapacity?</p> <p style="text-align: center;">NO</p> <p>Is this serious event life threatening?</p> <p style="text-align: center;">NO</p> <p>Other medically important serious event</p> <p style="text-align: center;">NO</p>
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8. Is this adverse event the result of a study Medication Error?
If Yes, record the type of medication error on the Medication Error Log.

Date	Location	User	Value	Reason
Jan-22-2021 14:55:30 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	<u>Data Entry:</u> NO	Initial Entry

9. Is this event related to study treatment:

Date	Location	User	Value	Reason
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Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete

Site No: 1054

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

Subject No: 10541168

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

Jan-22-2021 14:55:30 (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> pedestrian vs motor vehicle accident	Initial Entry
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10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Jan-22-2021 14:55:30 (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
Jan-22-2021 14:55:30 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: YES	Initial Entry

090177e196ae30e4\Final\Final On: 01-Apr-2021 04:18 (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

Site No: 1054

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

Subject No: 10541168

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Jan-22-2021 14:55:30 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	<u>Data Entry:</u> YES	Initial Entry

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

Date	Location	User	Value	Reason
Jan-22-2021 14:55:30 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	<u>Data Entry:</u> RECOVERING/RES OLVING	Initial Entry

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

Date	Location	User	Value	Reason
Jan-22-2021 14:55:30 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	<u>Data Entry:</u> NO	Initial Entry

15. Serious Adverse Event Number: For Pfizer Use Only

Date	Location	User	Value	Reason
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090177e196ae30e4\Final\Final On: 01-Apr-2021 04:18 (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

Site No: 1054

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

Subject No: 10541168

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

Jan-26-2021 06:36:49 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry: 2021067301	Initial Entry
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Header Text: c4591001

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

Form Version: 15-Sep-2020 21:55 **Form Status:** Data Complete, Locked, Frozen, Verified

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

Subject No: 10541168 **Subject Initials:** ---

Generated By: (b) (4) **Generated Time (GMT):** 29-Mar-2021 04:44

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1. Date of Completion/Discontinuation/Death :

Date	Location	User	Value	Reason
Nov-05-2020 08:43:28 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: Nov/5/2020	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Nov-05-2020 08:43:28 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: VACCINATION	Initial Entry

3. Status:

Date	Location	User	Value	Reason
Nov-05-2020 08:43:28 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: COMPLETED	Initial Entry

090177e196ae30e4\Final\Final On: 01-Apr-2021 04:18 (GMT)

Header Text: c4591001

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

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

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

Subject No: 10541168 **Subject Initials:** ---

Generated By: (b) (4) **Generated Time (GMT):** 29-Mar-2021 04:44

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1. Date of Visit

Date	Location	User	Value	Reason
Feb-10-2021 09:44:51 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	<u>Data Entry:</u> Feb/4/2021	Initial Entry

090177e196ae30e4\Final\Final On: 01-Apr-2021 04:18 (GMT)

Header Text: c4591001

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

Form Version: 10-Dec-2020 02:25 **Form Status:** Data Complete, Frozen

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

Subject No: 10541168 **Subject Initials:** ---

Generated By: (b) (4) **Generated Time (GMT):** 29-Mar-2021 04:44

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

Date	Location	User	Value	Reason
Feb-10-2021 09:45:26 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Feb-10-2021 09:45:00 (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-10-2021 09:45:00 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: Participant is willing to return for Vaccina tion 3 Participant is: eligible and NOT confirmed to hav e received only p	Initial Entry

090177e196ae30e4\Final\Final On: 01-Apr-2021 04:18 (GMT)

Header Text: c4591001

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

Form Version: 10-Dec-2020 02:25 **Form Status:** Data Complete, Frozen

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

Subject No: 10541168 **Subject Initials:** ---

Generated By: (b) (4) **Generated Time (GMT):** 29-Mar-2021 04:44

			lacebo at Vaccina tion 1/2	
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Header Text: c4591001

Visit: Disposition - Unscheduled

Form: TREATMENT UNBLINDED - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1054

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

Subject No: 10541168

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

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1. Date Treatment Unblinded :

Date	Location	User	Value	Reason
Feb-10-2021 09:45:26 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: Feb/4/2021	Initial Entry

2. Primary Reason for Unblinding:

Date	Location	User	Value	Reason
Feb-10-2021 09:45:26 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: ASSESS ELIGIBILIT Y FOR ADDITIONA L VACCINATION	Initial Entry

090177e196ae30e4\Final\Final On: 01-Apr-2021 04:18 (GMT)

Header Text: c4591001

Visit: Subject Status - Unscheduled

Form: SUBJECT STATUS - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Verified

Site No: 1054

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

Subject No: 10541168

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

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1. Subject Status

Date	Location	User	Value	Reason
Nov-05-2020 08:43:28 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: FOLLOW-UP	Initial Entry
Sep-17-2020 13:57:12 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: ENROLLED/RANDOMIZED	Initial Entry
Sep-17-2020 13:51:05 (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
Nov-05-2020 08:43:28 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Nov/5/2020	Initial Entry
Sep-17-2020	ACV0PFEINFP6000	auto calc	Data Entry:	Initial Entry

090177e196ae30e4\Final\Final On: 01-Apr-2021 04:18 (GMT)

Header Text: c4591001

Visit: Subject Status - Unscheduled

Form: SUBJECT STATUS - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Verified

Site No: 1054

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

Subject No: 10541168

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

13:57:12 (UTC-08:00) Pacific Time (US & Canada)		(autocalc)	Sep/17/2020	
Sep-17-2020 13:51:05 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sep/17/2020	Initial Entry

090177e196ae30e4\Final\Final On: 01-Apr-2021 04:18 (GMT)

Header Text: c4591001

Visit: Investigator Signature -
Unscheduled

Form Version: 22-Apr-2020 21:04

Site No: 1054

Subject No: 10541168

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): 29-Mar-2021 04:44

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1. Casebook Signature

Date	Location	User	Value	Reason
Sep-23-2020 10:24:41 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: Click Here to Enable	Initial Entry

090177e196ae30e4\Final\Final On: 01-Apr-2021 04:18 (GMT)