

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: 10541173

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

Header Text: c4591001

Visit: COHORT_SELECTION

Form Version: 22-Apr-2020 21:02

Site No: 1054

Subject No: 10541173

Generated By: (b) (4)

Form: MAIN INFORMED CONSENT

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Informed Consent

1.	Consent Was:	OBTAINED Date Written Consent Obtained Sep/18/2020
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Header Text: c4591001

Visit: COHORT_SELECTION

Form Version: 15-Sep-2020 21:54

Site No: 1054

Subject No: 10541173

Generated By: (b) (4)

Form: DEMOGRAPHY

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Demography

1.	Subject ID	[10541173]
2.	Birth Date:	(b) (6) /1961
3.	Sex:	MALE
4.	Ethnicity:	HISPANIC OR LATINO(A) OR OF SPANISH ORIGIN
5.	Race: (Check X all that apply):	WHITE
6.	Racial Designation:	

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:02

Site No: 1054

Subject No: 10541173

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/18/2020
2.	Erroneous Visit	

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 15-Sep-2020 21:53

Site No: 1054

Subject No: 10541173

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

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 15-Sep-2020 21:52

Site No: 1054

Subject No: 10541173

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/18/2020
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: 10541173

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:	[appendectomy]
	Start Date:	May/UNK/2005
	Ongoing:	NO End Date: May/UNK/2005
1.b	Line/MH Number:	[2]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[appendicitis]
	Start Date:	May/UNK/2005
	Ongoing:	NO End Date: May/UNK/2005
1.c	Line/MH Number:	[3]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[abdominal scar]
	Start Date:	May/UNK/2005
	Ongoing:	YES
1.d	Line/MH Number:	[4]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[bilateral lower legs edema 1+]
	Start Date:	UNK/UNK/2015
	Ongoing:	YES

090177e196ae30e5\Final\Final On: 01-Apr-2021 04:19 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1054

Subject No: 10541173

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.e	Line/MH Number:	[5]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[bilateral fungus toenails]
	Start Date:	UNK/UNK/2015
	Ongoing:	YES
1.f	Line/MH Number:	[6]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[nerve pain, cervical spine]
	Start Date:	Sep/11/2020
	Ongoing:	YES

090177e196ae30e5\Final\Final On: 01-Apr-2021 04:19 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 15-Sep-2020 21:57

Site No: 1054

Subject No: 10541173

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 Version: 15-Sep-2020 21:56

Site No: 1054

Subject No: 10541173

Generated By: (b) (4)

Form: VITAL SIGNS - BASELINE

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Vital Signs

1.	Date:	Sep/18/2020
2.	Weight:	[88.64]
3.	Unit:	kg
4.	Height:	[172.72]
5.	Unit:	cm
6.	Body Mass Index:	[29.7]

Vital Signs Details

7.a	Record Identifier:	1
	Temperature:	[97.6]
	Unit:	F
	Temperature Location:	ORAL CAVITY

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Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1054

Subject No: 10541173

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/18/2020
2.	Randomization Number:	[261406]
3.	Randomization Group:	[]

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1054

Subject No: 10541173

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

Generated Time (GMT): 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/18/2020
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[]

Aliquot

Please enter barcode for each aliquot.

5.a	Sample ID	[BM983G]
5.b	Sample ID	[BM983H]

090177e196ae30e5\Final\Final On: 01-Apr-2021 04:19 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1054

Subject No: 10541173

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

Generated Time (GMT): 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/18/2020
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[]

Aliquot

Please enter barcode for each aliquot.

5.a	Sample ID	[BM983J]
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090177e196ae30e5\Final\Final On: 01-Apr-2021 04:19 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:04

Site No: 1054

Subject No: 10541173

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/18/2020 11:50
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

090177e196ae30e5\Final\Final On: 01-Apr-2021 04:19 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 06-Jul-2020 21:53

Site No: 1054

Subject No: 10541173

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: 10541173

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/9/2020
2.	Erroneous Visit	

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 15-Sep-2020 21:54

Site No: 1054

Subject No: 10541173

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/9/2020
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Vital Signs Details

2.a	Record Identifier:	1
	Temperature:	[97.9]
	Unit:	F
	Temperature Location:	ORAL CAVITY

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:03

Site No: 1054

Subject No: 10541173

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

Generated Time (GMT): 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/9/2020
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	[BPYX1W]
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090177e196ae30e5\Final\Final On: 01-Apr-2021 04:19 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1054

Subject No: 10541173

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/9/2020 11:22
5.	Anatomical Location:	DELTOID MUSCLE
6.	Body Side:	LEFT
7.	Route:	INTRAMUSCULAR
8.	Actual Dose:	[]
9.	Unit:	
10.	Timeframe Subject Was Observed	THE PROTOCOL SPECIFIED OBSERVATION PERIOD
11.	Was the subject observed for at least the protocol specified observation period after investigational product administration?	YES

090177e196ae30e5\Final\Final On: 01-Apr-2021 04:19 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 1054

Subject No: 10541173

Generated By: (b) (4)

Form: DATE OF VISIT

Form Status: Data Complete, Frozen, Verified

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

Subject Initials: ---

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

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

Date of Visit

1.	Date of Visit	Not Done _____ //	Comments
2.	Erroneous Visit	Not Done _____	Comments

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form Version: 22-Apr-2020 21:03

Site No: 1054

Subject No: 10541173

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Status: Data Complete, Frozen, Verified

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

Subject Initials: ---

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

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

Electronic Sample Tracking

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

Aliquot

Please enter barcode for each aliquot.

5.	Sample ID	Not Done _____ []
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090177e196ae30e5\Final\Final On: 01-Apr-2021 04:19 (GMT)

Header Text: c4591001

Visit: V4_MONTH6_L

Form Version: 22-Apr-2020 21:02

Site No: 1054

Subject No: 10541173

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: 10541173

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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090177e196ae30e5\Final\Final On: 01-Apr-2021 04:19 (GMT)

Header Text: c4591001

Visit: V5_MONTH12_L

Form Version: 22-Apr-2020 21:02

Site No: 1054

Subject No: 10541173

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: 10541173

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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090177e196ae30e5\Final\Final On: 01-Apr-2021 04:19 (GMT)

Header Text: c4591001

Visit: V6_MONTH24_L

Form Version: 22-Apr-2020 21:02

Site No: 1054

Subject No: 10541173

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: 10541173

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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090177e196ae30e5\Final\Final On: 01-Apr-2021 04:19 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** DATE OF VISIT - ILLNESS ONSET
on Oct/20/2020

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: 10541173

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	Oct/20/2020
2.	Erroneous Visit	

COVID-19 Illness Visit

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

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 on Oct/20/2020

Form Version: 10-Oct-2020 16:02

Form Status: Data Complete, Frozen, Verified

Site No: 1054

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

Subject No: 10541173

Subject Initials: ---

Generated By: (b) (4)

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

[eCRF Audit Trail History](#)

Signs and Symptoms

1.	Date of Assessment:	Oct/20/2020
2.	Date of First Symptom Started:	Oct/19/2020
3.	Symptoms Ongoing?	NO Date of Last Symptom Resolved: Jan/UNK/2021

Symptoms

4.a	Symptoms:	FEVER
	Was symptom present?	NO
4.b	Symptoms:	NEW OR INCREASED COUGH
	Was symptom present?	YES
4.c	Symptoms:	NEW OR INCREASED SHORTNESS OF BREATH
	Was symptom present?	NO
4.d	Symptoms:	CHILLS
	Was symptom present?	YES
4.e	Symptoms:	NEW OR INCREASED MUSCLE PAIN
	Was symptom present?	YES
4.f	Symptoms:	NEW LOSS OF TASTE OR SMELL
	Was symptom present?	NO
4.g	Symptoms:	NEW OR INCREASED SORE THROAT
	Was symptom present?	NO
4.h	Symptoms:	DIARRHEA
	Was symptom present?	YES

090177e196ae30e5\Final\Final On: 01-Apr-2021 04:19 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 on Oct/20/2020

Form Version: 10-Oct-2020 16:02

Form Status: Data Complete, Frozen, Verified

Site No: 1054

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

Subject No: 10541173

Subject Initials: ---

Generated By: (b) (4)

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

4.i	Symptoms:	VOMITING
	Was symptom present?	NO

Symptoms - Other

5.	Symptoms - Other Text:	[]
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Header Text: c4591001

Visit: POT_COVID_ILL 1

Form: MICROBIOLOGY SPECIMEN

Form Version: 06-Jul-2020 21:54

Site No: 1054

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

Subject No: 10541173

Subject Initials: ---

Generated By: (b) (4)

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

#	Date of Collection	Specimen Type	Specimen Collection Location	Assay Code and Description	Device Type	Form Instance
1.	Oct/28/2020	SWABBED MATERIAL	NASOPHARYNX	SEVERE ACUTE RESP SYNDROME CORONAVIRUS 2	SARS-COV-2 DIAGNOSTIC TEST	Repeating Pages

090177e196ae30e5\Final\Final On: 01-Apr-2021 04:19 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** MICROBIOLOGY SPECIMEN
on Oct/20/2020

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen, Verified

Site No: 1054

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

Subject No: 10541173

Subject Initials: ---

Generated By: (b) (4)

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

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[Form Comments](#)
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[Form Audit Trail](#)

Microbiology Specimen

1.	Actual Date of Collection:	Oct/28/2020	Comments
2.	Specimen Type:	SWABBED MATERIAL	Comments
3.	Specimen Collection Location:	NASOPHARYNX	Comments
4.	Assay Code and Description:	SEVERE ACUTE RESP SYNDROME CORONAVIRUS 2	Comments
5.	Device Type:	SARS-COV-2 DIAGNOSTIC TEST	Comments
6.	Trade Name:	OTHER	Comments
7.	Test Result:	NEGATIVE	Comments
8.	Comments/Findings/Details:	[]	Comments
9.	Trade Name Other, Specify:	[CLIA-certified laboratory]	Comments

090177e196ae30e5\Final\Final On: 01-Apr-2021 04:19 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB SELF on Oct/20/2020

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: 10541173

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_SELF
3.	Sample Collected?	NO
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[Swab was collected on site.]

Aliquot

Please enter barcode for each aliquot.

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

090177e196ae30e5\Final\Final On: 01-Apr-2021 04:19 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB
on Oct/20/2020

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: 10541173

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/20/2020
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[]

Aliquot

Please enter barcode for each aliquot.

5.a	Sample ID	[BM983Y]
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090177e196ae30e5\Final\Final On: 01-Apr-2021 04:19 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** HEALTH CARE UTILIZATION
on Oct/20/2020

Form Version: 10-Oct-2020 15:59

Form Status: Data Complete, Frozen, Verified

Site No: 1054

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

Subject No: 10541173

Subject Initials: ---

Generated By: (b) (4)

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

[eCRF Audit Trail History](#)

Health Care Utilization

1.a	Physician or Healthcare Professional:	SPECIALIST
	Occurrence of Visits or Contacts:	NO
1.b	Physician or Healthcare Professional:	EMERGENCY ROOM
	Occurrence of Visits or Contacts:	NO
1.c	Physician or Healthcare Professional:	PRIMARY CARE PHYSICIAN
	Occurrence of Visits or Contacts:	NO
1.d	Physician or Healthcare Professional:	URGENT CARE
	Occurrence of Visits or Contacts:	NO
1.e	Physician or Healthcare Professional:	TELEPHONE CONSULTATION
	Occurrence of Visits or Contacts:	NO
1.f	Physician or Healthcare Professional:	OTHER
	Occurrence of Visits or Contacts:	NO

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?	NO
----	--	----

090177e196ae30e5\Final\Final On: 01-Apr-2021 04:19 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1

Form: RESPIRATORY TREATMENT

Form Version: 06-Jul-2020 21:53

Site No: 1054

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

Subject No: 10541173

Subject Initials: ---

Generated By: (b) (4)

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

#	Treatment Identifier	Con Non-Drug Treatments Pre-specified	Treatment	Treatment	Start Date	Form Instance
1.	Not Applicable	Not Applicable	Not Applicable	Not Applicable	Not Applicable	Repeating Pages

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** RESPIRATORY TREATMENT
on Oct/20/2020

Form Version: 06-Jul-2020 21:53

Form Status: Data Complete, Frozen, Verified

Site No: 1054

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

Subject No: 10541173

Subject Initials: ---

Generated By: (b) (4)

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

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Respiratory Treatment

1.	What is the treatment Identifier?	Not Applicable _____ []	Comments
2.	Concomitant Non-drug Treatment Pre-specified:	Not Applicable _____	Comments
3.	Treatment:	Not Applicable _____	Comments
4.	Treatment:	Not Applicable _____ []	Comments
5.	Start Date:	Not Applicable _____ //	Comments
6.	Ongoing?	Not Applicable _____	Comments

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Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** ILLNESS DETAILS
on Oct/20/2020

Form Version: 06-Jul-2020 21:52

Form Status: Data Complete, Frozen, Verified

Site No: 1054

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

Subject No: 10541173

Subject Initials: ---

Generated By: (b) (4)

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

[eCRF Audit Trail History](#)

Illness Details

1.	Category of Clinical Event:	POTENTIAL COVID-19 ILLNESS
2.	Was a diagnosis obtained for Potential COVID-19 Illness?	NO
3.	Toxicity Grade:	2

Header Text: c4591001

Visit: POT_COVID_ILL 1

Form: ILLNESS DETAILS - SEVERE

Form Version: 17-Jul-2020 21:55

Site No: 1054

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

Subject No: 10541173

Subject Initials: ---

Generated By: (b) (4)

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

#	Category of Clinical Event:	Subcategory of Clinical Event	Diagnosis Obtained	Toxicity Grade	Form Instance
1.	Not Applicable	Not Applicable	Not Applicable	Not Applicable	Repeating Pages

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** ILLNESS DETAILS - SEVERE
on Oct/20/2020

Form Version: 17-Jul-2020 21:55

Form Status: Data Complete, Frozen, Verified

Site No: 1054

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

Subject No: 10541173

Subject Initials: ---

Generated By: (b) (4)

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

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Illness Details

1.	Category of Clinical Event:	Not Applicable _____	Comments
2.	Subcategory of Clinical Event:	Not Applicable _____	Comments
3.	Was a diagnosis obtained?	Not Applicable _____	Comments
4.	Toxicity Grade:	Not Applicable _____	Comments

Header Text: c4591001

Visit: POT_COVID_ILL 1

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY

Form Version: 15-Sep-2020 21:51

Site No: 1054

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

Subject No: 10541173

Subject Initials: ---

Generated By: (b) (4)

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

#	Category for Lab Test	Vendor Name	Collection Date:	Specimen Type	Lab Result			Form Instance
1.	Not Applicable	Not Applicable	Not Applicable	Not Applicable	Sponsor-Defined Identifier	Test:	Result:	Repeating Pages
					Not Applicable	Not Applicable	Not Applicable	
					Not Applicable	Not Applicable	Not Applicable	
					Not Applicable	Not Applicable	Not Applicable	
					Not Applicable	Not Applicable	Not Applicable	
					Not Applicable	Not Applicable	Not Applicable	
					Not Applicable	Not Applicable	Not Applicable	
					Not Applicable	Not Applicable	Not Applicable	

090177e196ae30e5\Final\Final On: 01-Apr-2021 04:19 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY on Oct/20/2020

Form Version: 15-Sep-2020 21:51

Form Status: Data Complete, Frozen, Verified

Site No: 1054

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

Subject No: 10541173

Subject Initials: ---

Generated By: (b) (4)

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

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[eCRF Audit Trail History](#)

Lab Chemistry Details

1.	Lab Panel:	Not Applicable _____	Comments
2.	Laboratory Name and Address	Not Applicable _____ []	Comments
3.	Collection Date:	Not Applicable _____ //	Comments
4.	Specimen Type:	Not Applicable _____	Comments

Lab Result

5.a	Sponsor ID:	Not Applicable _____ []	Comments
	Test:	C Reactive Protein_PX329	
	Result:	Not Applicable _____ []	Comments
	Not Done:	Not Applicable _____	Comments
	LNMT	Not Applicable _____ Low [] High [] Unit	Comments

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Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY
on Oct/20/2020

Form Version: 15-Sep-2020 21:51

Form Status: Data Complete, Frozen, Verified

Site No: 1054

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

Subject No: 10541173

Subject Initials: ---

Generated By: (b) (4)

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

5.b	Sponsor ID:	Not Applicable _____ []	Comments
	Test:	Alanine Aminotransferase_PX30	
	Result:	Not Applicable _____ []	Comments
	Not Done:	Not Applicable _____	Comments
	LNMT	Not Applicable _____ Low [] High [] Unit	Comments
5.c	Sponsor ID:	Not Applicable _____ []	Comments
	Test:	Aspartate Aminotransferase_PX28	
	Result:	Not Applicable _____ []	Comments
	Not Done:	Not Applicable _____	Comments
	LNMT	Not Applicable _____ Low [] High [] Unit	Comments

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Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY on Oct/20/2020

Form Version: 15-Sep-2020 21:51

Form Status: Data Complete, Frozen, Verified

Site No: 1054

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

Subject No: 10541173

Subject Initials: ---

Generated By: (b) (4)

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

5.d	Sponsor ID:	Not Applicable _____ []	Comments
	Test:	Alkaline Phosphatase_PX35	
	Result:	Not Applicable _____ []	Comments
	Not Done:	Not Applicable _____	Comments
	LNMT	Not Applicable _____ Low [] High [] Unit	Comments
5.e	Sponsor ID:	Not Applicable _____ []	Comments
	Test:	Bilirubin_PX21	
	Result:	Not Applicable _____ []	Comments
	Not Done:	Not Applicable _____	Comments
	LNMT	Not Applicable _____ Low [] High [] Unit	Comments

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Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY on Oct/20/2020

Form Version: 15-Sep-2020 21:51

Form Status: Data Complete, Frozen, Verified

Site No: 1054

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

Subject No: 10541173

Subject Initials: ---

Generated By: (b) (4)

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

5.f	Sponsor ID:	Not Applicable _____ []	Comments
	Test:	Blood Urea Nitrogen_PX47	
	Result:	Not Applicable _____ []	Comments
	Not Done:	Not Applicable _____	Comments
	LNMT	Not Applicable _____ Low [] High [] Unit	Comments

5.g	Sponsor ID:	Not Applicable _____ []	Comments
	Test:	Creatinine_PX48	
	Result:	Not Applicable _____ []	Comments
	Not Done:	Not Applicable _____	Comments
	LNMT	Not Applicable _____ Low [] High [] Unit	Comments

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Header Text: c4591001

Visit: POT_COVID_ILL 1

Form: LOCAL LABORATORY DATA - REPEATING Hematology

Form Version: 15-Sep-2020 21:55

Site No: 1054

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

Subject No: 10541173

Subject Initials: ---

Generated By: (b) (4)

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

#	Category for Lab Test	Vendor Name (DERIVED)	Collection Date:	Specimen Type	Lab Result			Form Instance
1.	Not Applicable	Not Applicable	Not Applicable	Not Applicable	Sponsor-Defined Identifier	Test:	Result:	Repeating Pages
					Not Applicable	Not Applicable	Not Applicable	
					Not Applicable	Not Applicable	Not Applicable	
					Not Applicable	Not Applicable	Not Applicable	
					Not Applicable	Not Applicable	Not Applicable	
					Not Applicable	Not Applicable	Not Applicable	
					Not Applicable	Not Applicable	Not Applicable	
					Not Applicable	Not Applicable	Not Applicable	
					Not Applicable	Not Applicable	Not Applicable	
					Not Applicable	Not Applicable	Not Applicable	
					Not Applicable	Not Applicable	Not Applicable	
					Not Applicable	Not Applicable	Not Applicable	

090177e196ae30e5\Final\Final On: 01-Apr-2021 04:19 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** LOCAL LABORATORY DATA - REPEATING Hematology on Oct/20/2020

Form Version: 15-Sep-2020 21:55

Form Status: Data Complete, Frozen, Verified

Site No: 1054

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

Subject No: 10541173

Subject Initials: ---

Generated By: (b) (4)

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

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Laboratory Data Hematology

1.	Lab Panel:	Not Applicable _____	Comments
2.	Laboratory Name and Address	Not Applicable _____ []	Comments
3.	Collection Date:	Not Applicable _____ //	Comments
4.	Specimen Type:	Not Applicable _____	Comments

Lab Result

5.a	Sponsor ID:	Not Applicable _____ []	Comments
	Test:	Hemoglobin_PX1	
	Result:	Not Applicable _____ []	Comments
	Not Done:	Not Applicable _____	Comments
	LNMT	Not Applicable _____ Low [] High [] Unit	Comments

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Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** LOCAL LABORATORY DATA - REPEATING Hematology on Oct/20/2020

Form Version: 15-Sep-2020 21:55

Form Status: Data Complete, Frozen, Verified

Site No: 1054

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

Subject No: 10541173

Subject Initials: ---

Generated By: (b) (4)

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

5.b	Sponsor ID:	Not Applicable _____ []	Comments
	Test:	Hematocrit_PX2	
	Result:	Not Applicable _____ []	Comments
	Not Done:	Not Applicable _____	Comments
	LNMT	Not Applicable _____ Low [] High [] Unit	Comments

5.c	Sponsor ID:	Not Applicable _____ []	Comments
	Test:	Erythrocytes_PX3	
	Result:	Not Applicable _____ []	Comments
	Not Done:	Not Applicable _____	Comments
	LNMT	Not Applicable _____ Low [] High [] Unit	Comments

090177e196ae30e5\Final\Final On: 01-Apr-2021 04:19 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** LOCAL LABORATORY DATA - REPEATING Hematology on Oct/20/2020

Form Version: 15-Sep-2020 21:55

Form Status: Data Complete, Frozen, Verified

Site No: 1054

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

Subject No: 10541173

Subject Initials: ---

Generated By: (b) (4)

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

5.d	Sponsor ID:	Not Applicable _____ []	Comments
	Test:	Platelets_PX5	
	Result:	Not Applicable _____ []	Comments
	Not Done:	Not Applicable _____	Comments
	LNMT	Not Applicable _____ Low [] High [] Unit	Comments

5.e	Sponsor ID:	Not Applicable _____ []	Comments
	Test:	Leukocytes_PX7	
	Result:	Not Applicable _____ []	Comments
	Not Done:	Not Applicable _____	Comments
	LNMT	Not Applicable _____ Low [] High [] Unit	Comments

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Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** LOCAL LABORATORY DATA - REPEATING Hematology on Oct/20/2020

Form Version: 15-Sep-2020 21:55

Form Status: Data Complete, Frozen, Verified

Site No: 1054

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

Subject No: 10541173

Subject Initials: ---

Generated By: (b) (4)

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

5.f	Sponsor ID:	Not Applicable _____ []	Comments
	Test:	Neutrophils_PX608	
	Result:	Not Applicable _____ []	Comments
	Not Done:	Not Applicable _____	Comments
	LNMT	Not Applicable _____ Low [] High [] Unit	Comments

5.g	Sponsor ID:	Not Applicable _____ []	Comments
	Test:	Eosinophils_PX609	
	Result:	Not Applicable _____ []	Comments
	Not Done:	Not Applicable _____	Comments
	LNMT	Not Applicable _____ Low [] High [] Unit	Comments

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Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** LOCAL LABORATORY DATA - REPEATING Hematology on Oct/20/2020

Form Version: 15-Sep-2020 21:55

Form Status: Data Complete, Frozen, Verified

Site No: 1054

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

Subject No: 10541173

Subject Initials: ---

Generated By: (b) (4)

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

5.h	Sponsor ID:	Not Applicable _____ []	Comments
	Test:	Monocytes_PX612	
	Result:	Not Applicable _____ []	Comments
	Not Done:	Not Applicable _____	Comments
	LNMT	Not Applicable _____ Low [] High [] Unit	Comments

5.i	Sponsor ID:	Not Applicable _____ []	Comments
	Test:	Basophils_PX610	
	Result:	Not Applicable _____ []	Comments
	Not Done:	Not Applicable _____	Comments
	LNMT	Not Applicable _____ Low [] High [] Unit	Comments

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Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** LOCAL LABORATORY DATA - REPEATING Hematology on Oct/20/2020

Form Version: 15-Sep-2020 21:55

Form Status: Data Complete, Frozen, Verified

Site No: 1054

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

Subject No: 10541173

Subject Initials: ---

Generated By: (b) (4)

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

5.j	Sponsor ID:	Not Applicable _____ []	Comments
	Test:	Lymphocytes_PX611	
	Result:	Not Applicable _____ []	Comments
	Not Done:	Not Applicable _____	Comments
	LNMT	Not Applicable _____ Low [] High [] Unit	Comments

090177e196ae30e5\Final\Final On: 01-Apr-2021 04:19 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1

Form: VITAL SIGNS - COVID

Form Version: 15-Sep-2020 21:52

Site No: 1054

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

Subject No: 10541173

Subject Initials: ---

Generated By: (b) (4)

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

#	Date:	Vital Signs Details			Form Instance
1.	Not Applicable	Record Identifier:	Systolic:	Diastolic:	Repeating Pages
		Not Applicable	Not Applicable	Not Applicable	

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** VITAL SIGNS - COVID
on Oct/20/2020

Form Version: 15-Sep-2020 21:52

Form Status: Data Complete, Frozen, Verified

Site No: 1054

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

Subject No: 10541173

Subject Initials: ---

Generated By: (b) (4)

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

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Vital Signs

1.	Date:	Not Applicable _____ //	Comments
----	-------	-------------------------------	--------------------------

Vital Signs Details

2.a	Record Identifier:	Not Applicable _____ 1	
	Systolic:	Not Applicable _____ []	Comments
	Diastolic:	Not Applicable _____ []	Comments
	Respiratory Rate in respirations/minute:	Not Applicable _____ []	Comments
	Heart Rate in beats/minute:	Not Applicable _____ []	Comments

090177e196ae30e5\Final\Final On: 01-Apr-2021 04:19 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1

Form: VITAL SIGNS - PULSE OX ROOM AIR

Form Version: 15-Sep-2020 21:54

Site No: 1054

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

Subject No: 10541173

Subject Initials: ---

Generated By: (b) (4)

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

#	Date:	Vital Signs Details		Form Instance
1.	Not Applicable	Record Identifier:	Oxygen Saturation	Repeating Pages
		Not Applicable	Not Applicable	

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** VITAL SIGNS - PULSE OX ROOM AIR
on Oct/20/2020

Form Version: 15-Sep-2020 21:54

Form Status: Data Complete, Frozen, Verified

Site No: 1054

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

Subject No: 10541173

Subject Initials: ---

Generated By: (b) (4)

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

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

Vital Signs

1.	Date:	Not Applicable _____ //	Comments
----	-------	-------------------------------	--------------------------

Vital Signs Details

2.a	Record Identifier:	Not Applicable _____ 1	
	SPO2 Pulse Oximetry %	Not Applicable _____ []	Comments

090177e196ae30e5\Final\Final On: 01-Apr-2021 04:19 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1

Form: OXYGENATION PARAMETERS

Form Version: 06-Jul-2020 21:52

Site No: 1054

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

Subject No: 10541173

Subject Initials: ---

Generated By: (b) (4)

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

#	Date Time of Assessment	Arterial Blood Gases PaO2	FiO2 (Fraction of Inhaled Oxygen)	Form Instance
1.	Not Applicable	Not Applicable	Not Applicable	Repeating Pages

090177e196ae30e5\Final\Final On: 01-Apr-2021 04:19 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** OXYGENATION PARAMETERS
on Oct/20/2020

Form Version: 06-Jul-2020 21:52

Form Status: Data Complete, Frozen, Verified

Site No: 1054

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

Subject No: 10541173

Subject Initials: ---

Generated By: (b) (4)

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

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

Oxygenation Parameters

1.	Date Time of Assessment:	Not Applicable _____ //	Comments
2.	Arterial Blood Gases PaO2 (mmHg):	Not Applicable _____ []	Comments
3.	FiO2 (Fraction of Inhaled Oxygen):	Not Applicable _____ []	Comments

Header Text: c4591001

Visit: POT_COVID_ILL 1

Form: CONCOMITANT MEDICATIONS - VASOPRESSORS

Form Version: 06-Jul-2020 21:55

Site No: 1054

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

Subject No: 10541173

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.	Not Applicable	Not Applicable	Not Applicable	Not Applicable	Not Applicable	Repeating Pages

090177e196ae30e5\Final\Final On: 01-Apr-2021 04:19 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** CONCOMITANT MEDICATIONS - VASOPRESSORS
on Oct/20/2020

Form Version: 06-Jul-2020 21:55

Form Status: Data Complete, Frozen, Verified

Site No: 1054

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

Subject No: 10541173

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?	Not Applicable _____ []	Comments
2.	Category:	Not Applicable _____	Comments
3.	Concomitant Medications Pre-specified:	Not Applicable _____	Comments
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).	Not Applicable _____ []	Comments
5.	Start Date:	Not Applicable _____ //	Comments
6.	Ongoing?	Not Applicable _____	Comments

090177e196ae30e5\Final\Final On: 01-Apr-2021 04:19 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1

Form: IMAGING

Form Version: 06-Jul-2020 21:53

Site No: 1054

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

Subject No: 10541173

Subject Initials: ---

Generated By: (b) (4)

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

#	Date of Assessment	Location of Assessment	Imaging Method	Overall Assessment	Form Instance
1.	Not Applicable	Not Applicable	Not Applicable	Not Applicable	Repeating Pages

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** IMAGING
on Oct/20/2020

Form Version: 06-Jul-2020 21:53

Form Status: Data Complete, Frozen, Verified

Site No: 1054

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

Subject No: 10541173

Subject Initials: ---

Generated By: (b) (4)

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

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Imaging

1.	Date of Assessment:	Not Applicable _____ //	Comments
2.	Location of Assessment:	Not Applicable _____	Comments
3.	Type of Imaging Exam:	Not Applicable _____	Comments
4.	Assessment:	Not Applicable _____	Comments

090177e196ae30e5\Final\Final On: 01-Apr-2021 04:19 (GMT)

Header Text: c4591001

Visit: POT_COVID_CONVA 1 - Unscheduled **Form:** DATE OF VISIT - ILLNESS CONVALESCENT
Visit on Feb/22/2021

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Frozen, Verified

Site No: 1054

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

Subject No: 10541173

Subject Initials: ---

Generated By: (b) (4)

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

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Date of Visit

1.	Date of Visit	Feb/22/2021
2.	Erroneous Visit	

COVID-19 Illness Visit

3.	COVID-19 Illness Visit:	COVID_A1
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Header Text: c4591001

Visit: POT_COVID_CONVA 1 - Unscheduled
Visit on Feb/22/2021

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

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: 10541173

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: Feb/22/2021
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[]

Aliquot

Please enter barcode for each aliquot.

5.a	Sample ID	[BRMTKP]
5.b	Sample ID	[BRMTKR]
5.c	Sample ID	[BRMTKS]

090177e196ae30e5\Final\Final On: 01-Apr-2021 04:19 (GMT)

Header Text: c4591001

Visit: POT_COVID_REPEAT_SWAB - New
Unscheduled Visit

Form: DATE OF VISIT - REPEAT SWAB

Form Version: 10-Oct-2020 15:57

Form Status: Not Started

Site No: 1054

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

Subject No: 10541173

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:	
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Header Text: c4591001

Visit: POT_COVID_REPEAT_SWAB - New
Unscheduled Visit

Form: ELECTRONIC SAMPLE TRACKING - REPEAT SWAB

Form Version: 10-Oct-2020 15:57

Form Status: Not Started

Site No: 1054

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

Subject No: 10541173

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: Unplanned - New Unscheduled Visit

Form: DATE OF VISIT

Form Version: 22-Apr-2020 21:02

Form Status: Not Started

Site No: 1054

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

Subject No: 10541173

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: 10541173

Subject Initials: ---

Generated By: (b) (4)

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

Unplanned Assessments

1.	Assessments	
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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: 10541173

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	subacute bacterial endocarditis	Oct/28/2020 UNK:UNK	NO End Date Time: Dec/15/2020 UNK:UNK	Repeating Pages
2.	ADVERSE EVENT	2	pain L hamstring muscles	Oct/28/2020 UNK:UNK	YES	Repeating Pages
3.	ADVERSE EVENT	3	subarachnoid hemorrhage	Nov/5/2020 UNK:UNK	NO End Date Time: Nov/5/2020 UNK:UNK	Repeating Pages
4. DELETED	ADVERSE EVENT	4	bacterial endocarditis	Oct/28/2020 UNK:UNK	YES	Repeating Pages
5.	ADVERSE EVENT	5	intermittent atrial fibrillation	Nov/6/2020 UNK:UNK	YES	Repeating Pages
6.	ADVERSE EVENT	6	acute aortic insufficiency	Oct/28/2020 UNK:UNK	NO End Date Time: Dec/15/2020 UNK:UNK	Repeating Pages

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Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1054

Subject No: 10541173

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Frozen, Verified

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

Subject Initials: ---

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

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Adverse Event Report

1.	Category:	ADVERSE EVENT
2.	AE ID:	[1]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[subacute bacterial endocarditis]
4.	Start Date Time:	Oct/28/2020 UNK:UNK
5.	Is the adverse event still ongoing?	NO End Date Time: Dec/15/2020 UNK:UNK
6.	Toxicity Grade:	4
7.	Is the adverse event serious? If Yes, NOTIFY PFIZER IMMEDIATELY. Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).	YES Is this serious event associated with congenital anomaly or birth defect? NO Did this serious event result in death? NO Did this serious event require or prolong hospitalization? YES Did this serious event result in persistent or significant disability/incapacity? NO Is this serious event life threatening? YES Other medically important serious event NO
8.	Is this adverse event the result of a study Medication Error? If Yes, record the type of medication error on the Medication Error Log.	NO

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Header Text: c4591001

Visit: Logs - Unscheduled

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Site No: 1054

Subject No: 10541173

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Frozen, Verified

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

Subject Initials: ---

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

9.	Is this event related to study treatment:	NOT RELATED If Not Related to study treatment(s), this event is due to: OTHER If Other, specify: [gram positive cocci, source unknown]
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?:	RECOVERED/RESOLVED
14.	Did the adverse event cause the subject to be discontinued from the study?	NO
15.	Serious Adverse Event Number: For Pfizer Use Only	[2020423609]

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Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1054

Subject No: 10541173

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Verified

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

Subject Initials: ---

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Adverse Event Report

1.	Category:	ADVERSE EVENT
2.	AE ID:	[2]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[pain L hamstring muscles]
4.	Start Date Time:	Oct/28/2020 UNK:UNK
5.	Is the adverse event still ongoing?	YES
6.	Toxicity Grade:	2
7.	Is the adverse event serious? If Yes, NOTIFY PFIZER IMMEDIATELY. Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).	NO
8.	Is this adverse event the result of a study Medication Error? If Yes, record the type of medication error on the Medication Error Log.	NO
9.	Is this event related to study treatment:	NOT RELATED If Not Related to study treatment(s), this event is due to: OTHER If Other, specify: [heavy lifting]
10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE

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Header Text: c4591001

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Site No: 1054

Subject No: 10541173

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Verified

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

Subject Initials: ---

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

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

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Header Text: c4591001

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Subject No: 10541173

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Frozen, Verified

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

Subject Initials: ---

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Adverse Event Report

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

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Header Text: c4591001

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Site No: 1054

Subject No: 10541173

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Frozen, Verified

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

Subject Initials: ---

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9.	Is this event related to study treatment:	NOT RELATED If Not Related to study treatment(s), this event is due to: OTHER If Other, specify: [possibly secondary to underlying bacterial endocarditis (mycotic aneurysm)]
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?:	RECOVERED/RESOLVED
14.	Did the adverse event cause the subject to be discontinued from the study?	NO
15.	Serious Adverse Event Number: For Pfizer Use Only	[2020423609]

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Header Text: c4591001**Visit:** Logs - Unscheduled**Form Version:** 22-Apr-2020 21:02**Site No:** 1054**Subject No:** 10541173**Generated By:** (b) (4)**Form:** ADVERSE EVENT REPORT**Form Status:** Data Complete, Deleted, Verified**Site Name:** (1054) Collaborative Neuroscience Network, LLC.**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 04:44

*** THIS REPEATING FORM HAS BEEN DELETED ***

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Adverse Event Report

1.	Category:	ADVERSE EVENT
2.	AE ID:	[4]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[bacterial endocarditis]
4.	Start Date Time:	Oct/28/2020 UNK:UNK
5.	Is the adverse event still ongoing?	YES
6.	Toxicity Grade:	2
7.	Is the adverse event serious? If Yes, NOTIFY PFIZER IMMEDIATELY. Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).	NO
8.	Is this adverse event the result of a study Medication Error? If Yes, record the type of medication error on the Medication Error Log.	NO
9.	Is this event related to study treatment:	NOT RELATED If Not Related to study treatment(s), this event is due to: OTHER If Other, specify: [infection]

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Site No: 1054

Subject No: 10541173

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Deleted, Verified

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

Subject Initials: ---

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*** THIS REPEATING FORM HAS BEEN DELETED ***

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

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Site No: 1054

Subject No: 10541173

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Verified

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

Subject Initials: ---

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Adverse Event Report

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

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Header Text: c4591001

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Form Version: 22-Apr-2020 21:02

Site No: 1054

Subject No: 10541173

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Verified

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

Subject Initials: ---

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

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

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Header Text: c4591001

Visit: Logs - Unscheduled

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Site No: 1054

Subject No: 10541173

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Frozen, Verified

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

Subject Initials: ---

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Adverse Event Report

1.	Category:	ADVERSE EVENT
2.	AE ID:	[6]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[acute aortic insufficiency]
4.	Start Date Time:	Oct/28/2020 UNK:UNK
5.	Is the adverse event still ongoing?	NO End Date Time: Dec/15/2020 UNK:UNK
6.	Toxicity Grade:	4
7.	Is the adverse event serious? If Yes, NOTIFY PFIZER IMMEDIATELY. Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).	YES Is this serious event associated with congenital anomaly or birth defect? NO Did this serious event result in death? NO Did this serious event require or prolong hospitalization? YES Did this serious event result in persistent or significant disability/incapacity? NO Is this serious event life threatening? YES Other medically important serious event NO
8.	Is this adverse event the result of a study Medication Error? If Yes, record the type of medication error on the Medication Error Log.	NO

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Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1054

Subject No: 10541173

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Frozen, Verified

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

Subject Initials: ---

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

9.	Is this event related to study treatment:	NOT RELATED If Not Related to study treatment(s), this event is due to: OTHER If Other, specify: [subacute bacterial endocarditis]
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?:	RECOVERED/RESOLVED
14.	Did the adverse event cause the subject to be discontinued from the study?	NO
15.	Serious Adverse Event Number: For Pfizer Use Only	[2020423609]

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Header Text: c4591001

Visit: Logs

Form: MEDICATION ERROR

Form Version: 17-Jul-2020 21:54

Site No: 1054

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

Subject No: 10541173

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: 10541173

Generated By: (b) (4)

Form: MEDICATION ERROR

Form Status: Not Started

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

Subject Initials: ---

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Medication Error

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

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Header Text: c4591001

Visit: Logs

Form: CONCOMITANT MEDICATIONS - NON STUDY
VACCINATIONS

Form Version: 22-Apr-2020 21:03

Site No: 1054

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

Subject No: 10541173

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: 10541173

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Generated By: (b) (4)

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Concomitant Medications

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

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Header Text: c4591001

Visit: Logs

Form: CONCOMITANT MEDICATIONS - PROHIBITED

Form Version: 22-Apr-2020 21:03

Site No: 1054

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

Subject No: 10541173

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 Version: 22-Apr-2020 21:03

Site No: 1054

Subject No: 10541173

Generated By: (b) (4)

Form: CONCOMITANT MEDICATIONS - PROHIBITED

Form Status: Not Started

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

Subject Initials: ---

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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?	

090177e196ae30e5\Final\Final On: 01-Apr-2021 04:19 (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: 10541173

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 Version: 22-Apr-2020 21:02

Site No: 1054

Subject No: 10541173

Generated By: (b) (4)

Form: RADIATION TREATMENT

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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Radiation Treatment

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

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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: 10541173

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 Version: 22-Apr-2020 21:03

Site No: 1054

Subject No: 10541173

Generated By: (b) (4)

Form: TRANSFUSIONS

Form Status: Not Started

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

Subject Initials: ---

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

[Back to Form](#)

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

Header Text: c4591001

Visit: End of Treatment - Unscheduled

Form Version: 20-Feb-2021 02:26

Site No: 1054

Subject No: 10541173

Generated By: (b) (4)

Form: DISPOSITION - TREATMENT

Form Status: Data Complete, Queries, Verified

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

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Disposition - Treatment

1.	Date of Completion/Discontinuation/Death :	Feb/8/2021
2.	Phase of Disposition:	VACCINATION
3.	Status:	ADVERSE EVENT
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: 10541173

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: 10541173

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:	

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: 10541173

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?	

090177e196ae30e5\Final\Final On: 01-Apr-2021 04:19 (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: 10541173

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: 10541173

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 -
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: 10541173

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: 10541173

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: 10541173

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

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: 10541173

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

Header Text: c4591001

Visit: Follow-Up - Unscheduled

Form Version: 15-Sep-2020 21:53

Site No: 1054

Subject No: 10541173

Generated By: (b) (4)

Form: DISPOSITION - FOLLOW-UP

Form Status: Not Started

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

Subject Initials: ---

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:	[]

Header Text: c4591001

Visit: Potential ReVax Initial Contact -
Unscheduled

Form: DATE OF VISIT

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen, Verified

Site No: 1054

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

Subject No: 10541173

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/8/2021
2.	Erroneous Visit	

Header Text: c4591001

Visit: Potential ReVax Initial Contact -
Unscheduled

Form: FURTHER VACCINATION CONFIRMATION

Form Version: 10-Dec-2020 02:25

Form Status: Data Complete, Verified

Site No: 1054

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

Subject No: 10541173

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 per local/national recommendations and confirmed to have received only placebo at Vaccination 1/2
----	---	---

Header Text: c4591001

Visit: Disposition - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1054

Subject No: 10541173

Generated By: (b) (4)

Form: TREATMENT UNBLINDED

Form Status: Data Complete, Frozen, Verified

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

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Treatment Unblinded

1.	Date Treatment Unblinded :	Feb/8/2021
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: 10541173

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 :	//
----	------------------------------	----

Header Text: c4591001

Visit: Disposition - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1054

Subject No: 10541173

Generated By: (b) (4)

Form: DEATH DETAILS CODED

Form Status: Not Started

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

Subject Initials: ---

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:	[]

Header Text: c4591001

Visit: V101_VAX3

Form Version: 22-Apr-2020 21:02

Site No: 1054

Subject No: 10541173

Generated By: (b) (4)

Form: DATE OF VISIT

Form Status: Data Complete, Frozen, Verified

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

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Date of Visit

1.	Date of Visit	Mar/1/2021
2.	Erroneous Visit	ERRONEOUS VISIT

Header Text: c4591001

Visit: V101_VAX3

Form Version: 10-Dec-2020 02:31

Site No: 1054

Subject No: 10541173

Generated By: (b) (4)

Form: INFORMED CONSENT - FURTHER VACCINATION

Form Status: Not Started

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

Subject Initials: ---

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

Informed Consent - Further Vaccination

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

Header Text: c4591001

Visit: V101_VAX3

Form: INCLUSION/EXCLUSION CRITERIA - FURTHER VACCINATION

Form Version: 10-Dec-2020 02:30

Form Status: Not Started

Site No: 1054

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

Subject No: 10541173

Subject Initials: ---

Generated By: (b) (4)

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

Inclusion Criteria Not Met

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

Exclusion Criteria Met

2.	Description of Exclusion Criterion Met	
----	--	--

Header Text: c4591001

Visit: V101_VAX3

Form Version: 10-Dec-2020 02:31

Site No: 1054

Subject No: 10541173

Generated By: (b) (4)

Form: DISPOSITION - SCREENING FOR FURTHER VACCINATION

Form Status: Not Started

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

Subject Initials: ---

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

Disposition - Screening for Further Vaccination

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

Header Text: c4591001

Visit: Subject Status - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1054

Subject No: 10541173

Generated By: (b) (4)

Form: SUBJECT STATUS

Form Status: Data Complete, Verified

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

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Subject Status

1.	Subject Status	DISCONTINUED
2.	Subject Status Date	Feb/8/2021

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: 10541173

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: 10541173

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
------	-------------------	------	------	--------

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 15-Sep-2020 21:53

Site No: 1054

Subject No: 10541173

Generated By: (b) (4)

Form: INCLUSION/EXCLUSION CRITERIA - Comments

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

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Item	Date	User	Comment
Form	Sep-18-2020 13:35:30 (UTC-08:00) Pacific Time (US & Canada)	Steven Choi (b) (4)	Not Applicable

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 1054

Subject No: 10541173

Generated By: (b) (4)

Form: DATE OF VISIT - Comments

Form Status: Data Complete, Frozen, Verified

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

Subject Initials: ---

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

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Item	Date	User	Comment
Form	Mar-02-2021 08:17:51 (UTC-08:00) Pacific Time (US & Canada)	Steven Choi (b) (4)	Not Done

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 1054

Subject No: 10541173

Generated By: (b) (4)

Form: DATE OF VISIT - Comments

Form Status: Data Complete, Frozen, Verified

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

Subject Initials: ---

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

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Item	Date	User	Comment
1	Mar-02-2021 08:17:51 (UTC-08:00) Pacific Time (US & Canada)	Steven Choi (b) (4)	Not Done

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 1054

Subject No: 10541173

Generated By: (b) (4)

Form: DATE OF VISIT - Comments

Form Status: Data Complete, Frozen, Verified

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

Subject Initials: ---

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

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Item	Date	User	Comment
2	Mar-02-2021 08:17:51 (UTC-08:00) Pacific Time (US & Canada)	Steven Choi (b) (4)	Not Done

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - Comments

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: 10541173

Subject Initials: ---

Generated By: (b) (4)

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

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Item	Date	User	Comment
Form	Mar-04-2021 12:05:57 (UTC-08:00) Pacific Time (US & Canada)	Steven Choi (b) (4)	Not Done

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - Comments

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: 10541173

Subject Initials: ---

Generated By: (b) (4)

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

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Item	Date	User	Comment
1	Mar-04-2021 12:05:57 (UTC-08:00) Pacific Time (US & Canada)	Steven Choi (b) (4)	Not Done

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - Comments

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: 10541173

Subject Initials: ---

Generated By: (b) (4)

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

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Item	Date	User	Comment
2	Mar-04-2021 12:05:57 (UTC-08:00) Pacific Time (US & Canada)	Steven Choi (b) (4)	Not Done

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY -
Comments

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: 10541173

Subject Initials: ---

Generated By: (b) (4)

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

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Item	Date	User	Comment
3	Mar-04-2021 12:05:57 (UTC-08:00) Pacific Time (US & Canada)	Steven Choi (b) (4)	Not Done

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - Comments

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: 10541173

Subject Initials: ---

Generated By: (b) (4)

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

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Item	Date	User	Comment
4	Mar-04-2021 12:05:57 (UTC-08:00) Pacific Time (US & Canada)	Steven Choi (b) (4)	Not Done

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** MICROBIOLOGY SPECIMEN - Comments
on Oct/20/2020

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen, Verified

Site No: 1054

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

Subject No: 10541173

Subject Initials: ---

Generated By: (b) (4)

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

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Item	Date	User	Comment
Form	Nov-05-2020 14:38:47 (UTC-08:00) Pacific Time (US & Canada)	Steven Choi (b) (4)	
Form	Oct-21-2020 16:10:31 (UTC-08:00) Pacific Time (US & Canada)	Steven Choi (b) (4)	Not Done

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** MICROBIOLOGY SPECIMEN - Comments
on Oct/20/2020

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen, Verified

Site No: 1054

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

Subject No: 10541173

Subject Initials: ---

Generated By: (b) (4)

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

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Item	Date	User	Comment
1	Nov-05-2020 14:38:47 (UTC-08:00) Pacific Time (US & Canada)	Steven Choi (b) (4)	
1	Oct-21-2020 16:10:31 (UTC-08:00) Pacific Time (US & Canada)	Steven Choi (b) (4)	Not Done

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** MICROBIOLOGY SPECIMEN - Comments
on Oct/20/2020

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen, Verified

Site No: 1054

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

Subject No: 10541173

Subject Initials: ---

Generated By: (b) (4)

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

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Item	Date	User	Comment
2	Nov-05-2020 14:38:47 (UTC-08:00) Pacific Time (US & Canada)	Steven Choi (b) (4)	
2	Oct-21-2020 16:10:31 (UTC-08:00) Pacific Time (US & Canada)	Steven Choi (b) (4)	Not Done

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** MICROBIOLOGY SPECIMEN - Comments
on Oct/20/2020

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen, Verified

Site No: 1054

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

Subject No: 10541173

Subject Initials: ---

Generated By: (b) (4)

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

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Item	Date	User	Comment
3	Nov-05-2020 14:38:47 (UTC-08:00) Pacific Time (US & Canada)	Steven Choi (b) (4)	
3	Oct-21-2020 16:10:31 (UTC-08:00) Pacific Time (US & Canada)	Steven Choi (b) (4)	Not Done

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** MICROBIOLOGY SPECIMEN - Comments
on Oct/20/2020

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen, Verified

Site No: 1054

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

Subject No: 10541173

Subject Initials: ---

Generated By: (b) (4)

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

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Item	Date	User	Comment
4	Nov-05-2020 14:38:47 (UTC-08:00) Pacific Time (US & Canada)	Steven Choi (b) (4)	
4	Oct-21-2020 16:10:31 (UTC-08:00) Pacific Time (US & Canada)	Steven Choi (b) (4)	Not Done

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** MICROBIOLOGY SPECIMEN - Comments
on Oct/20/2020

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen, Verified

Site No: 1054

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

Subject No: 10541173

Subject Initials: ---

Generated By: (b) (4)

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

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Item	Date	User	Comment
5	Nov-05-2020 14:38:47 (UTC-08:00) Pacific Time (US & Canada)	Steven Choi (b) (4)	
5	Oct-21-2020 16:10:31 (UTC-08:00) Pacific Time (US & Canada)	Steven Choi (b) (4)	Not Done

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** MICROBIOLOGY SPECIMEN - Comments
on Oct/20/2020

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen, Verified

Site No: 1054

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

Subject No: 10541173

Subject Initials: ---

Generated By: (b) (4)

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

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Item	Date	User	Comment
6	Nov-05-2020 14:38:47 (UTC-08:00) Pacific Time (US & Canada)	Steven Choi (b) (4)	
6	Oct-21-2020 16:10:31 (UTC-08:00) Pacific Time (US & Canada)	Steven Choi (b) (4)	Not Done

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** MICROBIOLOGY SPECIMEN - Comments
on Oct/20/2020

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen, Verified

Site No: 1054

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

Subject No: 10541173

Subject Initials: ---

Generated By: (b) (4)

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

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Item	Date	User	Comment
7	Nov-05-2020 14:38:47 (UTC-08:00) Pacific Time (US & Canada)	Steven Choi (b) (4)	
7	Oct-21-2020 16:10:31 (UTC-08:00) Pacific Time (US & Canada)	Steven Choi (b) (4)	Not Done

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** MICROBIOLOGY SPECIMEN - Comments
on Oct/20/2020

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen, Verified

Site No: 1054

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

Subject No: 10541173

Subject Initials: ---

Generated By: (b) (4)

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

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Item	Date	User	Comment
8	Nov-05-2020 14:38:47 (UTC-08:00) Pacific Time (US & Canada)	Steven Choi (b) (4)	
8	Oct-21-2020 16:10:31 (UTC-08:00) Pacific Time (US & Canada)	Steven Choi (b) (4)	Not Done

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** MICROBIOLOGY SPECIMEN - Comments
on Oct/20/2020

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen, Verified

Site No: 1054

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9	Nov-05-2020 14:38:47 (UTC-08:00) Pacific Time (US & Canada)	Steven Choi (b) (4)	
9	Oct-21-2020 16:10:31 (UTC-08:00) Pacific Time (US & Canada)	Steven Choi (b) (4)	Not Done

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** RESPIRATORY TREATMENT - Comments
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Form Version: 06-Jul-2020 21:53

Form Status: Data Complete, Frozen, Verified

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Form	Oct-21-2020 16:11:15 (UTC-08:00) Pacific Time (US & Canada)	Steven Choi (b) (4)	Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** RESPIRATORY TREATMENT - Comments
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Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** RESPIRATORY TREATMENT - Comments
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4	Oct-21-2020 16:11:15 (UTC-08:00) Pacific Time (US & Canada)	Steven Choi (b) (4)	Not Applicable

Header Text: c4591001

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Form Version: 17-Jul-2020 21:55

Form Status: Data Complete, Frozen, Verified

Site No: 1054

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Form	Oct-21-2020 16:12:58 (UTC-08:00) Pacific Time (US & Canada)	Steven Choi (b) (4)	Not Applicable

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Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** ILLNESS DETAILS - SEVERE - Comments on Oct/20/2020

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1	Oct-21-2020 16:12:58 (UTC-08:00) Pacific Time (US & Canada)	Steven Choi (b) (4)	Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** ILLNESS DETAILS - SEVERE - Comments
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Item	Date	User	Comment
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Item	Date	User	Comment
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5.b	Oct-21-2020 16:13:15 (UTC-08:00) Pacific Time (US & Canada)	Steven Choi (b) (4)	Not Applicable

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5.b	Oct-21-2020 16:13:15 (UTC-08:00) Pacific Time (US & Canada)	Steven Choi (b) (4)	Not Applicable

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5.d	Oct-21-2020 16:13:15 (UTC-08:00) Pacific Time (US & Canada)	Steven Choi (b) (4)	Not Applicable

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Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/20/2020

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Form Version: 15-Sep-2020 21:55

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Site No: 1054

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Subject No: 10541173

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Site No: 1054

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Visit: Investigator Signature - Unscheduled

Form: CASEBOOK SIGNATURE FORM - Signature History

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Form Status: Data Complete, Verified

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- CRF_Sign
- CRF_Sign_1

Name	Signature Meaning	Date	Type	Action
Steven Choi	N/A	Nov-19-2020 13:16:31 (UTC-08:00) Pacific Time (US & Canada)		Edit - All signatures invalidated

Affidavit:

N/A

Mark Leibowitz	Approved	Nov-16-2020 16:08:51 (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	Nov-16-2020 11:52:13 (UTC-08:00) Pacific Time (US & Canada)		Edit - All signatures invalidated
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Affidavit:

N/A

Mark Leibowitz	Approved	Nov-16-2020 10:55:49 (UTC-08:00) Pacific Time (US & Canada)	BOOK	Signed
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Affidavit:

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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.

090177e196ae30e5\Final\Final On: 01-Apr-2021 04:19 (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:** 10541173**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 04:44

Steven Choi	N/A	Nov-16-2020 09:13:44 (UTC-08:00) Pacific Time (US & Canada)		Edit - All signatures invalidated
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Affidavit:

N/A

Mark Leibowitz	Approved	Nov-11-2020 10:08:52 (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	Nov-05-2020 13:11:06 (UTC-08:00) Pacific Time (US & Canada)		Edit - All signatures invalidated
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Affidavit:

N/A

Mark Leibowitz	Approved	Nov-03-2020 14:34:45 (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	Nov-03-2020 08:19:42 (UTC-08:00) Pacific Time (US & Canada)		Edit - All signatures invalidated
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Affidavit:

N/A

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: 10541173

Subject Initials: ---

Generated By: (b) (4)

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

Mark Leibowitz	Approved	Nov-02-2020 14:14:59 (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	Nov-02-2020 11:42:11 (UTC-08:00) Pacific Time (US & Canada)		Edit - All signatures invalidated
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Affidavit:

N/A

Mark Leibowitz	Approved	Nov-02-2020 07:49:08 (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	Oct-30-2020 14:56:35 (UTC-08:00) Pacific Time (US & Canada)		Edit - All signatures invalidated
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Affidavit:

N/A

Mark Leibowitz	Approved	Oct-30-2020 14:27:57 (UTC-08:00) Pacific Time (US & Canada)	BOOK	Signed
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090177e196ae30e5\Final\Final On: 01-Apr-2021 04:19 (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: 10541173

Subject Initials: ---

Generated By: (b) (4)

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

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.

Header Text: c4591001

Visit: COHORT_SELECTION

Form Version: 15-Sep-2020 21:55

Site No: 1054

Subject No: 10541173

Generated By: (b) (4)

Form: COHORT_SELECTION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

[Back to Form](#)

1. Select appropriate response - Protocol version

Date	Location	User	Value	Reason
Sep-18-2020 13:34:30 (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-18-2020 13:34:30 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: STAGE 3 COHORTS	Initial Entry

090177e196ae30e5\Final\Final On: 01-Apr-2021 04:19 (GMT)

Header Text: c4591001

Visit: COHORT_SELECTION

Form Version: 22-Apr-2020 21:02

Site No: 1054

Subject No: 10541173

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

[Back to Form](#)

I. Consent Was:

Date	Location	User	Value	Reason
Sep-18-2020 13:34:41 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: OBTAINED Date Written Consent Obtained Sep/18/2020	Initial Entry

Header Text: c4591001

Visit: COHORT_SELECTION

Form Version: 15-Sep-2020 21:54

Site No: 1054

Subject No: 10541173

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-18-2020 13:33:51 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 10541173	Item copied from previous form

2. Birth Date:

Date	Location	User	Value	Reason
Sep-18-2020 13:33:44 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: (b) (6)/1961	Enrollment Entry

3. Sex:

Date	Location	User	Value	Reason
Sep-18-2020 13:35:02 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: MALE	Initial Entry

4. Ethnicity:

Date	Location	User	Value	Reason
Sep-18-2020 13:35:02 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: HISPANIC OR LATINO(A) OR OF SPANISH ORIGIN	Initial Entry

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

Date	Location	User	Value	Reason
Sep-18-2020 13:35:02 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: WHITE	Initial Entry

090177e196ae30e5\Final\Final On: 01-Apr-2021 04:19 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:02

Site No: 1054

Subject No: 10541173

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

[Back to Form](#)

1. Date of Visit

Date	Location	User	Value	Reason
Sep-18-2020 13:35:15 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: Sep/18/2020	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 15-Sep-2020 21:52

Site No: 1054

Subject No: 10541173

Generated By: (b) (4)

Form: DISPOSITION - SCREENING - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

[Back to Form](#)

1. Date of Completion/Discontinuation/Death

Date	Location	User	Value	Reason
Sep-18-2020 13:35:44 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: Sep/18/2020	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Sep-18-2020 13:35:44 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SCREENING	Initial Entry

3. Status:

Date	Location	User	Value	Reason
Sep-18-2020 13:35:44 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: COMPLETED	Initial Entry

090177e196ae30e5\Final\Final On: 01-Apr-2021 04:19 (GMT)

Header Text: c4591001**Visit:** V1_DAY1_VAX1_L**Form Version:** 22-Apr-2020 21:03**Site No:** 1054**Subject No:** 10541173**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](#)**I.a**

Date	Location	User	Value	Reason
Sep-18-2020 13:36:07 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 1 Medical History appendectomy Term: Start Date: May/UNK/2005 Ongoing: NO End Date: May/UNK/ 2005	Initial Entry

I.a Line/MH Number:

Date	Location	User	Value	Reason
Sep-18-2020 13:36:07 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 1	Initial Entry

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

Date	Location	User	Value	Reason
Sep-18-2020 13:36:07 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: appendectomy	Initial Entry

I.a Start Date:

Date	Location	User	Value	Reason
Sep-18-2020 13:36:07 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: May/UNK/2005	Initial Entry

I.a Ongoing:

Date	Location	User	Value	Reason
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Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1054

Subject No: 10541173

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

Sep-18-2020 13:36:07 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: NO End Date: May/UNK/2005	Initial Entry
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1.b

Date	Location	User	Value	Reason
Sep-18-2020 13:36:36 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 2 Medical History Term: appendicitis Start Date: May/UNK/2005 Ongoing: NO End Date: May/UNK/ 2005	Initial Entry

090177e196ae30e5\Final\Final On: 01-Apr-2021 04:19 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1054

Subject No: 10541173

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

I.b Line/MH Number:

Date	Location	User	Value	Reason
Sep-18-2020 13:36:36 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 2	Initial Entry

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

Date	Location	User	Value	Reason
Sep-18-2020 13:36:36 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: appendicitis	Initial Entry

I.b Start Date:

Date	Location	User	Value	Reason
Sep-18-2020 13:36:36 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: May/UNK/2005	Initial Entry

I.b Ongoing:

Date	Location	User	Value	Reason
Sep-18-2020 13:36:36 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: NO End Date: May/UNK/2005	Initial Entry

I.c

Date	Location	User	Value	Reason
Sep-18-2020 13:44:30 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 3 Medical History Term: abdominal scar Start Date: May/UNK/2005 Ongoing: YES	Initial Entry

090177e196ae30e5\Final\Final On: 01-Apr-2021 04:19 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1054

Subject No: 10541173

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

I.c Line/MH Number:

Date	Location	User	Value	Reason
Sep-18-2020 13:44:30 (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-18-2020 13:44:30 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: abdominal scar	Initial Entry

I.c Start Date:

Date	Location	User	Value	Reason
Sep-18-2020 13:44:30 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: May/UNK/2005	Initial Entry

I.c Ongoing:

Date	Location	User	Value	Reason
Sep-18-2020 13:44:30 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: YES	Initial Entry

I.d

Date	Location	User	Value	Reason
Sep-18-2020 13:45:05 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 4 Medical History Term: bilateral lower leg edema 1+ Start Date: UNK/UNK/2015 Ongoing: YES	Initial Entry

090177e196ae30e5\Final\Final On: 01-Apr-2021 04:19 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1054

Subject No: 10541173

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

I.d Line/MH Number:

Date	Location	User	Value	Reason
Sep-18-2020 13:45:05 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 4	Initial Entry

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

Date	Location	User	Value	Reason
Sep-18-2020 13:45:05 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: bilateral lower legs edema 1+	Initial Entry

I.d Start Date:

Date	Location	User	Value	Reason
Sep-18-2020 13:45:05 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: UNK/UNK/2015	Initial Entry

I.d Ongoing:

Date	Location	User	Value	Reason
Sep-18-2020 13:45:05 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: YES	Initial Entry

I.e

Date	Location	User	Value	Reason
Sep-18-2020 13:45:26 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 5 Medical History Term: bilateral fungus toenails Start Date: UNK/UNK/2015 Ongoing: YES	Initial Entry

090177e196ae30e5\Final\Final On: 01-Apr-2021 04:19 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1054

Subject No: 10541173

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

I.e Line/MH Number:

Date	Location	User	Value	Reason
Sep-18-2020 13:45:26 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 5	Initial Entry

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

Date	Location	User	Value	Reason
Sep-18-2020 13:45:26 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: bilateral fungus toenails	Initial Entry

I.e Start Date:

Date	Location	User	Value	Reason
Sep-18-2020 13:45:26 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: UNK/UNK/2015	Initial Entry

I.e Ongoing:

Date	Location	User	Value	Reason
Sep-18-2020 13:45:26 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: YES	Initial Entry

I.f

Date	Location	User	Value	Reason
Nov-10-2020 13:29:25 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Num 6 ber: Medical Histor nerve pain, cervi y Term: cal spine Start Date: Sep/11/2020 Ongoing: YES	Initial Entry

090177e196ae30e5\Final\Final On: 01-Apr-2021 04:19 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1054

Subject No: 10541173

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

I.f Line/MH Number:

Date	Location	User	Value	Reason
Nov-10-2020 13:29:25 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 6	Initial Entry

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

Date	Location	User	Value	Reason
Nov-10-2020 13:29:25 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: nerve pain, cervical spine	Initial Entry

I.f Start Date:

Date	Location	User	Value	Reason
Nov-10-2020 13:29:25 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: Sep/11/2020	Initial Entry

I.f Ongoing:

Date	Location	User	Value	Reason
Nov-10-2020 13:29:25 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: YES	Initial Entry

090177e196ae30e5\Final\Final On: 01-Apr-2021 04:19 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 15-Sep-2020 21:57

Site No: 1054

Subject No: 10541173

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

[Back to Form](#)

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

Date	Location	User	Value	Reason
Sep-18-2020 13:36:55 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: The subject is NOT known to be HIV POSITIVE	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 15-Sep-2020 21:56

Site No: 1054

Subject No: 10541173

Generated By: (b) (4)

Form: VITAL SIGNS - BASELINE - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

[Back to Form](#)

1. Date:

Date	Location	User	Value	Reason
Sep-18-2020 13:39:29 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: Sep/18/2020	Initial Entry

2. Weight:

Date	Location	User	Value	Reason
Sep-18-2020 13:39:29 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: 88.64	Initial Entry

3. Unit:

Date	Location	User	Value	Reason
Sep-18-2020 13:39:29 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: kg	Initial Entry

4. Height:

Date	Location	User	Value	Reason
Sep-18-2020 13:39:29 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: 172.72	Initial Entry

5. Unit:

Date	Location	User	Value	Reason
Sep-18-2020 13:39:29 (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-18-2020 13:39:29 (UTC-08:00) Pacific	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 29.7	Initial Entry

090177e196ae30e5\Final\Final On: 01-Apr-2021 04:19 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 15-Sep-2020 21:56

Site No: 1054

Subject No: 10541173

Generated By: (b) (4)

Form: VITAL SIGNS - BASELINE - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

Time (US & Canada)				
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7.a

Date	Location	User	Value	Reason
Sep-18-2020 13:39:29 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: Record Identifier: 1 : Temperature: 97.6 Temperature Unit: F Temperature Location: ORAL CAVITY	Initial Entry

7.a Record Identifier:

Date	Location	User	Value	Reason
Sep-18-2020 13:39:29 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: 1	Initial Entry

7.a Temperature:

Date	Location	User	Value	Reason
Sep-18-2020 13:39:29 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: 97.6	Initial Entry

7.a Unit:

Date	Location	User	Value	Reason
Sep-18-2020 13:39:29 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: F	Initial Entry

7.a Temperature Location:

Date	Location	User	Value	Reason
Sep-18-2020 13:39:29 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: ORAL CAVITY	Initial Entry

090177e196ae30e5\Final\Final On: 01-Apr-2021 04:19 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1054

Subject No: 10541173

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-18-2020 13:39:45 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: Sep/18/2020	Initial Entry

2. Randomization Number:

Date	Location	User	Value	Reason
Sep-18-2020 13:39:45 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: 261406	Initial Entry

090177e196ae30e5\Final\Final On: 01-Apr-2021 04:19 (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: 10541173

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
Sep-18-2020 13:39:52 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Sep-18-2020 13:39:52 (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-18-2020 15:34:48 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Sep-18-2020 13:39:52 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Sep-18-2020 13:39:52 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: YES Date of Collection: Sep/18/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Sep-18-2020 15:34:48 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: Sample ID: BM983G	Initial Entry

090177e196ae30e5\Final\Final On: 01-Apr-2021 04:19 (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: 10541173

Subject Initials: ---

Generated By: (b) (4)

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

5.a Sample ID

Date	Location	User	Value	Reason
Sep-18-2020 15:34:48 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: BM983G	Initial Entry

5.b

Date	Location	User	Value	Reason
Sep-18-2020 15:35:09 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: Sample ID: BM983H	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Sep-18-2020 15:35:09 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: BM983H	Initial Entry

090177e196ae30e5\Final\Final On: 01-Apr-2021 04:19 (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: 10541173

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
Sep-18-2020 13:40:00 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Sep-18-2020 13:40:00 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: NASAL_SWAB	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Sep-18-2020 15:35:43 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Sep-18-2020 13:40:00 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Sep-18-2020 13:40:00 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: YES Date of Collection: Sep/18/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Sep-18-2020 15:35:43 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: Sample ID: BM983J	Initial Entry

090177e196ae30e5\Final\Final On: 01-Apr-2021 04:19 (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: 10541173

Subject Initials: ---

Generated By: (b) (4)

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

5.a Sample ID

Date	Location	User	Value	Reason
Sep-18-2020 15:35:43 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: BM983J	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:04

Site No: 1054

Subject No: 10541173

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-18-2020 13:41:29 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: NO	Initial Entry

2. Treatment Name

Date	Location	User	Value	Reason
Sep-18-2020 13:41:29 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: BLINDED THERAPY	Initial Entry

3. Formulation:

Date	Location	User	Value	Reason
Sep-18-2020 13:41:29 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INJECTION	Initial Entry

4. Dose Date Time:

Date	Location	User	Value	Reason
Sep-18-2020 13:41:29 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: Sep/18/2020 11:50	Initial Entry

5. Anatomical Location:

Date	Location	User	Value	Reason
Sep-18-2020 13:41:29 (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-18-2020 13:42:14 (UTC-08:00) Pacific	ACV0PFEINFP6000	Steven Choi	Data Entry: LEFT	Initial Entry

090177e196ae30e5\Final\Final On: 01-Apr-2021 04:19 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:04

Site No: 1054

Subject No: 10541173

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

Time (US & Canada)

(b) (4)

7. Route:

Date	Location	User	Value	Reason
Sep-18-2020 13:41:29 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INTRAMUSCULAR	Initial Entry

10. Timeframe Subject Was Observed

Date	Location	User	Value	Reason
Sep-18-2020 13:41:29 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: THE PROTOCOL SPECIFIED O BSERVATION PERIOD	Initial Entry

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

Date	Location	User	Value	Reason
Sep-18-2020 13:41:29 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: YES	Initial Entry

090177e196ae30e5\Final\Final On: 01-Apr-2021 04:19 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 06-Jul-2020 21:53

Site No: 1054

Subject No: 10541173

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-18-2020 13:41:48 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: NO - REACTOGENICITY E-DI ARY NOT COLLECTED FOR T HIS SUBJECT	Initial Entry

090177e196ae30e5\Final\Final On: 01-Apr-2021 04:19 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 1054

Subject No: 10541173

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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I. Date of Visit

Date	Location	User	Value	Reason
Nov-12-2020 11:38:40 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [Redacted]	Query 1: Closed	Response satisfies query
Nov-12-2020 08:09:39 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Query 1: Answered	According to source, site attempted to contact patient w/o success everyday from 16Oct20 until the patient showed up to the clinic w/o any prompting on 20Oct20 (day of COVID_A).
Nov-11-2020 21:25:43 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [Redacted]	Query 1: Reissued:Opened	RQ1: Thank you for response. However the symptoms start date on Covid illness form does not capture the Illness ediary entry on 16OCT2020. Please review and update, else clarify.
Nov-11-2020 13:38:46 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Query 1: Answered	Please see eCRF in COVID_A.
Nov-11-2020 12:05:25 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [Redacted]	Query 1: Opened	Illness eDiary: Subject reported "Yes" for the question "Have you experienced any of the following?" for the COVID-19 symptoms or diagnosis on 16Oct2020. But

090177e196ae30e5\Final\Final On: 01-Apr-2021 04:19 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 1054

Subject No: 10541173

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

				there is no COVID Illness visit reported in the database. Please clarify.
Oct-09-2020 14:32:47 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: Oct/9/2020	Initial Entry

090177e196ae30e5\Final\Final On: 01-Apr-2021 04:19 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 15-Sep-2020 21:54

Site No: 1054

Subject No: 10541173

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-09-2020 14:33:52 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: Oct/9/2020	Initial Entry

2.a

Date	Location	User	Value	Reason
Oct-09-2020 14:33:52 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: Record Identifier: 1 : Temperature: 97.9 Temperature Unit: F Temperature Location: ORAL CAV ity: ITY	Initial Entry

2.a Record Identifier:

Date	Location	User	Value	Reason
Oct-09-2020 14:33:52 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: 1	Initial Entry

2.a Temperature:

Date	Location	User	Value	Reason
Oct-09-2020 14:33:52 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: 97.9	Initial Entry

2.a Unit:

Date	Location	User	Value	Reason
Oct-09-2020 14:33:52 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: F	Initial Entry

090177e196ae30e5\Final\Final On: 01-Apr-2021 04:19 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 15-Sep-2020 21:54

Site No: 1054

Subject No: 10541173

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

2.a Temperature Location:

Date	Location	User	Value	Reason
Oct-09-2020 14:33:52 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: ORAL CAVITY	Initial Entry

Header Text: c4591001**Visit:** V2_VAX2_L**Form Version:** 22-Apr-2020 21:03**Site No:** 1054**Subject No:** 10541173**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[Back to Form](#)**1. Data Origin**

Date	Location	User	Value	Reason
Oct-09-2020 14:34:00 (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-09-2020 14:34:00 (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-09-2020 15:06:33 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Oct-09-2020 14:34:00 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Oct-09-2020 14:34:00 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: YES Date of Collection: Oct/9/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Oct-09-2020 15:06:33 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: Sample ID: BPYX1W	Initial Entry

Header Text: c4591001

Visit: V2_VAX2_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1054

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

Subject No: 10541173

Subject Initials: ---

Generated By: (b) (4)

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

5.a Sample ID

Date	Location	User	Value	Reason
Oct-09-2020 15:06:33 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: BPYX1W	Initial Entry

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1054

Subject No: 10541173

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-09-2020 14:34:10 (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-09-2020 14:34:10 (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-09-2020 14:34:10 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INJECTION	Initial Entry

4. Dose Date Time:

Date	Location	User	Value	Reason
Oct-09-2020 14:34:10 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: Oct/9/2020 11:22	Initial Entry

5. Anatomical Location:

Date	Location	User	Value	Reason
Oct-09-2020 14:34:10 (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-09-2020 14:34:10 (UTC-08:00) Pacific	ACV0PFEINFP6000	Steven Choi	Data Entry: LEFT	Initial Entry

090177e196ae30e5\Final\Final On: 01-Apr-2021 04:19 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1054

Subject No: 10541173

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

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

Date	Location	User	Value	Reason
Oct-09-2020 14:34:10 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> INTRAMUSCULAR	Initial Entry

10. Timeframe Subject Was Observed

Date	Location	User	Value	Reason
Oct-09-2020 14:34:10 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> THE PROTOCOL SPECIFIED O BSERVATION PERIOD	Initial Entry

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

Date	Location	User	Value	Reason
Oct-09-2020 14:34:10 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	<u>Data Entry:</u> YES	Initial Entry

090177e196ae30e5\Final\Final On: 01-Apr-2021 04:19 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 1054

Subject No: 10541173

Generated By: (b) (4)

Form: DATE OF VISIT - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

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

Subject Initials: ---

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

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1. Date of Visit

Date	Location	User	Value	Reason
Mar-02-2021 08:17:51 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: Not Done	Initial Entry

2. Erroneous Visit

Date	Location	User	Value	Reason
Mar-02-2021 08:17:51 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: Not Done	Initial Entry

Header Text: c4591001**Visit:** V3_MONTH1_POSTVAX2_L**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF Audit Trail History**Form Version:** 22-Apr-2020 21:03**Form Status:** Data Complete, Frozen, Verified**Site No:** 1054**Site Name:** (1054) Collaborative Neuroscience Network, LLC.**Subject No:** 10541173**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 04:44[Back to Form](#)**1. Data Origin**

Date	Location	User	Value	Reason
Mar-04-2021 12:05:57 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Not Done	Initial Entry
Mar-04-2021 12:05:30 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry:	Changed Information
Mar-04-2021 11:52:51 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Issue already resolved
Mar-04-2021 08:35:29 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry
Mar-02-2021 12:49:23 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	Please mark Date of Visit as 'Not Done' with form level comment

2. Sample Type

Date	Location	User	Value	Reason
Mar-04-2021 12:05:57 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Not Done	Initial Entry
Mar-04-2021 12:05:30 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry:	Changed Information
Mar-04-2021 08:35:29 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SERUM	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
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Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1054

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

Subject No: 10541173

Subject Initials: ---

Generated By: (b) (4)

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

Mar-04-2021 22:10:47 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Mar-04-2021 12:05:57 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: Not Done	Initial Entry
Mar-04-2021 12:05:30 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Changed Information
Mar-04-2021 12:05:30 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry:	Changed Information
Mar-04-2021 11:53:58 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued:Opened	DM: Response does not satisfy query. Clear the CRF then add a FORM level comment of Not Done/Not Applicable. Please refer to CRF Completion Requirements sections 4.10 and 4.11 for instructions.
Mar-04-2021 08:35:29 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Initial Entry
Mar-04-2021 08:35:29 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: NO	Initial Entry
Mar-04-2021 06:04:20 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	DM: DOV form is marked as Not Done. However, form level comment is not present on this form. Kindly consider to add form level comment by selecting Not

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Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1054

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

Subject No: 10541173

Subject Initials: ---

Generated By: (b) (4)

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

				Done or Not Applicable option on this form or else clarify.
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4. If no sample was collected or sample was not collected according to protocol, please provide reason:

Date	Location	User	Value	Reason
Mar-04-2021 12:05:57 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: Not Done	Initial Entry
Mar-04-2021 12:05:45 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry:	Changed Information
Mar-04-2021 08:35:29 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: V3 not done.	Initial Entry

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Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** DATE OF VISIT - ILLNESS ONSET - eCRF Audit Trail History on Oct/20/2020

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: 10541173

Subject Initials: ---

Generated By: (b) (4)

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

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I. Date of Visit

Date	Location	User	Value	Reason
Oct-21-2020 16:09:50 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Closed	Close Auto Query
Oct-21-2020 10:46:53 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Opened	Date of Visit is completed but Date of Assessment in the Signs and Symptoms form is missing. Please review and update as appropriate.
Oct-20-2020 16:02:21 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Oct-20-2020 16:02:03 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Candidate	Date of Visit is completed but Date of Assessment in the Signs and Symptoms form is missing. Please review and update as appropriate.
Oct-20-2020 16:02:03 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	Date of Visit is completed but Date of Collection in both Nasal Swab Self and Nasal Swab are missing. Please review and update as appropriate.
Oct-20-2020 16:02:03 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: Oct/20/2020	Initial Entry

090177e196ae30e5\Final\Final On: 01-Apr-2021 04:19 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** DATE OF VISIT - ILLNESS ONSET - eCRF Audit Trail History on Oct/20/2020

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: 10541173

Subject Initials: ---

Generated By: (b) (4)

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

3. COVID-19 Illness Visit:

Date	Location	User	Value	Reason
Oct-20-2020 16:02:03 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> COVID_A	Initial Entry

090177e196ae30e5\Final\Final On: 01-Apr-2021 04:19 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/20/2020

Form: SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF Audit Trail History

Form Version: 10-Oct-2020 16:02

Form Status: Data Complete, Frozen, Verified

Site No: 1054

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

Subject No: 10541173

Subject Initials: ---

Generated By: (b) (4)

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

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1. Date of Assessment:

Date	Location	User	Value	Reason
Oct-21-2020 16:09:50 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: Oct/20/2020	Initial Entry

2. Date of First Symptom Started:

Date	Location	User	Value	Reason
Oct-21-2020 16:09:50 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: Oct/19/2020	Initial Entry

3. Symptoms Ongoing?

Date	Location	User	Value	Reason
Feb-11-2021 00:57:01 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Feb-10-2021 13:17:29 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	New Information
Feb-10-2021 13:17:29 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: NO Date of Last Symptom Resolved: Jan/UNK/2021	New Information
Feb-02-2021 03:12:58 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	Please confirm the symptoms are still ongoing for this COVID illness. If all symptoms for this illness are resolved; please update the Last Symptoms Resolved Date else

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Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/20/2020

Form: SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF Audit Trail History

Form Version: 10-Oct-2020 16:02

Form Status: Data Complete, Frozen, Verified

Site No: 1054

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

Subject No: 10541173

Subject Initials: ---

Generated By: (b) (4)

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

				clarify.
Oct-21-2020 16:09:50 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: YES	Initial Entry

4.a

Date	Location	User	Value	Reason
Oct-21-2020 16:09:50 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: Symptoms: FEVER Symptom Present: NO	Initial Entry

4.a Symptoms:

Date	Location	User	Value	Reason
Oct-21-2020 16:09:50 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: FEVER	Initial Entry

4.a Was symptom present?

Date	Location	User	Value	Reason
Oct-21-2020 16:09:50 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: NO	Initial Entry

4.b

Date	Location	User	Value	Reason
Oct-21-2020 16:09:50 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: Symptoms: NEW OR INCREA SED COUGH Symptom Present: YES	Initial Entry

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Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/20/2020

Form: SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF Audit Trail History

Form Version: 10-Oct-2020 16:02

Form Status: Data Complete, Frozen, Verified

Site No: 1054

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

Subject No: 10541173

Subject Initials: ---

Generated By: (b) (4)

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4.b Symptoms:

Date	Location	User	Value	Reason
Oct-21-2020 16:09:50 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: NEW OR INCREASED COUGH	Initial Entry

4.b Was symptom present?

Date	Location	User	Value	Reason
Oct-21-2020 16:09:50 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: YES	Initial Entry

4.c

Date	Location	User	Value	Reason
Nov-09-2020 11:10:35 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: Symptom: NEW OR INCREASED SHORTNESS OF BREATH Symptom Present: NO	Changed Information
Nov-05-2020 14:38:34 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: Symptom: NEW OR INCREASED SHORTNESS OF BREATH Symptom Present: YES	New Information
Oct-26-2020 08:46:00 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: Symptom: NEW OR INCREASED SHORTNESS OF BREATH Symptom Present: NO	Transcription Error
Oct-21-2020 16:09:50 (UTC-08:00) Pacific	ACV0PFEINFP6000	Steven Choi	Data Entry: Symptom: NEW OR INCREASE	Initial Entry

090177e196ae30e5\Final\Final On: 01-Apr-2021 04:19 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/20/2020

Form: SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF Audit Trail History

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Form Status: Data Complete, Frozen, Verified

Site No: 1054

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

Subject No: 10541173

Subject Initials: ---

Generated By: (b) (4)

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

Time (US & Canada)	(b) (4)	ms: D SHORTNESS OF BREATH Symptom Present: YES
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4.c Symptoms:

Date	Location	User	Value	Reason
Oct-21-2020 16:09:50 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: NEW OR INCREASED SHORTNESS OF BREATH	Initial Entry

4.c Was symptom present?

Date	Location	User	Value	Reason
Nov-09-2020 11:10:35 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: NO	Changed Information
Nov-05-2020 14:38:34 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: YES	New Information
Oct-26-2020 10:07:39 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Oct-26-2020 08:46:00 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Transcription Error
Oct-26-2020 08:46:00 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: NO	Transcription Error
Oct-23-2020 11:53:06 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	Per source, NO shortness of breath. Please verify.
Oct-21-2020 16:09:50 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: YES	Initial Entry

4.d

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Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/20/2020

Form: SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF Audit Trail History

Form Version: 10-Oct-2020 16:02

Form Status: Data Complete, Frozen, Verified

Site No: 1054

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

Subject No: 10541173

Subject Initials: ---

Generated By: (b) (4)

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

Date	Location	User	Value	Reason
Oct-21-2020 16:09:50 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: Symptoms: CHILLS Symptom Present: YES	Initial Entry

4.d Symptoms:

Date	Location	User	Value	Reason
Oct-21-2020 16:09:50 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: CHILLS	Initial Entry

4.d Was symptom present?

Date	Location	User	Value	Reason
Oct-21-2020 16:09:50 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: YES	Initial Entry

4.e

Date	Location	User	Value	Reason
Oct-26-2020 08:46:18 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: Symptom NEW OR INCREASED MUSCLE PAIN Symptom Present: YES	Transcription Error
Oct-21-2020 16:09:50 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: Symptom NEW OR INCREASED MUSCLE PAIN Symptom Present: NO	Initial Entry

090177e196ae30e5\Final\Final On: 01-Apr-2021 04:19 (GMT)

Header Text: c4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit on Oct/20/2020**Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF Audit Trail History**Form Version:** 10-Oct-2020 16:02**Form Status:** Data Complete, Frozen, Verified**Site No:** 1054**Site Name:** (1054) Collaborative Neuroscience Network, LLC.**Subject No:** 10541173**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 04:44**4.e Symptoms:**

Date	Location	User	Value	Reason
Oct-21-2020 16:09:50 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: NEW OR INCREASED MUSCL E PAIN	Initial Entry

4.e Was symptom present?

Date	Location	User	Value	Reason
Oct-26-2020 10:08:14 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Oct-26-2020 08:46:18 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Transcription Error
Oct-26-2020 08:46:18 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: YES	Transcription Error
Oct-23-2020 11:53:59 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	Per source, YES for muscle pain. Please verify.
Oct-21-2020 16:09:50 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: NO	Initial Entry

4.f

Date	Location	User	Value	Reason
Oct-21-2020 16:09:50 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: Symptoms NEW LOSS OF TAS : TE OR SMELL Symptom NO Present:	Initial Entry

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/20/2020

Form: SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF Audit Trail History

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Subject No: 10541173

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Generated By: (b) (4)

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

4.f Symptoms:

Date	Location	User	Value	Reason
Oct-21-2020 16:09:50 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: NEW LOSS OF TASTE OR SME LL	Initial Entry

4.f Was symptom present?

Date	Location	User	Value	Reason
Oct-21-2020 16:09:50 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: NO	Initial Entry

4.g

Date	Location	User	Value	Reason
Oct-26-2020 08:46:37 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: Symptom NEW OR INCREASED SORE THROAT Symptom NO Present:	Transcription Error
Oct-21-2020 16:09:50 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: Symptom NEW OR INCREASED SORE THROAT Symptom YES Present:	Initial Entry

090177e196ae30e5\Final\Final On: 01-Apr-2021 04:19 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/20/2020

Form: SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF Audit Trail History

Form Version: 10-Oct-2020 16:02

Form Status: Data Complete, Frozen, Verified

Site No: 1054

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

Subject No: 10541173

Subject Initials: ---

Generated By: (b) (4)

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

4.g Symptoms:

Date	Location	User	Value	Reason
Oct-21-2020 16:09:50 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: NEW OR INCREASED SORE T HROAT	Initial Entry

4.g Was symptom present?

Date	Location	User	Value	Reason
Oct-26-2020 10:07:24 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Oct-26-2020 08:46:37 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Transcription Error
Oct-26-2020 08:46:37 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: NO	Transcription Error
Oct-23-2020 11:54:40 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	Per source, NO sore throat. Please verify.
Oct-21-2020 16:09:50 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: YES	Initial Entry

4.h

Date	Location	User	Value	Reason
Oct-26-2020 08:46:53 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: Symptoms: DIARRHE A Symptom Present YES :	Transcription Error
Oct-21-2020 16:09:50 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: Symptoms: DIARRHE A Symptom Present NO :	Initial Entry

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Header Text: c4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit on Oct/20/2020**Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF Audit Trail History**Form Version:** 10-Oct-2020 16:02**Form Status:** Data Complete, Frozen, Verified**Site No:** 1054**Site Name:** (1054) Collaborative Neuroscience Network, LLC.**Subject No:** 10541173**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 04:44**4.h Symptoms:**

Date	Location	User	Value	Reason
Oct-21-2020 16:09:50 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: DIARRHEA	Initial Entry

4.h Was symptom present?

Date	Location	User	Value	Reason
Oct-26-2020 10:08:23 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Oct-26-2020 08:46:53 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Transcription Error
Oct-26-2020 08:46:53 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: YES	Transcription Error
Oct-23-2020 11:55:07 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	Per source, YES for diarrhea. Please verify.
Oct-21-2020 16:09:50 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: NO	Initial Entry

4.i

Date	Location	User	Value	Reason
Oct-21-2020 16:09:50 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: Symptoms: VOMITING Symptom Present: NO	Initial Entry

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/20/2020

Form: SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF Audit Trail History

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Form Status: Data Complete, Frozen, Verified

Site No: 1054

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Generated By: (b) (4)

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4.i Symptoms:

Date	Location	User	Value	Reason
Oct-21-2020 16:09:50 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: VOMITING	Initial Entry

4.i Was symptom present?

Date	Location	User	Value	Reason
Oct-21-2020 16:09:50 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: NO	Initial Entry

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Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** MICROBIOLOGY SPECIMEN - Audit Trail
on Oct/20/2020

Form Version: 06-Jul-2020 21:54

Form Status:

Site No: 1054

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

Subject No: 10541173

Subject Initials: ---

Generated By: (b) (4)

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

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Date	Location	User	Value	Reason
Nov-05-2020 14:39:34 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Form Created	

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit Form: MICROBIOLOGY SPECIMEN - eCRF Audit Trail History on Oct/20/2020

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen, Verified

Site No: 1054

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

Subject No: 10541173

Subject Initials: ---

Generated By: (b) (4)

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1. Actual Date of Collection:

Date	Location	User	Value	Reason
Nov-05-2020 14:39:34 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: Oct/28/2020	Initial Entry
Nov-05-2020 14:38:47 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry:	Initial Entry
Oct-21-2020 16:10:31 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: Not Done	Initial Entry

2. Specimen Type:

Date	Location	User	Value	Reason
Nov-05-2020 14:39:34 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: SWABBED MATERIAL	Initial Entry
Nov-05-2020 14:38:47 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry:	Initial Entry
Oct-21-2020 16:10:31 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: Not Done	Initial Entry

3. Specimen Collection Location:

Date	Location	User	Value	Reason
Nov-05-2020 14:39:34 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: NASOPHARYNX	Initial Entry
Nov-05-2020 14:38:47 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry:	Initial Entry
Oct-21-2020 16:10:31 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: Not Done	Initial Entry

090177e196ae30e5\Final\Final On: 01-Apr-2021 04:19 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit Form: MICROBIOLOGY SPECIMEN - eCRF Audit Trail History on Oct/20/2020

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen, Verified

Site No: 1054

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

Subject No: 10541173

Subject Initials: ---

Generated By: (b) (4)

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

4. Assay Code and Description:

Date	Location	User	Value	Reason
Nov-05-2020 14:39:34 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SEVERE ACUTE RESP SYNDR OME CORONAVIRUS 2	Initial Entry
Nov-05-2020 14:38:47 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry:	Initial Entry
Oct-21-2020 16:10:31 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: Not Done	Initial Entry

5. Device Type:

Date	Location	User	Value	Reason
Nov-05-2020 14:39:34 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SARS-COV-2 DIAGNOSTIC TE ST	Initial Entry
Nov-05-2020 14:38:47 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry:	Initial Entry
Oct-21-2020 16:10:31 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: Not Done	Initial Entry

6. Trade Name:

Date	Location	User	Value	Reason
Nov-05-2020 14:39:43 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: OTHER	Initial Entry
Nov-05-2020 14:38:47 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry:	Initial Entry
Oct-21-2020 16:10:31 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: Not Done	Initial Entry

090177e196ae30e5\Final\Final On: 01-Apr-2021 04:19 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** MICROBIOLOGY SPECIMEN - eCRF Audit Trail History on Oct/20/2020

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen, Verified

Site No: 1054

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

Subject No: 10541173

Subject Initials: ---

Generated By: (b) (4)

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

7. Test Result:

Date	Location	User	Value	Reason
Nov-05-2020 14:39:34 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: NEGATIVE	Initial Entry
Nov-05-2020 14:38:47 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry:	Initial Entry
Oct-21-2020 16:10:31 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: Not Done	Initial Entry

8. Comments/Findings/Details:

Date	Location	User	Value	Reason
Nov-05-2020 14:38:47 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry:	Initial Entry
Oct-21-2020 16:10:31 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: Not Done	Initial Entry

9. Trade Name Other, Specify:

Date	Location	User	Value	Reason
Nov-05-2020 14:39:34 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: CLIA-certified laboratory	Initial Entry
Nov-05-2020 14:38:47 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry:	Initial Entry
Oct-21-2020 16:10:31 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: Not Done	Initial Entry

090177e196ae30e5\Final\Final On: 01-Apr-2021 04:19 (GMT)

Header Text: c4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit on Oct/20/2020**Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB SELF - 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:** 10541173**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 04:44[Back to Form](#)**1. Data Origin**

Date	Location	User	Value	Reason
Oct-20-2020 16:02:46 (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-20-2020 16:02:46 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: NASAL_SWAB_SELF	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Oct-20-2020 16:02:46 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: NO	Initial Entry

4. If no sample was collected or sample was not collected according to protocol, please provide reason:

Date	Location	User	Value	Reason
Oct-20-2020 16:03:21 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Oct-20-2020 16:03:21 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: Swab was collected on site.	Transcription Error
Oct-20-2020 16:02:46 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	Entered text has either a carriage return (line break) or extra spaces at the end of the text or between words. Please correct by removing all data in the field and re-enter

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/20/2020

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB SELF - 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: 10541173

Subject Initials: ---

Generated By: (b) (4)

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

				without adding extra spaces or using enter or tab keys.
Oct-20-2020 16:02:46 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: Swab was collected on site.	Initial Entry

Header Text: c4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit on Oct/20/2020**Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB - eCRF Audit Trail History**Form Version:** 22-Apr-2020 21:03**Form Status:** Data Complete, Frozen, Verified**Site No:** 1054**Site Name:** (1054) Collaborative Neuroscience Network, LLC.**Subject No:** 10541173**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 04:44[Back to Form](#)**1. Data Origin**

Date	Location	User	Value	Reason
Oct-20-2020 16:02:21 (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-20-2020 16:02:21 (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-20-2020 16:03:34 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Oct-20-2020 16:02:21 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Oct-20-2020 16:02:21 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: YES Date of Collection: Oct/20/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Oct-20-2020 16:03:34 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: Sample ID: BM983Y	Initial Entry

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/20/2020

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1054

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

Subject No: 10541173

Subject Initials: ---

Generated By: (b) (4)

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

5.a Sample ID

Date	Location	User	Value	Reason
Oct-20-2020 16:03:34 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	<u>Data Entry:</u> BM983Y	Initial Entry

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Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit Form: HEALTH CARE UTILIZATION - eCRF Audit Trail History on Oct/20/2020

Form Version: 10-Oct-2020 15:59

Form Status: Data Complete, Frozen, Verified

Site No: 1054

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

Subject No: 10541173

Subject Initials: ---

Generated By: (b) (4)

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

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I.a

Date	Location	User	Value	Reason
Oct-20-2020 16:02:31 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: Type of Practitioner: SPECIA LIST Occurrence of Visits o r Contacts:	Initial Entry

I.a Physician or Healthcare Professional:

Date	Location	User	Value	Reason
Oct-20-2020 16:02:31 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: SPECIALIST	Initial Entry

I.a Occurrence of Visits or Contacts:

Date	Location	User	Value	Reason
Oct-20-2020 16:02:31 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: NO	Initial Entry

I.b

Date	Location	User	Value	Reason
Oct-20-2020 16:02:31 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: Type of Practition EMERGEN er: CY ROOM Occurrence of Vis NO its or Contacts:	Initial Entry

090177e196ae30e5\Final\Final On: 01-Apr-2021 04:19 (GMT)

Header Text: c4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit **Form:** HEALTH CARE UTILIZATION - eCRF Audit Trail History on Oct/20/2020**Form Version:** 10-Oct-2020 15:59**Form Status:** Data Complete, Frozen, Verified**Site No:** 1054**Site Name:** (1054) Collaborative Neuroscience Network, LLC.**Subject No:** 10541173**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 04:44***I.b Physician or Healthcare Professional:***

Date	Location	User	Value	Reason
Oct-20-2020 16:02:31 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: EMERGENCY ROOM	Initial Entry

I.b Occurrence of Visits or Contacts:

Date	Location	User	Value	Reason
Oct-20-2020 16:02:31 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: NO	Initial Entry

I.c

Date	Location	User	Value	Reason
Oct-20-2020 16:02:31 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: Type of Practitioner: PRIMARY CARE PHYSICIAN Occurrence of Visits or Contacts: NO	Initial Entry

I.c Physician or Healthcare Professional:

Date	Location	User	Value	Reason
Oct-20-2020 16:02:31 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: PRIMARY CARE PHYSICIAN	Initial Entry

I.c Occurrence of Visits or Contacts:

Date	Location	User	Value	Reason
Oct-20-2020 16:02:31 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: NO	Initial Entry

I.d

Date	Location	User	Value	Reason
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Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** HEALTH CARE UTILIZATION - eCRF Audit Trail History on Oct/20/2020

Form Version: 10-Oct-2020 15:59

Form Status: Data Complete, Frozen, Verified

Site No: 1054

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

Subject No: 10541173

Subject Initials: ---

Generated By: (b) (4)

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

Oct-20-2020 16:02:31 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: Type of Practitioner URGENT : CARE Occurrence of Visits NO or Contacts:	Initial Entry
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1.d Physician or Healthcare Professional:

Date	Location	User	Value	Reason
Oct-20-2020 16:02:31 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: URGENT CARE	Initial Entry

1.d Occurrence of Visits or Contacts:

Date	Location	User	Value	Reason
Oct-20-2020 16:02:31 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: NO	Initial Entry

1.e

Date	Location	User	Value	Reason
Oct-20-2020 16:02:31 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: Type of Practitioner: TELEPHONE CONSULTATION Occurrence of Visits or Contacts: NO	Initial Entry

090177e196ae30e5\Final\Final On: 01-Apr-2021 04:19 (GMT)

Header Text: c4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit **Form:** HEALTH CARE UTILIZATION - eCRF Audit Trail History on Oct/20/2020**Form Version:** 10-Oct-2020 15:59**Form Status:** Data Complete, Frozen, Verified**Site No:** 1054**Site Name:** (1054) Collaborative Neuroscience Network, LLC.**Subject No:** 10541173**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 04:44***1.e Physician or Healthcare Professional:***

Date	Location	User	Value	Reason
Oct-20-2020 16:02:31 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: TELEPHONE CONSULTATION	Initial Entry

1.e Occurrence of Visits or Contacts:

Date	Location	User	Value	Reason
Oct-20-2020 16:02:31 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: NO	Initial Entry

1.f

Date	Location	User	Value	Reason
Oct-20-2020 16:02:31 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: Type of Practitioner: OTH ER Occurrence of Visits or Contacts: NO	Initial Entry

1.f Physician or Healthcare Professional:

Date	Location	User	Value	Reason
Oct-20-2020 16:02:31 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: OTHER	Initial Entry

1.f Occurrence of Visits or Contacts:

Date	Location	User	Value	Reason
Oct-20-2020 16:02:31 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: NO	Initial Entry

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

Date	Location	User	Value	Reason
Oct-20-2020 16:02:31	ACV0PFEINFP6000	Steven	Data Entry:	Initial Entry

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** HEALTH CARE UTILIZATION - eCRF Audit Trail History on Oct/20/2020

Form Version: 10-Oct-2020 15:59

Form Status: Data Complete, Frozen, Verified

Site No: 1054

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

Subject No: 10541173

Subject Initials: ---

Generated By: (b) (4)

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

(UTC-08:00) Pacific
Time (US & Canada)

Choi	NO
(b) (4)	

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit Form: RESPIRATORY TREATMENT - eCRF Audit Trail History on Oct/20/2020

Form Version: 06-Jul-2020 21:53

Form Status: Data Complete, Frozen, Verified

Site No: 1054

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

Subject No: 10541173

Subject Initials: ---

Generated By: (b) (4)

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

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1. What is the treatment Identifier?

Date	Location	User	Value	Reason
Oct-21-2020 16:11:15 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: Not Applicable	Initial Entry

2. Concomitant Non-drug Treatment Pre-specified:

Date	Location	User	Value	Reason
Oct-21-2020 16:11:15 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: Not Applicable	Initial Entry

3. Treatment:

Date	Location	User	Value	Reason
Oct-21-2020 16:11:15 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: Not Applicable	Initial Entry

4. Treatment:

Date	Location	User	Value	Reason
Oct-21-2020 16:11:15 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: Not Applicable	Initial Entry

5. Start Date:

Date	Location	User	Value	Reason
Oct-21-2020 16:11:15 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: Not Applicable	Initial Entry

6. Ongoing?

Date	Location	User	Value	Reason
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090177e196ae30e5\Final\Final On: 01-Apr-2021 04:19 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** RESPIRATORY TREATMENT - eCRF Audit Trail History on Oct/20/2020

Form Version: 06-Jul-2020 21:53

Form Status: Data Complete, Frozen, Verified

Site No: 1054

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

Subject No: 10541173

Subject Initials: ---

Generated By: (b) (4)

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

Oct-21-2020 16:11:15 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: Not Applicable	Initial Entry
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Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** ILLNESS DETAILS - eCRF Audit Trail History
on Oct/20/2020

Form Version: 06-Jul-2020 21:52

Form Status: Data Complete, Frozen, Verified

Site No: 1054

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

Subject No: 10541173

Subject Initials: ---

Generated By: (b) (4)

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

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1. Category of Clinical Event:

Date	Location	User	Value	Reason
Oct-21-2020 16:12:32 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: POTENTIAL COVID-19 ILLNES S	Initial Entry

2. Was a diagnosis obtained for Potential COVID-19 Illness?

Date	Location	User	Value	Reason
Oct-21-2020 16:12:32 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: NO	Initial Entry

3. Toxicity Grade:

Date	Location	User	Value	Reason
Oct-27-2020 15:05:10 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: 2	Transcription Error
Oct-21-2020 16:12:46 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: 1	Initial Entry

090177e196ae30e5\Final\Final On: 01-Apr-2021 04:19 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit Form: ILLNESS DETAILS - SEVERE - eCRF Audit Trail History on Oct/20/2020

Form Version: 17-Jul-2020 21:55

Form Status: Data Complete, Frozen, Verified

Site No: 1054

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

Subject No: 10541173

Subject Initials: ---

Generated By: (b) (4)

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

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1. Category of Clinical Event:

Date	Location	User	Value	Reason
Oct-21-2020 16:12:58 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: Not Applicable	Initial Entry

2. Subcategory of Clinical Event:

Date	Location	User	Value	Reason
Oct-21-2020 16:12:58 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: Not Applicable	Initial Entry

3. Was a diagnosis obtained?

Date	Location	User	Value	Reason
Oct-21-2020 16:12:58 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: Not Applicable	Initial Entry

4. Toxicity Grade:

Date	Location	User	Value	Reason
Oct-21-2020 16:12:58 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: Not Applicable	Initial Entry

090177e196ae30e5\Final\Final On: 01-Apr-2021 04:19 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/20/2020

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History

Form Version: 15-Sep-2020 21:51

Form Status: Data Complete, Frozen, Verified

Site No: 1054

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

Subject No: 10541173

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-21-2020 16:13:15 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: Not Applicable	Initial Entry

2. Laboratory Name and Address

Date	Location	User	Value	Reason
Oct-21-2020 16:13:15 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: Not Applicable	Initial Entry

3. Collection Date:

Date	Location	User	Value	Reason
Oct-21-2020 16:13:15 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: Not Applicable	Initial Entry

4. Specimen Type:

Date	Location	User	Value	Reason
Oct-21-2020 16:13:15 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: Not Applicable	Initial Entry

5.a

Date	Location	User	Value	Reason
Oct-21-2020 16:13:15 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: Sponsor-Defined Id Not Applicable Test:: Not Applicable Result:: Not Applicable	Initial Entry

090177e196ae30e5\Final\Final On: 01-Apr-2021 04:19 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/20/2020

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History

Form Version: 15-Sep-2020 21:51

Form Status: Data Complete, Frozen, Verified

Site No: 1054

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

Subject No: 10541173

Subject Initials: ---

Generated By: (b) (4)

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

			Not Done::	Not Applicable
			Lab Normal Range:	Not Applicable

5.a Sponsor ID:

Date	Location	User	Value	Reason
Oct-21-2020 16:13:15 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: Not Applicable	Initial Entry

5.a Test:

Date	Location	User	Value	Reason
Oct-21-2020 16:13:15 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: Not Applicable	Initial Entry

5.a Result:

Date	Location	User	Value	Reason
Oct-21-2020 16:13:15 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: Not Applicable	Initial Entry

5.a Not Done:

Date	Location	User	Value	Reason
Oct-21-2020 16:13:15 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: Not Applicable	Initial Entry

5.a LNMT

Date	Location	User	Value	Reason
Oct-21-2020 16:13:15 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: Not Applicable	Initial Entry

5.b

090177e196ae30e5\Final\Final On: 01-Apr-2021 04:19 (GMT)

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Oct-21-2020 16:13:15 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: Sponsor-Defined Identifier: Not Applicable Test:: Not Applicable Result:: Not Applicable Not Done:: Not Applicable Lab Normal Range: Not Applicable	Initial Entry

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5.b Sponsor ID:

Date	Location	User	Value	Reason
Oct-21-2020 16:13:15 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: Not Applicable	Initial Entry

5.b Test:

Date	Location	User	Value	Reason
Oct-21-2020 16:13:15 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: Not Applicable	Initial Entry

5.b Result:

Date	Location	User	Value	Reason
Oct-21-2020 16:13:15 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: Not Applicable	Initial Entry

5.b Not Done:

Date	Location	User	Value	Reason
Oct-21-2020 16:13:15 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: Not Applicable	Initial Entry

5.b LNMT

Date	Location	User	Value	Reason
Oct-21-2020 16:13:15 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: Not Applicable	Initial Entry

5.c

Date	Location	User	Value	Reason
Oct-21-2020 16:13:15 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: Sponsor-Defined Id Not Applicable entifier: able	Initial Entry

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5.c LNMT

Date	Location	User	Value	Reason
Oct-21-2020 16:13:15 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: Not Applicable	Initial Entry

5.d

Date	Location	User	Value	Reason
Oct-21-2020 16:13:15 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: Sponsor-Defined Id Not Applicable entifier: able	Initial Entry

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5.d LNMT

Date	Location	User	Value	Reason
Oct-21-2020 16:13:15 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: Not Applicable	Initial Entry

5.e

Date	Location	User	Value	Reason
Oct-21-2020 16:13:15 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: Sponsor-Defined Id Not Applicable entifier: able	Initial Entry

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Date	Location	User	Value	Reason
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5.f

Date	Location	User	Value	Reason
Oct-21-2020 16:13:15 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: Sponsor-Defined Id Not Applicable entifier: able	Initial Entry

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Oct-21-2020 16:13:15 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: Not Applicable	Initial Entry

5.f LNMT

Date	Location	User	Value	Reason
Oct-21-2020 16:13:15 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: Not Applicable	Initial Entry

5.g

Date	Location	User	Value	Reason
Oct-21-2020 16:13:15 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: Sponsor-Defined Id Not Applicable entifier: able	Initial Entry

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5.g LNMT

Date	Location	User	Value	Reason
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Header Text: c4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit on Oct/20/2020**Form:** LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History**Form Version:** 15-Sep-2020 21:55**Form Status:** Data Complete, Frozen, Verified**Site No:** 1054**Site Name:** (1054) Collaborative Neuroscience Network, LLC.**Subject No:** 10541173**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 04:44[Back to Form](#)**1. Lab Panel:**

Date	Location	User	Value	Reason
Oct-21-2020 16:13:33 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: Not Applicable	Initial Entry

2. Laboratory Name and Address

Date	Location	User	Value	Reason
Oct-21-2020 16:13:33 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: Not Applicable	Initial Entry

3. Collection Date:

Date	Location	User	Value	Reason
Oct-21-2020 16:13:33 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: Not Applicable	Initial Entry

4. Specimen Type:

Date	Location	User	Value	Reason
Oct-21-2020 16:13:33 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: Not Applicable	Initial Entry

5.a

Date	Location	User	Value	Reason
Oct-21-2020 16:13:33 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: Sponsor-Defined Id Not Applicable Test:: Not Applicable Result:: Not Applicable	Initial Entry

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5.a Sponsor ID:

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Date	Location	User	Value	Reason
Oct-21-2020 16:13:33 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: Not Applicable	Initial Entry

5.c Test:

Date	Location	User	Value	Reason
Oct-21-2020 16:13:33 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: Not Applicable	Initial Entry

5.c Result:

Date	Location	User	Value	Reason
Oct-21-2020 16:13:33 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: Not Applicable	Initial Entry

5.c Not Done:

Date	Location	User	Value	Reason
Oct-21-2020 16:13:33 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: Not Applicable	Initial Entry

5.c LNMT

Date	Location	User	Value	Reason
Oct-21-2020 16:13:33 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: Not Applicable	Initial Entry

5.d

Date	Location	User	Value	Reason
Oct-21-2020 16:13:33 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: Sponsor-Defined Id Not Applicable entifier: able	Initial Entry

090177e196ae30e5\Final\Final On: 01-Apr-2021 04:19 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/20/2020

Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

Form Version: 15-Sep-2020 21:55

Form Status: Data Complete, Frozen, Verified

Site No: 1054

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

Subject No: 10541173

Subject Initials: ---

Generated By: (b) (4)

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

			Test::	Not Applicable	
			Result::	Not Applicable	
			Not Done::	Not Applicable	
			Lab Normal Range:	Not Applicable	

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/20/2020

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Subject Initials: ---

Generated By: (b) (4)

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

5.d Sponsor ID:

Date	Location	User	Value	Reason
Oct-21-2020 16:13:33 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: Not Applicable	Initial Entry

5.d Test:

Date	Location	User	Value	Reason
Oct-21-2020 16:13:33 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: Not Applicable	Initial Entry

5.d Result:

Date	Location	User	Value	Reason
Oct-21-2020 16:13:33 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: Not Applicable	Initial Entry

5.d Not Done:

Date	Location	User	Value	Reason
Oct-21-2020 16:13:33 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: Not Applicable	Initial Entry

5.d LNMT

Date	Location	User	Value	Reason
Oct-21-2020 16:13:33 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: Not Applicable	Initial Entry

5.e

Date	Location	User	Value	Reason
Oct-21-2020 16:13:33 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: Sponsor-Defined Id Not Applicable entifier: able	Initial Entry

090177e196ae30e5\Final\Final On: 01-Apr-2021 04:19 (GMT)

Header Text: c4591001

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Generated By: (b) (4)

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

			Test::	Not Applicable	
			Result::	Not Applicable	
			Not Done::	Not Applicable	
			Lab Normal Range:	Not Applicable	

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/20/2020

Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

Form Version: 15-Sep-2020 21:55

Form Status: Data Complete, Frozen, Verified

Site No: 1054

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

Subject No: 10541173

Subject Initials: ---

Generated By: (b) (4)

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

5.e Sponsor ID:

Date	Location	User	Value	Reason
Oct-21-2020 16:13:33 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: Not Applicable	Initial Entry

5.e Test:

Date	Location	User	Value	Reason
Oct-21-2020 16:13:33 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: Not Applicable	Initial Entry

5.e Result:

Date	Location	User	Value	Reason
Oct-21-2020 16:13:33 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: Not Applicable	Initial Entry

5.e Not Done:

Date	Location	User	Value	Reason
Oct-21-2020 16:13:33 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: Not Applicable	Initial Entry

5.e LNMT

Date	Location	User	Value	Reason
Oct-21-2020 16:13:33 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: Not Applicable	Initial Entry

5.f

Date	Location	User	Value	Reason
Oct-21-2020 16:13:33 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: Sponsor-Defined Id Not Applicable entifier: able	Initial Entry

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Header Text: c4591001

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Form Status: Data Complete, Frozen, Verified

Site No: 1054

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

Subject No: 10541173

Subject Initials: ---

Generated By: (b) (4)

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

			Test::	Not Applicable	
			Result::	Not Applicable	
			Not Done::	Not Applicable	
			Lab Normal Range:	Not Applicable	

Header Text: c4591001

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

Subject No: 10541173

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Generated By: (b) (4)

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

5.f Sponsor ID:

Date	Location	User	Value	Reason
Oct-21-2020 16:13:33 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: Not Applicable	Initial Entry

5.f Test:

Date	Location	User	Value	Reason
Oct-21-2020 16:13:33 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: Not Applicable	Initial Entry

5.f Result:

Date	Location	User	Value	Reason
Oct-21-2020 16:13:33 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: Not Applicable	Initial Entry

5.f Not Done:

Date	Location	User	Value	Reason
Oct-21-2020 16:13:33 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: Not Applicable	Initial Entry

5.f LNMT

Date	Location	User	Value	Reason
Oct-21-2020 16:13:33 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: Not Applicable	Initial Entry

5.g

Date	Location	User	Value	Reason
Oct-21-2020 16:13:33 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: Sponsor-Defined Id Not Applicable entifier: able	Initial Entry

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Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/20/2020

Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

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Form Status: Data Complete, Frozen, Verified

Site No: 1054

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

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			Test::	Not Applicable	
			Result::	Not Applicable	
			Not Done::	Not Applicable	
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Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/20/2020

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

5.g Sponsor ID:

Date	Location	User	Value	Reason
Oct-21-2020 16:13:33 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: Not Applicable	Initial Entry

5.g Test:

Date	Location	User	Value	Reason
Oct-21-2020 16:13:33 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: Not Applicable	Initial Entry

5.g Result:

Date	Location	User	Value	Reason
Oct-21-2020 16:13:33 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: Not Applicable	Initial Entry

5.g Not Done:

Date	Location	User	Value	Reason
Oct-21-2020 16:13:33 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: Not Applicable	Initial Entry

5.g LNMT

Date	Location	User	Value	Reason
Oct-21-2020 16:13:33 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: Not Applicable	Initial Entry

5.h

Date	Location	User	Value	Reason
Oct-21-2020 16:13:33 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: Sponsor-Defined Id Not Applicable entifier: able	Initial Entry

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Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/20/2020

Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

Form Version: 15-Sep-2020 21:55

Form Status: Data Complete, Frozen, Verified

Site No: 1054

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

Subject No: 10541173

Subject Initials: ---

Generated By: (b) (4)

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

			Test::	Not Applicable	
			Result::	Not Applicable	
			Not Done::	Not Applicable	
			Lab Normal Range:	Not Applicable	

Header Text: c4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit on Oct/20/2020 **Form:** LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History**Form Version:** 15-Sep-2020 21:55**Form Status:** Data Complete, Frozen, Verified**Site No:** 1054**Site Name:** (1054) Collaborative Neuroscience Network, LLC.**Subject No:** 10541173**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 04:44**5.h Sponsor ID:**

Date	Location	User	Value	Reason
Oct-21-2020 16:13:33 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: Not Applicable	Initial Entry

5.h Test:

Date	Location	User	Value	Reason
Oct-21-2020 16:13:33 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: Not Applicable	Initial Entry

5.h Result:

Date	Location	User	Value	Reason
Oct-21-2020 16:13:33 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: Not Applicable	Initial Entry

5.h Not Done:

Date	Location	User	Value	Reason
Oct-21-2020 16:13:33 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: Not Applicable	Initial Entry

5.h LNMT

Date	Location	User	Value	Reason
Oct-21-2020 16:13:33 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: Not Applicable	Initial Entry

5.i

Date	Location	User	Value	Reason
Oct-21-2020 16:13:33 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: Sponsor-Defined Id Not Applicable entifier: able	Initial Entry

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/20/2020

Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

Form Version: 15-Sep-2020 21:55

Form Status: Data Complete, Frozen, Verified

Site No: 1054

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

Subject No: 10541173

Subject Initials: ---

Generated By: (b) (4)

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

			Test::	Not Applicable	
			Result::	Not Applicable	
			Not Done::	Not Applicable	
			Lab Normal Range:	Not Applicable	

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/20/2020

Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

Form Version: 15-Sep-2020 21:55

Form Status: Data Complete, Frozen, Verified

Site No: 1054

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

Subject No: 10541173

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Generated By: (b) (4)

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

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5.i Sponsor ID:

Date	Location	User	Value	Reason
Oct-21-2020 16:13:33 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: Not Applicable	Initial Entry

5.i Test:

Date	Location	User	Value	Reason
Oct-21-2020 16:13:33 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: Not Applicable	Initial Entry

5.i Result:

Date	Location	User	Value	Reason
Oct-21-2020 16:13:33 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: Not Applicable	Initial Entry

5.i Not Done:

Date	Location	User	Value	Reason
Oct-21-2020 16:13:33 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: Not Applicable	Initial Entry

5.i LNMT

Date	Location	User	Value	Reason
Oct-21-2020 16:13:33 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: Not Applicable	Initial Entry

5.j

Date	Location	User	Value	Reason
Oct-21-2020 16:13:33 (UTC-08:00) Pacific	ACV0PFEINFP6000	Steven Choi	Data Entry: Sponsor-Defined Id Not Applic	Initial Entry

090177e196ae30e5\Final\Final On: 01-Apr-2021 04:19 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/20/2020

Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

Form Version: 15-Sep-2020 21:55

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Site No: 1054

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

Subject No: 10541173

Subject Initials: ---

Generated By: (b) (4)

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

Time (US & Canada)	(b) (4)	entifier:	able
		Test::	Not Applicable
		Result::	Not Applicable
		Not Done::	Not Applicable
		Lab Normal Range:	Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/20/2020

Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

Form Version: 15-Sep-2020 21:55

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Subject No: 10541173

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Generated By: (b) (4)

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

5.j Sponsor ID:

Date	Location	User	Value	Reason
Oct-21-2020 16:13:33 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: Not Applicable	Initial Entry

5.j Test:

Date	Location	User	Value	Reason
Oct-21-2020 16:13:33 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: Not Applicable	Initial Entry

5.j Result:

Date	Location	User	Value	Reason
Oct-21-2020 16:13:33 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: Not Applicable	Initial Entry

5.j Not Done:

Date	Location	User	Value	Reason
Oct-21-2020 16:13:33 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: Not Applicable	Initial Entry

5.j LNMT

Date	Location	User	Value	Reason
Oct-21-2020 16:13:33 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: Not Applicable	Initial Entry

090177e196ae30e5\Final\Final On: 01-Apr-2021 04:19 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit Form: VITAL SIGNS - COVID - eCRF Audit Trail History on Oct/20/2020

Form Version: 15-Sep-2020 21:52

Form Status: Data Complete, Frozen, Verified

Site No: 1054

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

Subject No: 10541173

Subject Initials: ---

Generated By: (b) (4)

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

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1. Date:

Date	Location	User	Value	Reason
Oct-21-2020 16:13:52 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: Not Applicable	Initial Entry

2.a

Date	Location	User	Value	Reason
Oct-21-2020 16:13:52 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: Record Identifier:: Not Applicable Systolic:: Not Applicable Diastolic:: Not Applicable Respiratory Rate in re Not App spirations/minute: licable Heart Rate in beats/m Not App inute: licable	Initial Entry

2.a Record Identifier:

Date	Location	User	Value	Reason
Oct-21-2020 16:13:52 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: Not Applicable	Initial Entry

2.a Systolic:

Date	Location	User	Value	Reason
Oct-21-2020 16:13:52 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: Not Applicable	Initial Entry

2.a Diastolic:

Date	Location	User	Value	Reason
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090177e196ae30e5\Final\Final On: 01-Apr-2021 04:19 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** VITAL SIGNS - COVID - eCRF Audit Trail History on Oct/20/2020

Form Version: 15-Sep-2020 21:52

Form Status: Data Complete, Frozen, Verified

Site No: 1054

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

Subject No: 10541173

Subject Initials: ---

Generated By: (b) (4)

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

Oct-21-2020 16:13:52 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: Not Applicable	Initial Entry
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2.a Respiratory Rate in respirations/minute:

Date	Location	User	Value	Reason
Oct-21-2020 16:13:52 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: Not Applicable	Initial Entry

2.a Heart Rate in beats/minute:

Date	Location	User	Value	Reason
Oct-21-2020 16:13:52 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: Not Applicable	Initial Entry

090177e196ae30e5\Final\Final On: 01-Apr-2021 04:19 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/20/2020

Form: VITAL SIGNS - PULSE OX ROOM AIR - eCRF Audit Trail History

Form Version: 15-Sep-2020 21:54

Form Status: Data Complete, Frozen, Verified

Site No: 1054

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

Subject No: 10541173

Subject Initials: ---

Generated By: (b) (4)

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

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I. Date:

Date	Location	User	Value	Reason
Oct-21-2020 16:14:11 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: Not Applicable	Initial Entry

2.a

Date	Location	User	Value	Reason
Oct-21-2020 16:14:11 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: Record Identifier Not Applicab :: le Oxygen Saturatio Not Applicab n: le	Initial Entry

2.a Record Identifier:

Date	Location	User	Value	Reason
Oct-21-2020 16:14:11 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: Not Applicable	Initial Entry

2.a SPO2 Pulse Oximetry %

Date	Location	User	Value	Reason
Oct-21-2020 16:14:11 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: Not Applicable	Initial Entry

090177e196ae30e5\Final\Final On: 01-Apr-2021 04:19 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** OXYGENATION PARAMETERS - eCRF Audit Trail History on Oct/20/2020

Form Version: 06-Jul-2020 21:52

Form Status: Data Complete, Frozen, Verified

Site No: 1054

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

Subject No: 10541173

Subject Initials: ---

Generated By: (b) (4)

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

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1. Date Time of Assessment:

Date	Location	User	Value	Reason
Oct-21-2020 16:14:27 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: Not Applicable	Initial Entry

2. Arterial Blood Gases PaO2 (mmHg):

Date	Location	User	Value	Reason
Oct-21-2020 16:14:27 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: Not Applicable	Initial Entry

3. FiO2 (Fraction of Inhaled Oxygen):

Date	Location	User	Value	Reason
Oct-21-2020 16:14:27 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: Not Applicable	Initial Entry

090177e196ae30e5\Final\Final On: 01-Apr-2021 04:19 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/20/2020

Form: CONCOMITANT MEDICATIONS - VASOPRESSORS - eCRF Audit Trail History

Form Version: 06-Jul-2020 21:55

Form Status: Data Complete, Frozen, Verified

Site No: 1054

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

Subject No: 10541173

Subject Initials: ---

Generated By: (b) (4)

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

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1. What is the medication identifier?

Date	Location	User	Value	Reason
Oct-21-2020 16:14:41 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: Not Applicable	Initial Entry

2. Category:

Date	Location	User	Value	Reason
Oct-21-2020 16:14:41 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: Not Applicable	Initial Entry

3. Concomitant Medications Pre-specified:

Date	Location	User	Value	Reason
Oct-21-2020 16:14:41 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: Not Applicable	Initial Entry

4. Medication:

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

Date	Location	User	Value	Reason
Oct-21-2020 16:14:41 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: Not Applicable	Initial Entry

5. Start Date:

Date	Location	User	Value	Reason
Oct-21-2020 16:14:41 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: Not Applicable	Initial Entry

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Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/20/2020

Form: CONCOMITANT MEDICATIONS - VASOPRESSORS - eCRF Audit Trail History

Form Version: 06-Jul-2020 21:55

Form Status: Data Complete, Frozen, Verified

Site No: 1054

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

Subject No: 10541173

Subject Initials: ---

Generated By: (b) (4)

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

6. Ongoing?

Date	Location	User	Value	Reason
Oct-21-2020 16:14:41 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: Not Applicable	Initial Entry

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** IMAGING - eCRF Audit Trail History
on Oct/20/2020

Form Version: 06-Jul-2020 21:53

Form Status: Data Complete, Frozen, Verified

Site No: 1054

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

Subject No: 10541173

Subject Initials: ---

Generated By: (b) (4)

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

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1. Date of Assessment:

Date	Location	User	Value	Reason
Oct-21-2020 16:14:55 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: Not Applicable	Initial Entry

2. Location of Assessment:

Date	Location	User	Value	Reason
Oct-21-2020 16:14:55 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: Not Applicable	Initial Entry

3. Type of Imaging Exam:

Date	Location	User	Value	Reason
Oct-21-2020 16:14:55 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: Not Applicable	Initial Entry

4. Assessment:

Date	Location	User	Value	Reason
Oct-21-2020 16:14:55 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: Not Applicable	Initial Entry

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Header Text: c4591001

Visit: POT_COVID_CONVA 1 - Unscheduled Visit on Feb/22/2021

Form: DATE OF VISIT - ILLNESS CONVALESCENT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Frozen, Verified

Site No: 1054

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

Subject No: 10541173

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-22-2021 14:54:33 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: Feb/22/2021	Initial Entry

3. COVID-19 Illness Visit:

Date	Location	User	Value	Reason
Feb-22-2021 14:54:33 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: COVID_A1	Initial Entry

090177e196ae30e5\Final\Final On: 01-Apr-2021 04:19 (GMT)

Header Text: c4591001**Visit:** POT_COVID_CONVA 1 - Unscheduled
Visit on Feb/22/2021**Form Version:** 22-Apr-2020 21:03**Site No:** 1054**Subject No:** 10541173**Generated By:** (b) (4)**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY -
eCRF Audit Trail History**Form Status:** Data Complete, 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
Feb-22-2021 14:55:34 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Feb-22-2021 14:55:34 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SERUM	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Feb-22-2021 15:13:26 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Feb-22-2021 14:55:34 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Feb-22-2021 14:55:34 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: YES Date of Collection: Feb/22/2021	Initial Entry

5.a

Date	Location	User	Value	Reason
Feb-22-2021 15:13:26 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: Sample ID: BRMTKP	Initial Entry

Header Text: c4591001

Visit: POT_COVID_CONVA 1 - Unscheduled
Visit on Feb/22/2021

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

Site No: 1054

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Subject No: 10541173

Subject Initials: ---

Generated By: (b) (4)

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

5.a Sample ID

Date	Location	User	Value	Reason
Feb-22-2021 15:13:26 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: BRMTKP	Initial Entry

5.b

Date	Location	User	Value	Reason
Feb-22-2021 15:13:39 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: Sample ID: BRMTKR	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Feb-22-2021 15:13:39 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: BRMTKR	Initial Entry

5.c

Date	Location	User	Value	Reason
Feb-22-2021 15:13:57 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: Sample ID: BRMTKS	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Feb-22-2021 15:13:57 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: BRMTKS	Initial Entry

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Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1054

Subject No: 10541173

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - Audit Trail

Form Status:

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Subject Initials: ---

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Date	Location	User	Value	Reason
Oct-30-2020 14:56:35 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Form Created	

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1054

Subject No: 10541173

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - Audit Trail

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Date	Location	User	Value	Reason
Nov-02-2020 11:42:11 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Form Created	

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1054

Subject No: 10541173

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - Audit Trail

Form Status:

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

Subject Initials: ---

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Date	Location	User	Value	Reason
Nov-05-2020 13:11:06 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Form Created	

Header Text: c4591001

Visit: Logs - Unscheduled

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Site No: 1054

Subject No: 10541173

Generated By: (b) (4)

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*** THIS REPEATING FORM HAS BEEN DELETED ***

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Date	Location	User	Value	Reason
Dec-08-2020 08:18:42 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Form Deleted	Changed Information
Nov-16-2020 11:52:13 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Form Created	

Header Text: c4591001

Visit: Logs - Unscheduled

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Subject No: 10541173

Generated By: (b) (4)

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Date	Location	User	Value	Reason
Nov-16-2020 11:53:17 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Form Created	

Header Text: c4591001

Visit: Logs - Unscheduled

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Site No: 1054

Subject No: 10541173

Generated By: (b) (4)

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Date	Location	User	Value	Reason
Dec-18-2020 16:04:59 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Form Created	

Header Text: c4591001

Visit: Logs - Unscheduled

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Site No: 1054

Subject No: 10541173

Generated By: (b) (4)

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1. Category:

Date	Location	User	Value	Reason
Oct-30-2020 14:56:35 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: ADVERSE EVENT	Initial Entry

2. AE ID:

Date	Location	User	Value	Reason
Oct-30-2020 14:56:35 (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
Dec-22-2020 17:12:10 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 5: Closed	Queried on actual event of AI
Dec-22-2020 04:36:43 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 5: Reissued:Opened	SAE RECON 2: Please confirm seriousness of 'Aortic value insufficiency,' if non serious, please downgrade in Safety database.
Dec-18-2020 16:08:58 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Query 5: Answered	Changed data per query
Dec-18-2020 05:23:28 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 5: Reissued:Opened	SAE recon:Per PSSR comment 'remove the event of "Aortic value insufficiency," we would need a new SAE form clarifying this event needs to be removed and which events should be retained as SAEs for this subject.'

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				Please submit a AE form to clarify terms.
Dec-11-2020 04:04:41 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 5: Reissued:Candi date	PSSR review
Dec-09-2020 08:52:06 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Query 5: Answered	As written. SAE term has been changed from acute severe AI to SBE, as SBE has been determined to be the underlying diagnosis.
Dec-09-2020 04:38:38 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 5: Opened	SAE RECON:AER#2020423609, the term was updated to 'subacute bacterial endocarditis' however 'Acute Severe Aortic insufficiency' was still recorded as separate SAE in SDB. Please confirm if acute sever aortic insufficiency is not an SAE.
Dec-04-2020 12:37:34 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: subacute bacterial endocardi rditis	Changed Information
Nov-16-2020 12:22:19 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 4: Closed	Response satisfies query
Nov-16-2020 12:03:18 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Query 4: Answered	Changed data per query
Nov-16-2020 09:45:31 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 4: Reissued:Opene d	CLINICAL - Please report the Additional reported new events of 1) A fib, and 2) SBE separately on the AE CRF log
Nov-16-2020	ACV0PFEINFP6000	Steven Choi	Query 4: Answered	As written. Dx stays the

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Header Text: c4591001**Visit:** Logs - Unscheduled**Form Version:** 22-Apr-2020 21:02**Site No:** 1054**Subject No:** 10541173**Generated By:** (b) (4)**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History**Form Status:** Data Complete, Frozen, Verified**Site Name:** (1054) Collaborative Neuroscience Network, LLC.**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 04:44

09:14:51 (UTC-08:00) Pacific Time (US & Canada)		(b) (4)		same. Etiology of acute severe aortic insufficiency has been determined due to gram + cocci bacterial endocarditis (unknown source).
Nov-15-2020 06:26:12 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 4: Opened	CLINICAL - Based on discussion with safety, subject has been diagnosed with SBE (gram +) and intermittent Atrial Fibrillation; please review and if appropriate, report as new events on AE CRF
Nov-10-2020 15:25:28 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Closed	Response satisfies query
Nov-10-2020 13:30:16 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Query 3: Answered	Updated MedHx.
Nov-10-2020 12:43:14 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Opened	GPD CLINQUERY: According to SAE case number 2020423609, the patient reported 'nerve neck pain' from 11Sep2020 (ongoing) with concomitant medication ibuprofen. To ensure data consistency, please add event to Inform or update SAE form as appropriate.
Nov-08-2020 12:18:47 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Closed	Response satisfies query
Nov-06-2020 08:28:07 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Query 2: Answered	This was recorded on AE Line 3. "Central nervous system bleed" was what was on the SAE form for this specific SAE.

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Nov-05-2020 23:43:00 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Opened	CLINICAL Per site discussions, subject underwent Head CT with evidence of cerebral bleed. Please evaluate for clinical significance and report as a new event, if applicable
Nov-05-2020 11:12:58 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Candidate	CLINICAL Per site discussions, subject underwent Head CT with evidence of cerebral bleed. Please evaluate for clinical significance and report as a new event, if applicable
Nov-03-2020 08:21:07 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: acute severe aortic insufficiency	New Information
Nov-02-2020 14:54:01 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Nov-02-2020 11:43:31 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Query 1: Answered	Per source, "no past medical hx of aortic insufficiency reporting during screening, V2, and COVID-19 illness visit."
Nov-02-2020 08:30:48 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	GPD CLINQUERY: Please confirm if there is a previous medical history of aortic insufficiency.
Oct-30-2020 14:56:35 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: aortic insufficiency	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason
Dec-17-2020 14:29:23 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Closed	CRA will address

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Dec-16-2020 11:41:20 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Query 2: Answered	As written. MM instructed PI to report SBE as the term for this SAE; SBE is the underlying etiology for the severe AI. No SAE forms were merged.
Dec-11-2020 11:42:29 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Dec-11-2020 11:37:47 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Reissued:Opened	CLINICAL When SAE report is merged, all (>1) SAEs are reported together. SAE Aortic Insufficiency is an independent event, related to the event SBE by causality. Please re-enter the SAE Aortic Insufficiency in AE and SAE.
Dec-08-2020 08:21:28 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Query 2: Answered	SAE term has been changed from severe AI to SBE, as SBE has been determined to be the underlying diagnosis.
Dec-08-2020 08:21:17 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Query 1: Answered	SAE term has been changed from severe AI to SBE, as SBE has been determined to be the underlying diagnosis.
Dec-08-2020 08:19:37 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Opened	CLINICAL - SAE report includes SAE of Aortic Insufficiency which

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				is now missing from AE CRF. Consider revising this event term back to AI, and making updates for new SAE of SBE on the AE event of bacterial endocarditis.
Dec-08-2020 08:18:10 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	CLINICAL SAE of SBE has start date of 28Oct20; however, SAE report for SBE event has no start date. Please consider SBE start date with respect to 28Oct20 start date of severe AI. Update SBE start date as appropriate in AE and SAE.
Oct-30-2020 14:56:35 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: Oct/28/2020 UNK:UNK	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Feb-04-2021 14:31:30 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: NO End Date Time: Dec/15/2020 UNK:UNK	New Information
Feb-01-2021 16:20:08 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Closed	Response satisfies query
Jan-29-2021 11:54:35 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Query 3: Answered	Last dose of abx were given a couple of days ago. Will update as

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				information from pt comes.
Jan-08-2021 17:20:05 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Opened	CLINICAL SAE report states subject received aortic valve replacement on 09Nov2020; latest update 18Dec does not report antibiotics still. Please review for potential end date for event SBE; if appropriate update AE and SAE
Jan-08-2021 17:18:05 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Closed	re-wording
Jan-08-2021 17:16:56 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Opened	CLINICAL SAE report states subject received aortic valve replacement on 09Nov2020. Please review for potential end date for event Acute Aortic Insufficiency; if appropriate update AE and SAE
Dec-06-2020 07:26:14 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Dec-02-2020 08:40:25 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Query 1: Answered	Follow-up report for this SAE has been submitted to Safety on 30Nov20.
Dec-01-2020 15:47:36 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	CLINICAL SAE report states subject received aortic valve replacement on 09Nov2020.

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				Please review for potential end date for event Acute Aortic Insufficiency; if appropriate update AE and SAE
Oct-30-2020 14:56:35 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: YES	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
Oct-30-2020 14:56:35 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: 4	Initial Entry

7. Is the adverse event serious?

If Yes, NOTIFY PFIZER IMMEDIATELY.

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

Date	Location	User	Value	Reason
Nov-08-2020 12:19:46 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 4: Closed	Response satisfies query
Nov-05-2020 13:19:49 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Query 4: Answered	Per f/u SAE report submitted on 04-Nov-20, pulmonary edema and decreased oxygen saturation are findings consistent with the primary dx of acute severe aortic insufficiency and do not represent separate medical conditions.

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Nov-05-2020 11:08:32 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Query 5: Closed	information received
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7. Is the adverse event serious?

If Yes, NOTIFY PFIZER IMMEDIATELY.

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

Date	Location	User	Value	Reason
Nov-03-2020 04:27:01 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Closed	Response satisfies query
Nov-02-2020 22:38:50 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 4: Opened	Clinical - Per SAE report, subject's chest Xray report described pulmonary edema, and oxygen saturation was <90% on 2L oxygen. Please consider an additional event report describing a relevant event for these findings.
Nov-02-2020 22:36:47 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 5: Opened	Clinical - Thank you for report of in-hosp COVID test. Please include DATE of test (possibly ER on 28Oct20) when result is reported.
Nov-02-2020 21:42:47 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Closed	Response satisfies query
Nov-02-2020 11:48:59 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Query 2: Answered	F/u SAE form has been submitted to Safety.
Nov-02-2020 11:44:29 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Query 3: Answered	Changed data per query

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Nov-02-2020 09:48:16 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 5: Candidate	Clinical - Thank you for report of in-hosp COVID test. Please include DATE of test (possibly ER on 28Oct20) when result is reported.
Nov-02-2020 09:38:39 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 4: Candidate	Clinical - Per SAE report, subject's chest Xray report described pulmonary edema, and oxygen saturation was <90% on 2L oxygen. Please consider an additional event report describing a relevant event for these findings.
Nov-02-2020 09:35:35 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Opened	CLINICAL - Per SAE report, subject presented to Emergency for evaluation of Pain in Hamstring. Please consider an additional AE report for the event of pain in hamstring.
Nov-01-2020 06:33:41 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Opened	SAE RECON: aortic insufficiency(Onset date:28Oct2020) 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
Nov-01-2020 06:33:12 (UTC-08:00) Pacific	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Deleted	Query can be addressed internally

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Time (US & Canada)		(b) (4), (b) (6)		
Oct-30-2020 14:56:35 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	For AE aortic insufficiency: Response to "Is the adverse event serious?" is 'Yes' but "Serious Adverse Event Number" is blank.
Oct-30-2020 14:56:35 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	<p>Data Entry:</p> <p>YES</p> <p>Is this serious event associated with congenital anomaly or birth defect?</p> <p>NO</p> <p>Did this serious event result in death?</p> <p>NO</p> <p>Did this serious event require or prolong hospitalization?</p> <p>YES</p> <p>Did this serious event result in persistent or significant disability/incapacity?</p> <p>NO</p> <p>Is this serious event life threatening?</p> <p>YES</p> <p>Other medically important serious event</p> <p>NO</p>	Initial Entry

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

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

Date	Location	User	Value	Reason
Oct-30-2020 14:56:35 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: NO	Initial Entry

9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Dec-04-2020 12:37:52 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: NOT RELATED If Not Related to study tr eatment(s), this event is due to: OTHER If Other, specify: gram positive cocci, source unknown	Changed Information
Nov-16-2020 11:08:49 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Closed	Query closed; will follow for SAE update with the requested relationship info
Nov-16-2020 09:42:34 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Closed	Response satisfies query
Nov-16-2020 09:13:44 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 3: Answered	Changed Information
Nov-16-2020 09:13:44 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Answered	Changed Information
Nov-16-2020 09:13:44 (UTC-08:00) Pacific	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: NOT RELATED If Not Related to study tr	Changed Information

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Time (US & Canada)			<p>reatment(s), this event is due to:</p> <p>OTHER</p> <p><i>If Other, specify:</i></p> <p>gram positive cocci bacterial endocarditis, source unknown</p>	
Nov-16-2020 07:45:17 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Opened	SAE RECON:AER#2020423609 ,causality was updated to Related in AE CRF while retained as UNRELATED in Safety database.Per Clinical etiology diagnosis now appears to be SBE (gram +). Please confirm and update accordingly.
Nov-15-2020 06:28:30 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Opened	CLINICAL Event of Aortic Insufficiency recorded as related to study drug; however, etiology diagnosis now appears to be SBE (gram +). Please review SAE relationship; update if appropriate on AE & SAE followup
Nov-04-2020 21:55:13 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Per PSSR confirmation 'AER # 2020423609 was received mentioned that SAE is related to the study vaccine' Issue resolved.
Nov-04-2020 02:24:04 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	SAE RECON:AER#2020423609 ,causality was updated to related in AE CRF while retained as UNRELATED in Safety database. Please confirm correct causality. If safety update is required, please submit a follow-up

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				form.
Nov-03-2020 08:19:42 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: RELATED	New Information
Oct-30-2020 14:56:35 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: NOT RELATED If Not Related to study tr eatment(s), this event is due to: OTHER <i>If Other, specify:</i> unknown	Initial Entry

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Oct-30-2020 14:56:35 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: NOT APPLICABLE	Initial Entry

11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
Oct-30-2020 14:56:35 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: YES	Initial Entry

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Oct-30-2020 14:56:35 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: YES	Initial Entry

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

Date	Location	User	Value	Reason

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Feb-04-2021 14:30:47 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: RECOVERED/RESOLVED	Changed Information
Dec-01-2020 23:55:19 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Dec-01-2020 08:12:20 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Changed Information
Dec-01-2020 08:12:20 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: RECOVERING/RESOLVING	Changed Information
Dec-01-2020 02:14:29 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	SAE RECON:AER#2020423609,outcome was reported as Recovering/Resolving to Safety DB however, recorded as NOT RECOVERED/NOT RESOLVED on AE CRF. Please confirm correct outcome. If safety update is required, please submit a follow-up form.
Oct-30-2020 14:56:35 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: NOT RECOVERED/ NOT RESOLVED	Initial Entry

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

Date	Location	User	Value	Reason
Oct-30-2020 14:56:35 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: NO	Initial Entry

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15. Serious Adverse Event Number: For Pfizer Use Only

Date	Location	User	Value	Reason
Nov-02-2020 04:04:18 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 2020423609	Initial Entry

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1. Category:

Date	Location	User	Value	Reason
Nov-02-2020 11:42:11 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> ADVERSE EVENT	Initial Entry

2. AE ID:

Date	Location	User	Value	Reason
Nov-02-2020 11:42:11 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> 2	Initial Entry

3. Adverse Event:

(If possible specify diagnosis, not individual symptoms)

Date	Location	User	Value	Reason
Nov-12-2020 11:39:40 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [Redacted]	Query 2: Clos ed	Response satisfies query
Nov-11-2020 14:19:05 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Query 2: Ans wered	As written. 1) This AE is specific to an anatomic location. "New or increased muscle pain" on Section 8.13 is describing a constitutional symptom. 2) 28Oct20, the date of this AE is the same date as the "severe acute aortic insufficiency" SAE on AE Line

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				1
Nov-11-2020 13:52:13 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Katherine Liao (b) (4)	Query 2: Opened	Per Section 8.1, muscle pain should have triggered a COVID illness visit irrespective of causality. Please conduct a COVID illness visit and swab collection as soon as possible. Symptom should be captured on SOD form only. Please review and update.
Nov-05-2020 18:33:31 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	PFETMS Oracle (b) (4)	Query 1: Closed	Discrepancy has been closed.
Nov-05-2020 13:16:30 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Changed Information
Nov-05-2020 13:16:30 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: pain L hamstring muscles	Changed Information
Nov-02-2020 16:13:32 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	PFETMS Oracle (b) (4)	Query 1: Opened	Clarify the term PAIN L HAMSTRING as follows...Please clarify further if reporting muscle pain or tendon pain. Are you reporting PAIN L

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				HAMSTRING MUSCLE ? or PAIN L HAMSTRING TENDON? If so, please edi to such. Or else, please clarify the term further. Thank you.
Nov-02-2020 11:42:11 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: pain L hamstr ing	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason
Nov-02-2020 11:42:11 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: Oct/28/2020 UNK:UNK	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Nov-02-2020 11:42:11 (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
Nov-02-2020 11:42:11 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: 2	Initial Entry

7. Is the adverse event serious?

If Yes, NOTIFY PFIZER IMMEDIATELY.

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

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require medical/surgical intervention to prevent above outcomes).

Date	Location	User	Value	Reason
Nov-02-2020 11:42:11 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: NO	Initial Entry

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

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

Date	Location	User	Value	Reason
Nov-02-2020 11:42:11 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: NO	Initial Entry

9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Nov-02-2020 11:42:11 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: NOT RELATED If Not Related to study treatment (s), this event is due to: OTHER If Other, specify: heavy lifting	Initial Entry

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Nov-02-2020 11:42:11 (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
Nov-02-2020 11:42:11 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: YES	Initial Entry

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12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Nov-02-2020 11:42:11 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: NO	Initial Entry

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

Date	Location	User	Value	Reason
Nov-02-2020 11:42:11 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: NOT RECOVERED/NOT RESO LVED	Initial Entry

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

Date	Location	User	Value	Reason
Nov-02-2020 11:42:11 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: NO	Initial Entry

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Generated By: (b) (4)

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1. Category:

Date	Location	User	Value	Reason
Nov-05-2020 13:11:06 (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
Nov-05-2020 13:11:06 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 3	Initial Entry

3. Adverse Event:

(If possible specify diagnosis, not individual symptoms)

Date	Location	User	Value	Reason
Nov-11-2020 06:05:24 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Cl osed	Response satisfies query
Nov-11-2020 00:05:50 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	PFETMS Oracle (b) (4)	Query 2: Cl osed	Discrepancy has been closed.
Nov-10-2020 13:02:41 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: A nswered	Changed Information
Nov-10-2020 13:02:41 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry : subarachnoi d hemorrhha ge	Changed Information
Nov-10-2020	ACV0PFEINFP6000.InFormAdapter.Discrepancy	PFETMS	Query 2: O	Multiple concepts

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12:50:49 (UTC-08:00) Pacific Time (US & Canada)		Oracle (b) (4)	pened	in the term SUBARACHNOID HEMORRHAGE, S/P EMBOLIZATION PROCEDURE. Split the term into SUBARACHNOID HEMORRHAGE and S/P EMBOLIZATION PROCEDURE and report as separate entries. Thank you.
Nov-10-2020 08:34:36 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry : subarachnoi d hemorrha ge, s/p emb olization pr ocedure	Changed Information
Nov-10-2020 08:32:25 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: A nswered	Changed Information
Nov-10-2020 08:32:25 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry : subarachnoi d hemorrha ge	Changed Information
Nov-08-2020 14:48:31 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: O pened	Clinical - Please provide clinical course for the event CNS bleeding including presenting symptoms of the bleed, and any anticoagulation that the subject was receiving.

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Nov-05-2020 13:11:06 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry : central nerv ous system bleed	Initial Entry
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4. Start Date Time:

Date	Location	User	Value	Reason
Nov-05-2020 13:11:06 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: Nov/5/2020 UNK:UNK	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Nov-21-2020 13:03:10 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Query closed; will follow for SAE update with the requested end date info
Nov-19-2020 13:16:31 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	New Information
Nov-19-2020 13:16:31 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: NO End Date Time: Nov/5/2020 UNK:UNK	New Information
Nov-18-2020 22:04:11 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	CLINICAL - please review ongoing vs resolved status for event of Subarachnoid hemorrhage; if appropriate please add end date to AE and as a SAE safety update
Nov-05-2020 13:11:06 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: YES	Initial Entry

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6. Toxicity Grade:

Date	Location	User	Value	Reason
Nov-05-2020 13:11:06 (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 medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).

Date	Location	User	Value	Reason
Dec-06-2020 07:25:34 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Closed	Response satisfies query
Dec-03-2020 08:50:02 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 3: Answered	Transcription Error
Dec-03-2020 08:50:02 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	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 Did this serious event result in persistent or significant disability/incapacity?	Transcription Error

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			NO Is this serious event life threatening? NO Other medically important serious event NO	
Dec-02-2020 16:21:55 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Reissued:Opened	Clinical - the serious criterion checked in the SAE report is only Hospitalization; does not match the AE report of Hosp and Medically Important
Dec-02-2020 08:39:31 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Query 3: Answered	Query is ambiguous
Dec-01-2020 15:45:17 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Opened	Clinical Criteria for serious are both Hosp and Medically Important; however, SAE criterion for this event is just Hosp. Please review, harmonize reporting, and update in the appropriate location.
Nov-10-2020 20:46:02 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Closed	Response satisfies query
Nov-10-2020 08:36:58 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Query 2: Answered	As written. The severe aortic insufficiency is still considered to be acute in nature. We will have more information once pt's aortic valve path

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				report comes back.
Nov-08-2020 14:44:31 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Opened	Clinical - For this new SAE (#2020434514), the event of Aortic Insufficiency is now past medical history; please submit a safety update with AI in past history
Nov-06-2020 03:05:54 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Nov-05-2020 13:11:06 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	For AE central nervous system bleed: Response to "Is the adverse event serious?" is 'Yes' but "Serious Adverse Event Number" is blank.
Nov-05-2020 13:11:06 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	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 Did this serious event result in persistent or significant disability/incapacity?	Initial Entry

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			NO	
			Is this serious event life threatening?	
			NO	
			Other medically important serious event	
			YES	

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

Date	Location	User	Value	Reason
Nov-05-2020 13:11:06 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: NO	Initial Entry

9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Nov-16-2020 09:18:34 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: NOT RELATED If Not Related to study treatment(s), this event is due to: OTHER If Other, specify: possibly secondary	Changed Information

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			ndary to underlying bacterial endocarditis (mycotic aneurysm)	
Nov-12-2020 16:49:26 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Nov-12-2020 08:19:40 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Query 1: Answered	Per f/u SAE report submitted on 09-Nov-20, "Pt had CT angiography which showed a small aneurysm." This SAE is a clinical sequelae of the aneurysm, and do not represent separate medical conditions, events, or abnormal findings.
Nov-11-2020 16:47:55	ACV0PFEINFP6000.InFormAdapter.Discrepancy	PFE SDQ PROD (b) (4)	Query 1: Opened	Please review "If not related

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<p>(UTC-08:00) Pacific Time (US & Canada)</p>				<p>to study treatment other" field, the following text was indicated in the comment field [aneurysm]. Any symptoms, AEs or other key data should be collected on the appropriate page. Please review and update as necessary. (b) (4)</p>
<p>Nov-05-2020 13:11:06 (UTC-08:00) Pacific Time (US & Canada)</p>	<p>ACV0PFEINFP6000</p>	<p>Steven Choi (b) (4)</p>	<p>Data Entry: NOT RELATED If Not Related to study treatment(s), this event is due to: OTHER <i>If Other, specify:</i> possible secondary to</p>	<p>Initial Entry</p>

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10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Nov-05-2020 13:11:06 (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
Nov-05-2020 13:11:06 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: YES	Initial Entry

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Nov-05-2020 13:11:06 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: YES	Initial Entry

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

Date	Location	User	Value	Reason
Nov-19-2020 13:16:51 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Nov-19-2020 13:16:51 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: RECOVERED/RESOLVED	Changed Information
Nov-19-2020 13:16:31 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	For AE subarachnoid hemorrhage: Response to "What was the outcome of this adverse event?" is 'Not Recovered/Not

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				Resolved' but AE End Date/Time is present.
Nov-05-2020 13:11:06 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: NOT RECOVERED/NOT RESO LVED	Initial Entry

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

Date	Location	User	Value	Reason
Nov-05-2020 13:11:06 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: NO	Initial Entry

15. Serious Adverse Event Number: For Pfizer Use Only

Date	Location	User	Value	Reason
Dec-01-2020 02:12:30 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 2020423609	AER number updated in SDB
Nov-06-2020 03:05:54 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 2020434514	Initial Entry

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1. Category:

Date	Location	User	Value	Reason
Nov-16-2020 11:52:13 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> ADVERSE EVENT	Initial Entry

2. AE ID:

Date	Location	User	Value	Reason
Nov-16-2020 11:52:13 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> 4	Initial Entry

3. Adverse Event:

(If possible specify diagnosis, not individual symptoms)

Date	Location	User	Value	Reason
Dec-16-2020 03:49:26 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Delete data.
Dec-11-2020 11:36:47 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued:Candidate	Query deleted as on deleted AE
Dec-08-2020 08:18:13 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Query 1: Answered	Changed data per query
Dec-08-2020 08:07:05 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	CLINICAL - Is AE 'Bacterial Endocarditis' a separate event from SAE 'Subacute Bacterial Endocarditis'? Was removal of Aortic Insufficiency SAE due to revising that SAE and not this

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				'Bacterial Endocarditis' AE?
Nov-16-2020 11:52:13 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	<u>Data Entry:</u> bacterial endocarditis	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason
Nov-16-2020 11:52:13 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	<u>Data Entry:</u> Oct/28/2020 UNK:UNK	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Nov-16-2020 11:52:13 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	<u>Data Entry:</u> YES	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
Nov-16-2020 11:52:13 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	<u>Data Entry:</u> 2	Initial Entry

7. Is the adverse event serious?

If Yes, NOTIFY PFIZER IMMEDIATELY.

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

Date	Location	User	Value	Reason
Dec-08-2020 08:05:13 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Closed	Response satisfies query
Nov-23-2020 08:16:33 (UTC-08:00) Pacific	ACV0PFEINFP6000	Steven Choi (b) (4)	Query 2: Answered	As written. Please refer to follow-up

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Time (US & Canada)				SAE safety report submitted on 19Nov20, and email correspondence with CRA on 19Nov20.
Nov-22-2020 20:16:21 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Opened	Clinical Bacterial Endocarditis is reported as the underlying cause for AI and subarachnoid hemorrhage; yet is not reported as a serious event. Please review serious criteria for this event; if appropriate, submit a SAE safety update to revise SAE status.
Nov-21-2020 13:05:58 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Query closed; will follow for SAE update with the new SAE event info
Nov-19-2020 16:18:34 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Query 1: Answered	As written.
Nov-18-2020 22:01:16 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	Clinical Bacterial Endocarditis is reported as the underlying cause for AI and subarachnoid hemorrhage; yet is not reported as a serious event. Please review serious criteria for this event; if appropriate, submit a SAE safety update to revise SAE status.
Nov-16-2020 11:52:13	ACV0PFEINFP6000	Steven Choi	Data Entry:	Initial Entry

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(UTC-08:00) Pacific Time (US & Canada)		(b) (4)	NO	
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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
Nov-16-2020 11:52:13 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: NO	Initial Entry

9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Nov-16-2020 11:52:13 (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> infection	Initial Entry

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Nov-16-2020 11:52:13 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: NOT APPLICABLE	Initial Entry

11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
Nov-16-2020 11:52:13 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: YES	Initial Entry

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
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Visit: Logs - Unscheduled

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Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Deleted, Verified

Site No: 1054

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

Subject No: 10541173

Subject Initials: ---

Generated By: (b) (4)

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

*** THIS REPEATING FORM HAS BEEN DELETED ***

Nov-16-2020 11:52:13 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: NO	Initial Entry
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13. What was the outcome of this adverse event?:

Date	Location	User	Value	Reason
Nov-16-2020 11:52:13 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: RECOVERING/RESOLVING	Initial Entry

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

Date	Location	User	Value	Reason
Nov-16-2020 11:52:13 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: NO	Initial Entry

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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

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Site No: 1054

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Subject Initials: ---

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1. Category:

Date	Location	User	Value	Reason
Nov-16-2020 11:53:17 (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
Nov-16-2020 11:53:17 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 5	Initial Entry

3. Adverse Event:

(If possible specify diagnosis, not individual symptoms)

Date	Location	User	Value	Reason
Nov-16-2020 11:53:17 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: intermittent atrial fibrillation	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason
Nov-16-2020 11:53:17 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: Nov/6/2020 UNK:UNK	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Nov-16-2020 11:53:17 (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
Nov-16-2020 11:53:17	ACV0PFEINFP6000	Steven	Data Entry:	Initial Entry

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Header Text: c4591001

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(UTC-08:00) Pacific Time (US & Canada)		Choi (b) (4)	2	
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7. Is the adverse event serious?

If Yes, NOTIFY PFIZER IMMEDIATELY.

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

Date	Location	User	Value	Reason
Nov-16-2020 11:53:17 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: NO	Initial Entry

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

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

Date	Location	User	Value	Reason
Nov-16-2020 11:53:17 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: NO	Initial Entry

9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Nov-16-2020 11:53:17 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: NOT RELATED If Not Related to study treatment (s), this event is due to: OTHER If Other, specify: bacterial endocarditis	Initial Entry

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Nov-16-2020 11:53:17 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: NOT APPLICABLE	Initial Entry

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Generated By: (b) (4)

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11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
Nov-16-2020 11:53:17 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: YES	Initial Entry

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Nov-16-2020 11:53:17 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: NO	Initial Entry

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

Date	Location	User	Value	Reason
Nov-16-2020 11:53:17 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: RECOVERING/RESOLVING	Initial Entry

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

Date	Location	User	Value	Reason
Nov-16-2020 11:53:17 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: NO	Initial Entry

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Header Text: c4591001

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Site No: 1054

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

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Subject Initials: ---

Generated By: (b) (4)

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1. Category:

Date	Location	User	Value	Reason
Dec-18-2020 16:04:59 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: ADVERSE EVENT	Initial Entry

2. AE ID:

Date	Location	User	Value	Reason
Dec-18-2020 16:04:59 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 6	Initial Entry

3. Adverse Event:

(If possible specify diagnosis, not individual symptoms)

Date	Location	User	Value	Reason
Dec-30-2020 09:12:08 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Dec-29-2020 15:00:57 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Changed Information
Dec-29-2020 15:00:57 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: acute aortic insufficiency	Changed Information
Dec-21-2020 09:31:29 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	clinical: pls advise on treatment received for condition and confirm that does not meet seriousness criteria eg prolongation of hospitalization see protocol section 10.3.2 Thanks
Dec-18-2020 16:04:59	ACV0PFEINFP6000	Steven Choi	Data Entry:	Initial Entry

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(UTC-08:00) Pacific Time (US & Canada)		(b) (4)	aortic valve insufficiency	
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4. Start Date Time:

Date	Location	User	Value	Reason
Dec-18-2020 16:04:59 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: Oct/28/2020 UNK:UNK	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Feb-18-2021 23:05:29 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Closed	Response satisfies query
Feb-04-2021 14:35:29 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Answered	New Information
Feb-04-2021 14:35:29 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: NO End Date Time: Dec/15/2020 UNK:UNK	New Information
Jan-08-2021 17:17:40 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Opened	CLINICAL SAE report states subject received aortic valve replacement on 09Nov2020. Please review for potential end date for event Acute Aortic Insufficiency; if appropriate update AE and SAE
Dec-31-2020 16:05:56 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Dec-29-2020 14:52:17 (UTC-08:00) Pacific	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Changed Information

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Time (US & Canada)				
Dec-29-2020 14:52:17 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: YES	Changed Information
Dec-22-2020 17:08:47 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	Clinical Event end date is 09Nov20 (date of aortic valve replacement); however, SAE report has no end date. Please review, harmonize reporting, and update in the applicable location
Dec-18-2020 16:08:41 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: NO End Date Time: Nov/9/2020 UNK:UNK	Transcription Error
Dec-18-2020 16:04:59 (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
Dec-31-2020 16:04:53 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Dec-29-2020 14:52:40 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	New Information
Dec-29-2020 14:52:40 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: 4	New Information
Dec-22-2020 17:11:40 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	CLINICAL Toxicity level for event of Aortic Insufficiency; however, in SAE report this event is

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				life-threatening (toxicity grade 4). Please review and update.
Dec-18-2020 16:07:04 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: 3	Transcription Error
Dec-18-2020 16:04:59 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: 2	Initial Entry

7. Is the adverse event serious?

If Yes, NOTIFY PFIZER IMMEDIATELY.

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

Date	Location	User	Value	Reason
Jan-04-2021 04:23:55 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Deleted	Close Auto Query
Dec-31-2020 16:08:29 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Dec-29-2020 15:00:57 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Candidate	For AE acute aortic insufficiency: Response to "Is the adverse event serious?" is 'Yes' but "Serious Adverse Event Number" is blank.
Dec-29-2020 14:59:23 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Candidate	For AE aortic valve insufficiency: Response to "Is the adverse event serious?" is 'Yes' but "Serious Adverse Event Number" is blank.

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Dec-29-2020 14:59:23 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Changed Information
Dec-29-2020 14:59:23 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	<p>Data Entry: YES</p> <p>Is this serious event associated with congenital anomaly or birth defect?</p> <p>NO</p> <p>Did this serious event result in death?</p> <p>NO</p> <p>Did this serious event require or prolong hospitalization?</p> <p>YES</p> <p>Did this serious event result in persistent or significant disability/incapacity?</p> <p>NO</p> <p>Is this serious event life threatening?</p> <p>YES</p> <p>Other medically important serious event</p> <p>NO</p>	Changed Information
Dec-22-2020 17:10:45 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	CLINICAL Serious criteria for event Aortic Insufficiency is NO; however, SAE report (#202423609) reports AI as serious based on criteria of Hospitalization and

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				Life-threatening. Please review and update.
Dec-18-2020 16:04:59 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: NO	Initial Entry

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

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

Date	Location	User	Value	Reason
Dec-18-2020 16:04:59 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: NO	Initial Entry

9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Dec-18-2020 16:04:59 (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> subacute bacterial endocardi tis	Initial Entry

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Dec-18-2020 16:04:59 (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
Dec-18-2020 16:04:59 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: YES	Initial Entry

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Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

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

Subject Initials: ---

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12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Dec-18-2020 16:04:59 (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
Feb-04-2021 14:36:33 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Feb-04-2021 14:36:33 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	<u>Data Entry:</u> RECOVERED/RESOLVED	New Information
Feb-04-2021 14:35:29 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	For AE acute aortic insufficiency: Response to "What was the outcome of this adverse event?" is 'Recovering/Resolving' but AE End Date/Time is present.
Dec-29-2020 15:00:16 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	<u>Data Entry:</u> RECOVERING/RESOLVING	Changed Information
Dec-18-2020 16:07:34 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	<u>Data Entry:</u> RECOVERED/RESOLVED WI TH SEQUELAE	Transcription Error
Dec-18-2020 16:04:59 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	<u>Data Entry:</u> RECOVERED/RESOLVED	Initial Entry

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

Date	Location	User	Value	Reason
Dec-18-2020 16:04:59 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	<u>Data Entry:</u> NO	Initial Entry

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Generated By: (b) (4)

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Form Status: Data Complete, Frozen, Verified

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Subject Initials: ---

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15. Serious Adverse Event Number: For Pfizer Use Only

Date	Location	User	Value	Reason
Jan-04-2021 04:23:55 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 2020423609	Initial Entry

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Visit: End of Treatment - Unscheduled

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Form Status: Data Complete, Queries, Verified

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

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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
Mar-09-2021 08:27:30 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: Feb/8/2021	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Mar-09-2021 08:27:30 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: VACCINATION	Initial Entry

3. Status:

Date	Location	User	Value	Reason
Mar-12-2021 14:42:58 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Hayley Wyper (b) (4)	Query 1: Rei ssued: Opene d	query closed; appears no prior date to place as EOT
Mar-12-2021 08:08:41 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Clo sed	Response satisfies query
Mar-11-2021 08:48:03 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Query 3: An swere d	According to CRF guidelines, DRUG WITHDRAWN is only selected if a subsequent dose of vaccination wasn't administered due to the AE. Pt got VAX2, but didn't get Visit 3 done, b/c of SAE.

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Header Text: c4591001

Visit: End of Treatment - Unscheduled

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Form Status: Data Complete, Queries, Verified

Site No: 1054

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Subject Initials: ---

Generated By: (b) (4)

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Mar-10-2021 15:28:52 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (b) (4)	Query 3: Op ened	DMW7665968;Status is reported as Adverse Event, but there is no Adverse Event with 'Latest Action Taken with Study Treatment' reported as DRUG WITHDRAWN. Please review and update as appropriate.
Mar-10-2021 08:45:03 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Clo sed	Close Auto Query
Mar-10-2021 08:44:43 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Op ened	Response to "Status" is ADVERSE EVENT but "Specify Status" is Provided.
Mar-10-2021 08:44:43 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: An swere d	Please advise on what to put down for EOT date; I can't find any pertinent instructions about this. 08Feb21 is the day pt was unblinded.
Mar-10-2021 08:44:43 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry : ADV ERSE EVE NT	Please advise on what to put down for EOT date; I can't find any pertinent instructions about this. 08Feb21 is the day pt was unblinded.
Mar-10-2021 01:24:00 (UTC-08:00) Pacific Time (US &	ACV0PFEINFP6000	Hayley Wyper (b) (4)	Query 1: Op ened	CLINQUERY: CRF reports SAE during period when V3 was due. If this was the reason for missed V3,

090177e196ae30e5\Final\Final On: 01-Apr-2021 04:19 (GMT)

Header Text: c4591001

Visit: End of Treatment - Unscheduled

Form: DISPOSITION - TREATMENT - eCRF Audit Trail History

Form Version: 20-Feb-2021 02:26

Form Status: Data Complete, Queries, Verified

Site No: 1054

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

Subject No: 10541173

Subject Initials: ---

Generated By: (b) (4)

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

Canada)				please review status selection eg ADVERSE EVENT status may better reflect circumstance. Please also review date for EOT
Mar-09-2021 08:27:30 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry : OTH ER	Initial Entry

4. Specify Status:

Date	Location	User	Value	Reason
Mar-10-2021 08:45:03 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry:	Changed Information
Mar-09-2021 08:27:30 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: Pt unblinded for revaccination purposes; visit 3 not done due to SAE timeline.	Initial Entry

090177e196ae30e5\Final\Final On: 01-Apr-2021 04:19 (GMT)

Header Text: c4591001

Visit: Potential ReVax Initial Contact -
Unscheduled

Form: DATE OF VISIT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen, Verified

Site No: 1054

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

Subject No: 10541173

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 13:19:42 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: Feb/8/2021	Initial Entry

090177e196ae30e5\Final\Final On: 01-Apr-2021 04:19 (GMT)

Header Text: c4591001**Visit:** Potential ReVax Initial Contact -
Unscheduled**Form Version:** 10-Dec-2020 02:25**Site No:** 1054**Subject No:** 10541173**Generated By:** (b) (4)**Form:** FURTHER VACCINATION CONFIRMATION - 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[Back to Form](#)**I. Select appropriate response - Is participant willing to return for Vaccination 3?**

Date	Location	User	Value	Reason
Mar-05-2021 10:52:05 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Reissued:Candidate	Waiting on patient to confirm V101 date.
Mar-05-2021 08:14:50 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Query 2: Answered	Waiting on patient to confirm V101 date.
Mar-05-2021 04:53:50 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Opened	DM: Participant is eligible and confirmed to have received Placebo, but Date Written Consent Obtained is missing in Informed Consent - Further Vaccination CRF. Please review and update as appropriate.
Feb-10-2021 13:20:20 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Feb-10-2021 13:20:05 (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 13:20:05 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: Participant is willing to return f or Vaccination 3 Participant is:	Initial Entry

Header Text: c4591001

Visit: Potential ReVax Initial Contact -
Unscheduled

Form Version: 10-Dec-2020 02:25

Site No: 1054

Subject No: 10541173

Generated By: (b) (4)

Form: FURTHER VACCINATION CONFIRMATION - 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

			eligible per local/national re commendations and confir med to have received only p lacebo at Vaccination 1/2	
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Header Text: c4591001

Visit: Disposition - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1054

Subject No: 10541173

Generated By: (b) (4)

Form: TREATMENT UNBLINDED - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

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

Subject Initials: ---

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

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1. Date Treatment Unblinded :

Date	Location	User	Value	Reason
Feb-10-2021 13:20:20 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: Feb/8/2021	Initial Entry

2. Primary Reason for Unblinding:

Date	Location	User	Value	Reason
Feb-10-2021 13:20:20 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: ASSESS ELIGIBILITY FOR AD DITIONAL VACCINATION	Initial Entry

090177e196ae30e5\Final\Final On: 01-Apr-2021 04:19 (GMT)

Header Text: c4591001

Visit: V101_VAX3

Form Version: 22-Apr-2020 21:02

Site No: 1054

Subject No: 10541173

Generated By: (b) (4)

Form: DATE OF VISIT - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

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

Subject Initials: ---

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

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1. Date of Visit

Date	Location	User	Value	Reason
Mar-02-2021 02:26:23 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Deleted	Query is invalid or does not apply
Mar-01-2021 14:06:44 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	Erroneous Visit is marked, but date of visit is entered. Please either untick the erroneous visit button if visit occurred, or mark any forms containing data within this visit as Not Done/Not Applicable at the form level.
Mar-01-2021 14:06:19 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: Mar/1/2021	Initial Entry

2. Erroneous Visit

Date	Location	User	Value	Reason
Mar-01-2021 14:06:44 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: ERRONEOUS VISIT	Initial Entry

090177e196ae30e5\Final\Final On: 01-Apr-2021 04:19 (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: 10541173

Subject Initials: ---

Generated By: (b) (4)

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

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I. Subject Status

Date	Location	User	Value	Reason
Mar-10-2021 08:44:43 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: DISCONTINUED	Please advise on what to put down for EOT date; I can't find any pertinent instructions about this. 08Feb21 is the day pt was unblinded.
Mar-10-2021 01:24:37 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Hayley Wyper (b) (4)	Query 2: Closed	Response satisfies query
Mar-09-2021 08:36:36 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Query 2: Answered	Changed data per query
Mar-09-2021 08:27:30 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: DISCONTINUED	Initial Entry
Mar-09-2021 05:25:34 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Hayley Wyper (b) (4)	Query 2: Opened	CLINQUERY: V3 has not been reported yet timepoint has passed - please clarify reason for lack of V3 to determine date/status for end of first treatment phase (vax1/vax2/V3). First EOT page to be updated with this status
Mar-02-2021 12:49:03 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Mar-02-2021 08:19:28 (UTC-08:00) Pacific	ACV0PFEINFP6000	Steven Choi (b) (4)	Query 1: Answered	Changed data per query

090177e196ae30e5\Final\Final On: 01-Apr-2021 04:19 (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: 10541173

Subject Initials: ---

Generated By: (b) (4)

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

Time (US & Canada)				
Mar-02-2021 06:38:52 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued:Open	DM: Visit 3 is overdue based on expected visit window. If visit 3 will never occur, please mark Date of Visit as 'Not Done' with form level comment. If subject is no longer in the trial, please complete the Disposition Follow Up form.
Feb-22-2021 23:00:09 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued:Candidate	Please review this query once data is entered for Visit 3.
Feb-22-2021 11:55:53 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Query 1: Answered	V3 not done due to SAE; pt unblinded on 08Feb21; VAX3 visit date pending. Will file PD for V3 not being done due to SAE.
Feb-22-2021 11:39:10 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Rivkah Rosen (b) (4)	Query 1: Opened	DM: Visit "V3_MONTH1_POSTVAX2_L" was expected to occur on 13-NOV-2020. Please enter data or confirm reason why visit has not yet occurred. If subject is no longer in the trial, please complete the Disposition Follow Up form.
Sep-18-2020 13:39:45 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: ENROLLED/RANDOMIZED	Initial Entry
Sep-18-2020 13:35:44 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SCREENED	Initial Entry

2. Subject Status Date

090177e196ae30e5\Final\Final On: 01-Apr-2021 04:19 (GMT)

Header Text: c4591001

Visit: Subject Status - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1054

Subject No: 10541173

Generated By: (b) (4)

Form: SUBJECT STATUS - eCRF Audit Trail History

Form Status: Data Complete, Verified

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

Subject Initials: ---

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

Date	Location	User	Value	Reason
Mar-10-2021 08:44:43 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Feb/8/2021	Please advise on what to put down for EOT date; I can't find any pertinent instructions about this. 08Feb21 is the day pt was unblinded.
Mar-09-2021 08:27:30 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Feb/8/2021	Initial Entry
Sep-18-2020 13:39:45 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sep/18/2020	Initial Entry
Sep-18-2020 13:35:44 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sep/18/2020	Initial Entry

090177e196ae30e5\Final\Final On: 01-Apr-2021 04:19 (GMT)

Header Text: c4591001

Visit: Investigator Signature - Unscheduled

Form: CASEBOOK SIGNATURE FORM - eCRF Audit Trail 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: 10541173

Subject Initials: ---

Generated By: (b) (4)

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

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I. Casebook Signature

Date	Location	User	Value	Reason
Sep-23-2020 09:02:04 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: Click Here to Enable	Initial Entry

090177e196ae30e5\Final\Final On: 01-Apr-2021 04:19 (GMT)