

Header Text: c4591001

Visit: COHORT_SELECTION

Form Version: 15-Sep-2020 21:55

Site No: 1149

Subject No: 11491313

Generated By: (b) (4)

Form: COHORT SELECTION

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1149) Collaborative Neuroscience Network, LLC.

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:56

[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	Form: MAIN INFORMED CONSENT
Visit: COHORT_SELECTION	Form Status: Data Complete, Locked, Frozen, Verified
Form Version: 22-Apr-2020 21:02	Site Name: (1149) Collaborative Neuroscience Network, LLC.
Site No: 1149	Subject Initials: ---
Subject No: 11491313	Generated Time (GMT): 29-Mar-2021 11:56
Generated By: (b) (4)	

[eCRF Audit Trail History](#)

Informed Consent				
1.	Consent Was: <table border="1" style="margin-left: 20px;"> <tr> <td>OBTAINED</td> </tr> <tr> <td>Date Written Consent Obtained</td> </tr> <tr> <td>Sep/24/2020</td> </tr> </table>	OBTAINED	Date Written Consent Obtained	Sep/24/2020
OBTAINED				
Date Written Consent Obtained				
Sep/24/2020				

Header Text: c4591001
Visit: COHORT_SELECTION **Form:** DEMOGRAPHY
Form Version: 15-Sep-2020 21:54 **Form Status:** Data Complete, Locked, Frozen, Verified
Site No: 1149 **Site Name:** (1149) Collaborative Neuroscience Network, LLC.
Subject No: 11491313 **Subject Initials:** ---
Generated By: (b) (4) **Generated Time (GMT):** 29-Mar-2021 11:56

[eCRF Audit Trail History](#)

Demography		
1.	Subject ID	[11491313]
2.	Birth Date:	(b) (6)/1952
3.	Sex:	FEMALE
4.	Ethnicity:	NOT HISPANIC OR LATINO(A) OR OF SPANISH ORIGIN
5.	Race: (Check X all that apply):	WHITE
6.	Racial Designation:	

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:02

Site No: 1149

Subject No: 11491313

Generated By: (b) (4)

Form: DATE OF VISIT

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1149) Collaborative Neuroscience Network, LLC.

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:56

[eCRF Audit Trail History](#)

Date of Visit

1.	Date of Visit	Sep/24/2020
2.	Erroneous Visit	

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 15-Sep-2020 21:53

Site No: 1149

Subject No: 11491313

Generated By: (b) (4)

Form: INCLUSION/EXCLUSION CRITERIA

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1149) Collaborative Neuroscience Network, LLC.

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:56

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

090177e196ae30c8\Final\Final On: 01-Apr-2021 04:16 (GMT)

Header Text: c4591001	Form: DISPOSITION - SCREENING
Visit: V1_DAY1_VAX1_L	Form Status: Data Complete, Locked, Frozen, Verified
Form Version: 15-Sep-2020 21:52	Site Name: (1149) Collaborative Neuroscience Network, LLC.
Site No: 1149	Subject Initials: ---
Subject No: 11491313	Generated Time (GMT): 29-Mar-2021 11:56
Generated By: (b) (4)	

[eCRF Audit Trail History](#)

Disposition - Screening		
1.	Date of Completion/Discontinuation /Death	Sep/24/2020
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: 1149

Subject No: 11491313

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1149) Collaborative Neuroscience Network, LLC.

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:56

[eCRF Audit Trail History](#)

Medical History Details

1.a	Line/MH Number:	[1]
	Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:	[lyrica allergy]
	Start Date:	UNK/UNK/2012
	Ongoing:	YES
1.b	Line/MH Number:	[2]
	Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:	[gabapentin allergy]
	Start Date:	UNK/UNK/2012
	Ongoing:	YES
1.c	Line/MH Number:	[3]
	Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:	[partial denture - WEARER]
	Start Date:	UNK/UNK/2016
	Ongoing:	YES
1.d	Line/MH Number:	[4]
	Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:	[hypertension]
	Start Date:	Jan/UNK/2020
	Ongoing:	YES
1.e	Line/MH Number:	[5]
	Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:	[intermittent heart murmur]
	Start Date:	UNK/UNK/1954
	Ongoing:	YES
1.f	Line/MH Number:	[6]
	Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:	[hyperlipidemia]
	Start Date:	Jan/UNK/2020
	Ongoing:	YES

090177e196ae30c8\Final\Final On: 01-Apr-2021 04:16 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1149

Subject No: 11491313

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1149) Collaborative Neuroscience Network, LLC.

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:56

1.g	Line/MH Number:	[7]
	Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:	[type 2 diabetes]
	Start Date:	UNK/UNK/2019
	Ongoing:	YES
1.h	Line/MH Number:	[8]
	Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:	[left thumb osteoarthritis]
	Start Date:	UNK/UNK/2018
	Ongoing:	YES
1.i	Line/MH Number:	[9]
	Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:	[right knee osteoarthritis]
	Start Date:	UNK/UNK/2018
	Ongoing:	YES
1.j	Line/MH Number:	[10]
	Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:	[lumbar degenerative disc disease]
	Start Date:	UNK/UNK/2013
	Ongoing:	YES
1.k	Line/MH Number:	[11]
	Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:	[femoral hernia]
	Start Date:	Jan/UNK/2020
	Ongoing:	NO End Date: UNK/UNK/2020
1.l	Line/MH Number:	[12]
	Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:	[hernia]
	Start Date:	UNK/UNK/2013
	Ongoing:	YES

090177e196ae30c8\Final\Final On: 01-Apr-2021 04:16 (GMT)

Header Text: c4591001	Form: HIV STATUS
Visit: V1_DAY1_VAX1_L	Form Status: Data Complete, Locked, Frozen, Verified
Form Version: 15-Sep-2020 21:57	Site Name: (1149) Collaborative Neuroscience Network, LLC.
Site No: 1149	Subject Initials: ---
Subject No: 11491313	Generated Time (GMT): 29-Mar-2021 11:56
Generated By: (b) (4)	

[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: 1149

Subject No: 11491313

Generated By: (b) (4)

Form: VITAL SIGNS - BASELINE

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1149) Collaborative Neuroscience Network, LLC.

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:56

[eCRF Audit Trail History](#)

Vital Signs

1.	Date:	Sep/24/2020
2.	Weight:	[72.8]
3.	Unit:	kg
4.	Height:	[152.0]
5.	Unit:	cm
6.	Body Mass Index:	[31.5]

Vital Signs Details

7.a	Record Identifier:	1
	Temperature:	[36.2]
	Unit:	C
	Temperature Location:	FOREHEAD

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 15-Sep-2020 21:51

Site No: 1149

Subject No: 11491313

Generated By: (b) (4)

Form: LAB URINALYSIS - PREGNANCY TEST

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1149) Collaborative Neuroscience Network, LLC.

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:56

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

Lab Urinalysis

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

Lab Result

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

090177e196ae30c8\Final\Final On: 01-Apr-2021 04:16 (GMT)

Header Text: c4591001
Visit: V1_DAY1_VAX1_L
Form Version: 22-Apr-2020 21:03
Site No: 1149
Subject No: 11491313
Generated By: (b) (4)

Form: RANDOMIZATION
Form Status: Data Complete, Locked, Frozen, Verified
Site Name: (1149) Collaborative Neuroscience Network, LLC.
Subject Initials: ---
Generated Time (GMT): 29-Mar-2021 11:56

[eCRF Audit Trail History](#)

Disposition		
1.	Randomization Date :	Sep/24/2020
2.	Randomization Number:	[265035]
3.	Randomization Group:	[]

090177e196ae30c8\Final\Final On: 01-Apr-2021 04:16 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1149

Subject No: 11491313

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1149) Collaborative Neuroscience Network, LLC.

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:56

[eCRF Audit Trail History](#)

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	SERUM
3.	Sample Collected?	YES Date of Collection: Sep/24/2020
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	[BLCBTS]
5.b	Sample ID	[BLCBTT]
5.c	Sample ID	[BR7WBB]
5.d	Sample ID	[BR7WBC]

090177e196ae30c8\Final\Final On: 01-Apr-2021 04:16 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1149

Subject No: 11491313

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1149) Collaborative Neuroscience Network, LLC.

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:56

[eCRF Audit Trail History](#)

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Sep/24/2020
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	[BR7WB9]
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Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:04

Site No: 1149

Subject No: 11491313

Generated By: (b) (4)

Form: VACCINATION

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1149) Collaborative Neuroscience Network, LLC.

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:56

[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/24/2020 13:20
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

090177e196ae30c8\Final\Final On: 01-Apr-2021 04:16 (GMT)

Header Text: c4591001	Form: REACTOGENICITY DIARY
Visit: V1_DAY1_VAX1_L	Form Status: Data Complete, Locked, Frozen, Verified
Form Version: 06-Jul-2020 21:53	Site Name: (1149) Collaborative Neuroscience Network, LLC.
Site No: 1149	Subject Initials: ---
Subject No: 11491313	Generated Time (GMT): 29-Mar-2021 11:56
Generated By: (b) (4)	

[eCRF Audit Trail History](#)

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

090177e196ae30c8\Final\Final On: 01-Apr-2021 04:16 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 1149

Subject No: 11491313

Generated By: (b) (4)

Form: DATE OF VISIT

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1149) Collaborative Neuroscience Network, LLC.

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:56

[eCRF Audit Trail History](#)

Date of Visit

1.	Date of Visit	Oct/15/2020
2.	Erroneous Visit	

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 10-Oct-2020 16:01

Site No: 1149

Subject No: 11491313

Generated By: (b) (4)

Form: VITAL SIGNS - TEMP

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1149) Collaborative Neuroscience Network, LLC.

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:56

[eCRF Audit Trail History](#)

Vital Signs

1.	Date:	Oct/15/2020
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Vital Signs Details

2.a	Record Identifier:	1
	Temperature:	[35.8]
	Unit:	C
	Temperature Location:	FOREHEAD

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 15-Sep-2020 21:51

Site No: 1149

Subject No: 11491313

Generated By: (b) (4)

Form: LAB URINALYSIS - PREGNANCY TEST

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1149) Collaborative Neuroscience Network, LLC.

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:56

[eCRF Audit Trail History](#)

Lab Urinalysis

1.	Lab Panel:	URINALYSIS
2.	Lab Sub-Panel:	PREGNANCY
3.	Collection Date:	Oct/15/2020
4.	Laboratory Name and Address (Derived)	[STUDY SITE]
5.	Specimen Type:	URINE

Lab Result

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

090177e196ae30c8\Final\Final On: 01-Apr-2021 04:16 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:03

Site No: 1149

Subject No: 11491313

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1149) Collaborative Neuroscience Network, LLC.

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:56

[eCRF Audit Trail History](#)

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Oct/15/2020
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	[BR7WR8]
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090177e196ae30c8\Final\Final On: 01-Apr-2021 04:16 (GMT)

Header Text: c4591001
Visit: V2_VAX2_L **Form:** VACCINATION
Form Version: 22-Apr-2020 21:04 **Form Status:** Data Complete, Locked, Frozen, Verified
Site No: 1149 **Site Name:** (1149) Collaborative Neuroscience Network, LLC.
Subject No: 11491313 **Subject Initials:** ---
Generated By: (b) (4) **Generated Time (GMT):** 29-Mar-2021 11:56

[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/15/2020 12:31
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

090177e196ae30c8\Final\Final On: 01-Apr-2021 04:16 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 1149

Subject No: 11491313

Generated By: (b) (4)

Form: DATE OF VISIT

Form Status: Data Complete, Frozen, Verified

Site Name: (1149) Collaborative Neuroscience Network, LLC.

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:56

[eCRF Audit Trail History](#)

Date of Visit			
1.	Date of Visit	Dec/10/2020	Comments
2.	Erroneous Visit		

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form Version: 22-Apr-2020 21:03

Site No: 1149

Subject No: 11491313

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Status: Data Complete, Frozen, Verified

Site Name: (1149) Collaborative Neuroscience Network, LLC.

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:56

[eCRF Audit Trail History](#)

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	SERUM
3.	Sample Collected?	NO
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[this was a combined with convalescent visit. Blood sample was collected and barcoded in Convalescent visit.]

Aliquot

Please enter barcode for each aliquot.

5.	Sample ID	[]
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Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on
Nov/03/2020

Form: DATE OF VISIT - ILLNESS ONSET

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1149

Site Name: (1149) Collaborative Neuroscience Network, LLC.

Subject No: 11491313

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

[eCRF Audit Trail History](#)

Date of Visit

1.	Date of Visit	Nov/3/2020
2.	Erroneous Visit	

COVID-19 Illness Visit

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

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/03/2020

Form: SIGNS AND SYMPTOMS OF POTENTIAL COVID-19

Form Version: 10-Oct-2020 16:02

Form Status: Data Complete, Frozen, Not Complete

Site No: 1149

Site Name: (1149) Collaborative Neuroscience Network, LLC.

Subject No: 11491313

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

[eCRF Audit Trail History](#)

Signs and Symptoms

1.	Date of Assessment:	Nov/3/2020
2.	Date of First Symptom Started:	Nov/1/2020
3.	Symptoms Ongoing?	NO Date of Last Symptom Resolved: Nov/5/2020

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?	NO
4.e	Symptoms:	NEW OR INCREASED MUSCLE PAIN
	Was symptom present?	NO
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?	NO
4.i	Symptoms:	VOMITING
	Was symptom present?	NO

Symptoms - Other

5.	Symptoms - Other Text:	[]
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090177e196ae30c8\Final\Final On: 01-Apr-2021 04:16 (GMT)

Header Text: c4591001
Visit: POT_COVID_ILL 1 **Form:** MICROBIOLOGY SPECIMEN
Form Version: 06-Jul-2020 21:54
Site No: 1149 **Site Name:** (1149) Collaborative Neuroscience Network, LLC.
Subject No: 11491313 **Subject Initials:** ---
Generated By: (b) (4) **Generated Time (GMT):** 29-Mar-2021 11:56

#	Date of Collection	Specimen Type	Specimen Collection Location	Assay Code and Description	Device Type	Form Instance
1.	Unknown	Unknown	Unknown	Unknown	Unknown	Repeating Pages

090177e196ae30c8\Final\Final On: 01-Apr-2021 04:16 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on
Nov/03/2020

Form: MICROBIOLOGY SPECIMEN

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen, Verified

Site No: 1149

Site Name: (1149) Collaborative Neuroscience Network, LLC.

Subject No: 11491313

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

[Back to Form](#)

[Form Comments](#)

[eCRF Audit Trail History](#)

Microbiology Specimen

1.	Actual Date of Collection:	Unknown //	Comments
2.	Specimen Type:	Unknown	Comments
3.	Specimen Collection Location:	Unknown	Comments
4.	Assay Code and Description:	Unknown	Comments
5.	Device Type:	Unknown	Comments
6.	Trade Name:	Unknown	Comments
7.	Test Result:	Unknown	Comments
8.	Comments/Findings/Details:	Unknown []	Comments
9.	Trade Name Other, Specify:	Unknown []	Comments

090177e196ae30c8\Final\Final On: 01-Apr-2021 04:16 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on
Nov/03/2020

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB SELF

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1149

Site Name: (1149) Collaborative Neuroscience Network, LLC.

Subject No: 11491313

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

[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:	[Subject is admitted to the hospital and doesn't have self swab kit with her.]

Aliquot

Please enter barcode for each aliquot.

5.	Sample ID	[]
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Header Text: c4591001
Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/03/2020 **Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB
Form Version: 22-Apr-2020 21:03 **Form Status:** Data Complete, Frozen, Verified
Site No: 1149 **Site Name:** (1149) Collaborative Neuroscience Network, LLC.
Subject No: 11491313 **Subject Initials:** ---
Generated By: (b) (4) **Generated Time (GMT):** 29-Mar-2021 11:56

[eCRF Audit Trail History](#)

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	NO
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[Subject is admitted to the hospital and doesn't have self swab kit with her.]

Aliquot

Please enter barcode for each aliquot.

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

Header Text: c4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit on
Nov/03/2020**Form:** HEALTH CARE UTILIZATION**Form Version:** 10-Oct-2020 15:59**Form Status:** Data Complete, Frozen, Verified**Site No:** 1149**Site Name:** (1149) Collaborative Neuroscience Network, LLC.**Subject No:** 11491313**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 11:56[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:	YES Number of Visits or Contacts: [1]
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?	YES Has the subject been in intensive care due to potential COVID-19 illness? NO
----	--	--

Header Text: c4591001

Visit: POT_COVID_ILL 1

Form: HOSPITALIZATION DETAILS

Form Version: 22-Apr-2020 21:02

Site No: 1149

Site Name: (1149) Collaborative Neuroscience Network, LLC.

Subject No: 11491313

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

#	Hospitalization Category	Hospitalization Term	Admission Date	Ongoing	Form Instance
1.	HOSPITALIZATION STATUS	HOSPITAL	Nov/1/2020	NO Discharge Date: Nov/13/2020	Repeating Pages

090177e196ae30c8\Final\Final On: 01-Apr-2021 04:16 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on
Nov/03/2020

Form: HOSPITALIZATION DETAILS

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen, Not Complete

Site No: 1149

Site Name: (1149) Collaborative Neuroscience Network, LLC.

Subject No: 11491313

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

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[Form Audit Trail](#)

Hospitalization Details

1.	Hospitalization Category:	HOSPITALIZATION STATUS
2.	Hospitalization Term:	HOSPITAL
3.	Admission Date:	Nov/1/2020
4.	Ongoing?	NO Discharge Date: Nov/13/2020

Header Text: c4591001

Visit: POT_COVID_ILL 1

Form: RESPIRATORY TREATMENT

Form Version: 06-Jul-2020 21:53

Site No: 1149

Site Name: (1149) Collaborative Neuroscience Network, LLC.

Subject No: 11491313

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

#	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

090177e196ae30c8\Final\Final On: 01-Apr-2021 04:16 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on
Nov/03/2020

Form: RESPIRATORY TREATMENT

Form Version: 06-Jul-2020 21:53

Form Status: Data Complete, Frozen, Verified

Site No: 1149

Site Name: (1149) Collaborative Neuroscience Network, LLC.

Subject No: 11491313

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

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[eCRF Audit Trail History](#)

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

090177e196ae30c8\Final\Final On: 01-Apr-2021 04:16 (GMT)

Header Text: c4591001
Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/03/2020 **Form:** ILLNESS DETAILS
Form Version: 06-Jul-2020 21:52 **Form Status:** Data Complete, Frozen, Verified
Site No: 1149 **Site Name:** (1149) Collaborative Neuroscience Network, LLC.
Subject No: 11491313 **Subject Initials:** ---
Generated By: (b) (4) **Generated Time (GMT):** 29-Mar-2021 11:56

[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:	1

090177e196ae30c8\Final\Final On: 01-Apr-2021 04:16 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1

Form: ILLNESS DETAILS - SEVERE

Form Version: 17-Jul-2020 21:55

Site No: 1149

Site Name: (1149) Collaborative Neuroscience Network, LLC.

Subject No: 11491313

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

#	Category of Clinical Event:	Subcategory of Clinical Event	Diagnosis Obtained	Toxicity Grade	Form Instance
1.					Repeating Pages

090177e196ae30c8\Final\Final On: 01-Apr-2021 04:16 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on
Nov/03/2020

Form: ILLNESS DETAILS - SEVERE

Form Version: 17-Jul-2020 21:55

Form Status: Not Started

Site No: 1149

Site Name: (1149) Collaborative Neuroscience Network, LLC.

Subject No: 11491313

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

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Illness Details

1.	Category of Clinical Event:	
2.	Subcategory of Clinical Event:	
3.	Was a diagnosis obtained?	
4.	Toxicity Grade:	

Header Text: c4591001

Visit: POT_COVID_ILL 1

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY

Form Version: 15-Sep-2020 21:51

Site No: 1149

Site Name: (1149) Collaborative Neuroscience Network, LLC.

Subject No: 11491313

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

#	Category for Lab Test	Vendor Name	Collection Date:	Specimen Type	Lab Result			Form Instance
1.	CLINICAL CHEMISTRY	Los Alamitos Medical Center, 3751 Katella Avenue, Los Alamitos, CA 90720	Nov/1/2020	BLOOD	Sponsor-Defined Identifier	Test:	Result:	Repeating Pages
					329	C Reactive Protein_PX329	[]	
					30	Alanine Aminotransferase_PX30	23	
					28	Aspartate Aminotransferase_PX28	20	
					35	Alkaline Phosphatase_PX35	68	
					21	Bilirubin_PX21	[]	
					47	Blood Urea Nitrogen_PX47	18	
					48	Creatinine_PX48	1.0	

090177e196ae30c8\Final\Final On: 01-Apr-2021 04:16 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/03/2020

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY

Form Version: 15-Sep-2020 21:51

Form Status: Data Complete, Frozen, Verified

Site No: 1149

Site Name: (1149) Collaborative Neuroscience Network, LLC.

Subject No: 11491313

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

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[Form Audit Trail](#)

Lab Chemistry Details

1.	Lab Panel:	CLINICAL CHEMISTRY
2.	Laboratory Name and Address	[Los Alamitos Medical Center,3751 Katella Avenue, Los Alamitos, CA 90720]
3.	Collection Date:	Nov/1/2020
4.	Specimen Type:	BLOOD

Lab Result

5.a	Sponsor ID:	[329]
	Test:	C Reactive Protein_PX329
	Result:	[]
	Not Done:	NOT DONE
	LNMT	Low [] High [] Unit
5.b	Sponsor ID:	[30]
	Test:	Alanine Aminotransferase_PX30
	Result:	[23]
	Not Done:	
	LNMT	Low [7] High [35] Unit U/L
5.c	Sponsor ID:	[28]
	Test:	Aspartate Aminotransferase_PX28
	Result:	[20]
	Not Done:	
	LNMT	Low [8] High [20] Unit U/L

090177e196ae30c8\Final\Final On: 01-Apr-2021 04:16 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/03/2020

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY

Form Version: 15-Sep-2020 21:51

Form Status: Data Complete, Frozen, Verified

Site No: 1149

Site Name: (1149) Collaborative Neuroscience Network, LLC.

Subject No: 11491313

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

5.d	Sponsor ID:	[35]
	Test:	Alkaline Phosphatase_PX35
	Result:	[68]
	Not Done:	
	LNMT	Low [38] High [136] Unit U/L
5.e	Sponsor ID:	[21]
	Test:	Bilirubin_PX21
	Result:	[]
	Not Done:	NOT DONE
	LNMT	Low [] High [] Unit
5.f	Sponsor ID:	[47]
	Test:	Blood Urea Nitrogen_PX47
	Result:	[18]
	Not Done:	
	LNMT	Low [6] High [20] Unit mg/dL
5.g	Sponsor ID:	[48]
	Test:	Creatinine_PX48
	Result:	[1.0]
	Not Done:	
	LNMT	Low [0.6] High [20] Unit mg/dL

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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: 1149

Site Name: (1149) Collaborative Neuroscience Network, LLC.

Subject No: 11491313

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

#	Category for Lab Test	Vendor Name (DERIVED)	Collection Date:	Specimen Type	Lab Result			Form Instance
1.	HEMATOLOGY	Los Alamitos Medical Center, 3751 Katella Avenue CA, 90720	Nov/1/2020	BLOOD	Sponsor-Defined Identifier	Test:	Result:	Repeating Pages
					1	Hemoglobin_PX1	12.1	
					2	Hematocrit_PX2	36.6	
					3	Erythrocytes_PX3	[]	
					5	Platelets_PX5	221	
					7	Leukocytes_PX7	[]	
					608	Neutrophils_PX608	2.4	
					609	Eosinophils_PX609	0.2	
					612	Monocytes_PX612	0.5	
					610	Basophils_PX610	0.1	
					611	Lymphocytes_PX611	2.2	

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Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/03/2020

Form: LOCAL LABORATORY DATA - REPEATING Hematology

Form Version: 15-Sep-2020 21:55

Form Status: Data Complete, Frozen, Verified

Site No: 1149

Site Name: (1149) Collaborative Neuroscience Network, LLC.

Subject No: 11491313

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

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Laboratory Data Hematology

1.	Lab Panel:	HEMATOLOGY
2.	Laboratory Name and Address	[Los Alamitos Medical Center, 3751 Katella Avenue CA, 90720]
3.	Collection Date:	Nov/1/2020
4.	Specimen Type:	BLOOD

Lab Result

5.a	Sponsor ID:	[1]
	Test:	Hemoglobin_PX1
	Result:	[12.1]
	Not Done:	
	LNMT	Low [12.0] High [15.6] Unit 10 ³ /uL
5.b	Sponsor ID:	[2]
	Test:	Hematocrit_PX2
	Result:	[36.6]
	Not Done:	
	LNMT	Low [35.0] High [46.0] Unit 10 ³ /uL
5.c	Sponsor ID:	[3]
	Test:	Erythrocytes_PX3
	Result:	[]
	Not Done:	NOT DONE
	LNMT	Low [] High [] Unit

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Form: LOCAL LABORATORY DATA - REPEATING Hematology

Form Version: 15-Sep-2020 21:55

Form Status: Data Complete, Frozen, Verified

Site No: 1149

Site Name: (1149) Collaborative Neuroscience Network, LLC.

Subject No: 11491313

Subject Initials: ---

Generated By: (b) (4)

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5.d	Sponsor ID:	[5]
	Test:	Platelets_PX5
	Result:	[221]
	Not Done:	
	LNMT	Low [130] High [400] Unit 10^3/uL
5.e	Sponsor ID:	[7]
	Test:	Leukocytes_PX7
	Result:	[]
	Not Done:	NOT DONE
	LNMT	Low [] High [] Unit
5.f	Sponsor ID:	[608]
	Test:	Neutrophils_PX608
	Result:	[2.4]
	Not Done:	
	LNMT	Low [1.0] High [7.8] Unit 10^3/uL
5.g	Sponsor ID:	[609]
	Test:	Eosinophils_PX609
	Result:	[0.2]
	Not Done:	
	LNMT	Low [0.0] High [0.6] Unit 10^3/uL

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Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on
Nov/03/2020

Form: LOCAL LABORATORY DATA - REPEATING Hematology

Form Version: 15-Sep-2020 21:55

Form Status: Data Complete, Frozen, Verified

Site No: 1149

Site Name: (1149) Collaborative Neuroscience Network, LLC.

Subject No: 11491313

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

5.h	Sponsor ID:	[612]
	Test:	Monocytes_PX612
	Result:	[0.5]
	Not Done:	
	LNMT	Low [0.2] High [1.1] Unit 10^3/uL
5.i	Sponsor ID:	[610]
	Test:	Basophils_PX610
	Result:	[0.1]
	Not Done:	
	LNMT	Low [0.0] High [0.2] Unit 10^3/uL
5.j	Sponsor ID:	[611]
	Test:	Lymphocytes_PX611
	Result:	[2.2]
	Not Done:	
	LNMT	Low [0.8] High [4.1] Unit 10^3/uL

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Header Text: c4591001

Visit: POT_COVID_ILL 1

Form Version: 15-Sep-2020 21:52

Site No: 1149

Subject No: 11491313

Generated By: (b) (4)

Form: VITAL SIGNS - COVID

Site Name: (1149) Collaborative Neuroscience Network, LLC.

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:56

#	Date:	Vital Signs Details			Form Instance
1.	Nov/3/2020	Record Identifier:	Systolic:	Diastolic:	Repeating Pages
		1	180	85	

090177e196ae30c8\Final\Final On: 01-Apr-2021 04:16 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1

Form Version: 10-Oct-2020 15:59

Site No: 1149

Subject No: 11491313

Generated By: (b) (4)

Form: VITAL SIGNS - COVID

Site Name: (1149) Collaborative Neuroscience Network, LLC.

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:56

#	Date:	Vital Signs Details			Form Instance
2. DELETED	Nov/3/2020	Record Identifier:	Systolic:	Diastolic:	Repeating Pages
		1	180	85	

090177e196ae30c8\Final\Final On: 01-Apr-2021 04:16 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on
Nov/03/2020

Form: VITAL SIGNS - COVID

Form Version: 15-Sep-2020 21:52

Form Status: Data Complete, Frozen, Verified

Site No: 1149

Site Name: (1149) Collaborative Neuroscience Network, LLC.

Subject No: 11491313

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

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Vital Signs

1.	Date:	Nov/3/2020
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Vital Signs Details

2.a	Record Identifier:	1
	Systolic:	[180]
	Diastolic:	[85]
	Respiratory Rate in respirations/minute:	[20]
	Heart Rate in beats/minute:	[110]

090177e196ae30c8\Final\Final On: 01-Apr-2021 04:16 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on
Nov/03/2020

Form: VITAL SIGNS - COVID

Form Version: 10-Oct-2020 15:59

Form Status: Data Complete, Deleted, Frozen, Verified

Site No: 1149

Site Name: (1149) Collaborative Neuroscience Network, LLC.

Subject No: 11491313

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

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

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Vital Signs

1.	Date:	Nov/3/2020
----	-------	------------

Vital Signs Details

2.a	Record Identifier:	1
	Systolic:	[180]
	Diastolic:	[85]
	Respiratory Rate in respirations/minute:	[20]
	Heart Rate in beats/minute:	[110]

Header Text: c4591001

Visit: POT_COVID_ILL 1

Form: VITAL SIGNS - PULSE OX ROOM AIR

Form Version: 15-Sep-2020 21:54

Site No: 1149

Site Name: (1149) Collaborative Neuroscience Network, LLC.

Subject No: 11491313

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

#	Date:	Vital Signs Details		Form Instance
1.	Nov/3/2020	Record Identifier:	Oxygen Saturation	Repeating Pages
		1	97.0	

090177e196ae30c8\Final\Final On: 01-Apr-2021 04:16 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1

Form Version: 10-Oct-2020 16:04

Site No: 1149

Subject No: 11491313

Generated By: (b) (4)

Form: VITAL SIGNS - PULSE OX ROOM AIR

Site Name: (1149) Collaborative Neuroscience Network, LLC.

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:56

#	Date:	Vital Signs Details		Form Instance
2. DELETED	Nov/3/2020	Record Identifier:	Oxygen Saturation	Repeating Pages
		1	97.0	

090177e196ae30c8\Final\Final On: 01-Apr-2021 04:16 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on
Nov/03/2020

Form: VITAL SIGNS - PULSE OX ROOM AIR

Form Version: 15-Sep-2020 21:54

Form Status: Data Complete, Frozen, Verified

Site No: 1149

Site Name: (1149) Collaborative Neuroscience Network, LLC.

Subject No: 11491313

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

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Vital Signs

1.	Date:	Nov/3/2020
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Vital Signs Details

2.a	Record Identifier:	1
	SPO2 Pulse Oximetry %	[97.0]

090177e196ae30c8\Final\Final On: 01-Apr-2021 04:16 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on
Nov/03/2020

Form: VITAL SIGNS - PULSE OX ROOM AIR

Form Version: 10-Oct-2020 16:04

Form Status: Data Complete, Deleted, Frozen, Verified

Site No: 1149

Site Name: (1149) Collaborative Neuroscience Network, LLC.

Subject No: 11491313

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

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

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Vital Signs

1.	Date:	Nov/3/2020
----	-------	------------

Vital Signs Details

2.a	Record Identifier:	1
	SPO2 Pulse Oximetry %	[97.0]

Header Text: c4591001

Visit: POT_COVID_ILL 1

Form: OXYGENATION PARAMETERS

Form Version: 06-Jul-2020 21:52

Site No: 1149

Site Name: (1149) Collaborative Neuroscience Network, LLC.

Subject No: 11491313

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

#	Date Time of Assessment	Arterial Blood Gases PaO2	FiO2 (Fraction of Inhaled Oxygen)	Form Instance
1.				Repeating Pages

090177e196ae30c8\Final\Final On: 01-Apr-2021 04:16 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on
Nov/03/2020

Form: OXYGENATION PARAMETERS

Form Version: 06-Jul-2020 21:52

Form Status: Not Started

Site No: 1149

Site Name: (1149) Collaborative Neuroscience Network, LLC.

Subject No: 11491313

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

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Oxygenation Parameters

1.	Date Time of Assessment:	//
2.	Arterial Blood Gases PaO2 (mmHg):	[]
3.	FiO2 (Fraction of Inhaled Oxygen):	[]

Header Text: c4591001
Visit: POT_COVID_ILL 1
Form Version: 06-Jul-2020 21:55
Site No: 1149
Subject No: 11491313
Generated By: (b) (4)

Form: CONCOMITANT MEDICATIONS - VASOPRESSORS
Site Name: (1149) Collaborative Neuroscience Network, LLC.
Subject Initials: ---
Generated Time (GMT): 29-Mar-2021 11:56

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

090177e196ae30c8\Final\Final On: 01-Apr-2021 04:16 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on
Nov/03/2020

Form: CONCOMITANT MEDICATIONS - VASOPRESSORS

Form Version: 06-Jul-2020 21:55

Form Status: Not Started

Site No: 1149

Site Name: (1149) Collaborative Neuroscience Network, LLC.

Subject No: 11491313

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

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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.	Start Date:	//
6.	Ongoing?	

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Header Text: c4591001

Visit: POT_COVID_ILL 1

Form: IMAGING

Form Version: 06-Jul-2020 21:53

Site No: 1149

Site Name: (1149) Collaborative Neuroscience Network, LLC.

Subject No: 11491313

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

#	Date of Assessment	Location of Assessment	Imaging Method	Overall Assessment	Form Instance
1.	Oct/30/2020	HEAD	CT SCAN	NORMAL	Repeating Pages
2.	Oct/31/2020	OTHER <i>If other, specify:</i> Neck	MRI	NORMAL	Repeating Pages

090177e196ae30c8\Final\Final On: 01-Apr-2021 04:16 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on
Nov/03/2020

Form: IMAGING

Form Version: 06-Jul-2020 21:53

Form Status: Data Complete, Frozen, Verified

Site No: 1149

Site Name: (1149) Collaborative Neuroscience Network, LLC.

Subject No: 11491313

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

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Imaging

1.	Date of Assessment:	Oct/30/2020
2.	Location of Assessment:	HEAD
3.	Type of Imaging Exam:	CT SCAN
4.	Assessment:	NORMAL

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on
Nov/03/2020

Form: IMAGING

Form Version: 06-Jul-2020 21:53

Form Status: Data Complete, Frozen, Verified

Site No: 1149

Site Name: (1149) Collaborative Neuroscience Network, LLC.

Subject No: 11491313

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

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Imaging

1.	Date of Assessment:	Oct/31/2020
2.	Location of Assessment:	OTHER If other, specify: [Neck]
3.	Type of Imaging Exam:	MRI
4.	Assessment:	NORMAL

Header Text: c4591001

Visit: POT_COVID_CONVA 1 - Unscheduled Visit on **Form:** DATE OF VISIT - ILLNESS CONVALESCENT
Dec/10/2020

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Frozen, Verified

Site No: 1149

Site Name: (1149) Collaborative Neuroscience Network, LLC.

Subject No: 11491313

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

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Date of Visit		
1.	Date of Visit	Dec/10/2020
2.	Erroneous Visit	
COVID-19 Illness Visit		
3.	COVID-19 Illness Visit:	COVID_A1

Header Text: c4591001

Visit: POT_COVID_CONVA 1 - Unscheduled Visit on **Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY
Dec/10/2020

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1149

Site Name: (1149) Collaborative Neuroscience Network, LLC.

Subject No: 11491313

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

[eCRF Audit Trail History](#)

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	SERUM
3.	Sample Collected?	YES Date of Collection: Dec/10/2020
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	[BRJ947]
5.b	Sample ID	[BRVJYJ]
5.c	Sample ID	[BRVJYK]

090177e196ae30c8\Final\Final On: 01-Apr-2021 04:16 (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: 1149

Site Name: (1149) Collaborative Neuroscience Network, LLC.

Subject No: 11491313

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

COVID-19 Repeat Swab

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

Header Text: c4591001

Visit: POT_COVID_REPEAT_SWAB - New
Unscheduled Visit

Form: ELECTRONIC SAMPLE TRACKING - REPEAT SWAB

Form Version: 10-Oct-2020 15:57

Form Status: Not Started

Site No: 1149

Site Name: (1149) Collaborative Neuroscience Network, LLC.

Subject No: 11491313

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

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: Unplanned - New Unscheduled Visit

Form: DATE OF VISIT

Form Version: 22-Apr-2020 21:02

Form Status: Not Started

Site No: 1149

Site Name: (1149) Collaborative Neuroscience Network, LLC.

Subject No: 11491313

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

Header Text: c4591001		Form: UNPLANNED VISIT
Visit: Unplanned - New Unscheduled Visit		Form Status: Not Started
Form Version: 22-Apr-2020 21:04		Site Name: (1149) Collaborative Neuroscience Network, LLC.
Site No: 1149		Subject Initials: ---
Subject No: 11491313		Generated Time (GMT): 29-Mar-2021 11:56
Generated By: (b) (4)		
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: 1149

Site Name: (1149) Collaborative Neuroscience Network, LLC.

Subject No: 11491313

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

#	Category	AE Identifier	Adverse Event	Start Date	Is the Adverse Event Still On going	Form Instance
1.	ADVERSE EVENT	1	Acute Trauma Head Injury	Oct/30/2020 08:00	NO End Date Time: Nov/3/2020 UNK:UNK	Repeating Pages
2.	ADVERSE EVENT	2	Cervicogenic headache	Oct/30/2020 UNK:UNK	NO End Date Time: Nov/3/2020 UNK:UNK	Repeating Pages
3.	ADVERSE EVENT	3	fall	Oct/UNK/2020 UNK:UNK	NO End Date Time: Oct/UNK/2020 UNK:UNK	Repeating Pages
4.	ADVERSE EVENT	4	fall	Oct/UNK/2020 UNK:UNK	NO End Date Time: Oct/UNK/2020 UNK:UNK	Repeating Pages
5.	ADVERSE EVENT	5	fall	Oct/UNK/2020 UNK:UNK	NO End Date Time: Oct/UNK/2020 UNK:UNK	Repeating Pages

090177e196ae30c8\Final\Final On: 01-Apr-2021 04:16 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1149

Subject No: 11491313

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Frozen, Not Complete

Site Name: (1149) Collaborative Neuroscience Network, LLC.

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:56

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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)	[Acute Trauma Head Injury]
4.	Start Date Time:	Oct/30/2020 08:00
5.	Is the adverse event still ongoing?	NO End Date Time: Nov/3/2020 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
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: [3 subsequent falls]
10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE
11.	Was a Concomitant Medication given?	NO

090177e196ae30c8\Final\Final On: 01-Apr-2021 04:16 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1149

Subject No: 11491313

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Frozen, Not Complete

Site Name: (1149) Collaborative Neuroscience Network, LLC.

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:56

12.	Was a Non-Drug Treatment given?	NO
13.	What was the outcome of this adverse event?:	RECOVERED/RESOLVED
14.	Did the adverse event cause the subject to be discontinued from the study?	NO
15.	Serious Adverse Event Number: For Pfizer Use Only	[2020427994]

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1149

Subject No: 11491313

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Frozen, Not Complete

Site Name: (1149) 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)	[Cervicogenic headache]
4.	Start Date Time:	Oct/30/2020 UNK:UNK
5.	Is the adverse event still ongoing?	NO End Date Time: Nov/3/2020 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
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: [Head Trauma]
10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE
11.	Was a Concomitant Medication given?	NO

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Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1149

Subject No: 11491313

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Frozen, Not Complete

Site Name: (1149) Collaborative Neuroscience Network, LLC.

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:56

12.	Was a Non-Drug Treatment given?	NO
13.	What was the outcome of this adverse event?:	RECOVERED/RESOLVED
14.	Did the adverse event cause the subject to be discontinued from the study?	NO
15.	Serious Adverse Event Number: For Pfizer Use Only	[2020427994]

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1149

Subject No: 11491313

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Frozen

Site Name: (1149) 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)	[fall]
4.	Start Date Time:	Oct/UNK/2020 UNK:UNK
5.	Is the adverse event still ongoing?	NO End Date Time: Oct/UNK/2020 UNK:UNK
6.	Toxicity Grade:	1
7.	Is the adverse event serious? If Yes, NOTIFY PFIZER IMMEDIATELY. Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).	NO
8.	Is this adverse event the result of a study Medication Error? If Yes, record the type of medication error on the Medication Error Log.	NO
9.	Is this event related to study treatment:	NOT RELATED If Not Related to study treatment(s), this event is due to: OTHER If Other, specify: [unknown]
10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE
11.	Was a Concomitant Medication given?	NO
12.	Was a Non-Drug Treatment given?	NO
13.	What was the outcome of this adverse event?:	RECOVERED/RESOLVED

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Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1149

Subject No: 11491313

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Frozen

Site Name: (1149) Collaborative Neuroscience Network, LLC.

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:56

14.	Did the adverse event cause the subject to be discontinued from the study?	NO
15.	Serious Adverse Event Number: For Pfizer Use Only	[]

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1149

Subject No: 11491313

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Frozen

Site Name: (1149) Collaborative Neuroscience Network, LLC.

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:56

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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)	[fall]
4.	Start Date Time:	Oct/UNK/2020 UNK:UNK
5.	Is the adverse event still ongoing?	NO End Date Time: Oct/UNK/2020 UNK:UNK
6.	Toxicity Grade:	1
7.	Is the adverse event serious? If Yes, NOTIFY PFIZER IMMEDIATELY. Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).	NO
8.	Is this adverse event the result of a study Medication Error? If Yes, record the type of medication error on the Medication Error Log.	NO
9.	Is this event related to study treatment:	NOT RELATED If Not Related to study treatment(s), this event is due to: OTHER If Other, specify: [unk]
10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE
11.	Was a Concomitant Medication given?	NO
12.	Was a Non-Drug Treatment given?	NO
13.	What was the outcome of this adverse event?:	RECOVERED/RESOLVED

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Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1149

Subject No: 11491313

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Frozen

Site Name: (1149) Collaborative Neuroscience Network, LLC.

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:56

14.	Did the adverse event cause the subject to be discontinued from the study?	NO
15.	Serious Adverse Event Number: For Pfizer Use Only	[]

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1149

Subject No: 11491313

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Frozen

Site Name: (1149) 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)	[fall]
4.	Start Date Time:	Oct/UNK/2020 UNK:UNK
5.	Is the adverse event still ongoing?	NO End Date Time: Oct/UNK/2020 UNK:UNK
6.	Toxicity Grade:	1
7.	Is the adverse event serious? If Yes, NOTIFY PFIZER IMMEDIATELY. Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).	NO
8.	Is this adverse event the result of a study Medication Error? If Yes, record the type of medication error on the Medication Error Log.	NO
9.	Is this event related to study treatment:	NOT RELATED If Not Related to study treatment(s), this event is due to: OTHER If Other, specify: [unk]
10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE
11.	Was a Concomitant Medication given?	NO
12.	Was a Non-Drug Treatment given?	NO
13.	What was the outcome of this adverse event?:	RECOVERED/RESOLVED

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Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1149

Subject No: 11491313

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Frozen

Site Name: (1149) Collaborative Neuroscience Network, LLC.

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:56

14.	Did the adverse event cause the subject to be discontinued from the study?	NO
15.	Serious Adverse Event Number: For Pfizer Use Only	[]

Header Text: c4591001

Visit: Logs

Form: MEDICATION ERROR

Form Version: 17-Jul-2020 21:54

Site No: 1149

Site Name: (1149) Collaborative Neuroscience Network, LLC.

Subject No: 11491313

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

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

090177e196ae30c8\Final\Final On: 01-Apr-2021 04:16 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 17-Jul-2020 21:54

Site No: 1149

Subject No: 11491313

Generated By: (b) (4)

Form: MEDICATION ERROR

Form Status: Not Started

Site Name: (1149) Collaborative Neuroscience Network, LLC.

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:56

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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	[]

090177e196ae30c8\Final\Final On: 01-Apr-2021 04:16 (GMT)

Header Text: c4591001
Visit: Logs **Form:** CONCOMITANT MEDICATIONS - NON STUDY VACCINATIONS
Form Version: 22-Apr-2020 21:03
Site No: 1149 **Site Name:** (1149) Collaborative Neuroscience Network, LLC.
Subject No: 11491313 **Subject Initials:** ---
Generated By: (b) (4) **Generated Time (GMT):** 29-Mar-2021 11:56

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

090177e196ae30c8\Final\Final On: 01-Apr-2021 04:16 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1149

Subject No: 11491313

Generated By: (b) (4)

Form: CONCOMITANT MEDICATIONS - NON STUDY VACCINATIONS

Form Status: Not Started

Site Name: (1149) Collaborative Neuroscience Network, LLC.

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:56

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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:	//

090177e196ae30c8\Final\Final On: 01-Apr-2021 04:16 (GMT)

Header Text: c4591001
Visit: Logs **Form:** CONCOMITANT MEDICATIONS - PROHIBITED
Form Version: 22-Apr-2020 21:03
Site No: 1149 **Site Name:** (1149) Collaborative Neuroscience Network, LLC.
Subject No: 11491313 **Subject Initials:** ---
Generated By: (b) (4) **Generated Time (GMT):** 29-Mar-2021 11:56

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

090177e196ae30c8\Final\Final On: 01-Apr-2021 04:16 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1149

Subject No: 11491313

Generated By: (b) (4)

Form: CONCOMITANT MEDICATIONS - PROHIBITED

Form Status: Not Started

Site Name: (1149) Collaborative Neuroscience Network, LLC.

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:56

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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?	

090177e196ae30c8\Final\Final On: 01-Apr-2021 04:16 (GMT)

Header Text: c4591001

Visit: Logs

Form: RADIATION TREATMENT

Form Version: 22-Apr-2020 21:02

Site No: 1149

Site Name: (1149) Collaborative Neuroscience Network, LLC.

Subject No: 11491313

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

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

090177e196ae30c8\Final\Final On: 01-Apr-2021 04:16 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1149

Subject No: 11491313

Generated By: (b) (4)

Form: RADIATION TREATMENT

Form Status: Not Started

Site Name: (1149) Collaborative Neuroscience Network, LLC.

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:56

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Radiation Treatment

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

Header Text: c4591001			
Visit: Logs		Form: TRANSFUSIONS	
Form Version: 22-Apr-2020 21:03			
Site No: 1149		Site Name: (1149) Collaborative Neuroscience Network, LLC.	
Subject No: 11491313		Subject Initials: ---	
Generated By: (b) (4)		Generated Time (GMT): 29-Mar-2021 11:56	
#	Transfusion Type	Date of Transfusion	Form Instance
1.			Repeating Pages

090177e196ae30c8\Final\Final On: 01-Apr-2021 04:16 (GMT)

Header Text: c4591001	Form: TRANSFUSIONS
Visit: Logs - Unscheduled	Form Status: Not Started
Form Version: 22-Apr-2020 21:03	Site Name: (1149) Collaborative Neuroscience Network, LLC.
Site No: 1149	Subject Initials: ---
Subject No: 11491313	Generated Time (GMT): 29-Mar-2021 11:56
Generated By: (b) (4)	

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

Header Text: c4591001

Visit: End of Treatment - Unscheduled

Form Version: 10-Dec-2020 02:29

Site No: 1149

Subject No: 11491313

Generated By: (b) (4)

Form: DISPOSITION - TREATMENT

Form Status: Data Complete, Frozen, Verified

Site Name: (1149) Collaborative Neuroscience Network, LLC.

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:56

[eCRF Audit Trail History](#)

Disposition - Treatment

1.	Date of Completion/Discontinuation /Death :	Dec/10/2020
2.	Phase of Disposition:	VACCINATION
3.	Status:	COMPLETED
4.	Specify Status:	[]

Header Text: c4591001

Visit: Unplanned Vaccination - Unscheduled

Form: DATE OF VISIT

Form Version: 22-Apr-2020 21:02

Form Status: Not Started

Site No: 1149

Site Name: (1149) Collaborative Neuroscience Network, LLC.

Subject No: 11491313

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

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: 1149

Site Name: (1149) Collaborative Neuroscience Network, LLC.

Subject No: 11491313

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

Vital Signs

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

Vital Signs Details

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

Header Text: c4591001

Visit: Unplanned Vaccination - Unscheduled

Form: LAB URINALYSIS - PREGNANCY TEST

Form Version: 20-Feb-2021 02:14

Form Status: Not Started

Site No: 1149

Site Name: (1149) Collaborative Neuroscience Network, LLC.

Subject No: 11491313

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

Lab Urinalysis

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

Lab Result

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

Header Text: c4591001
Visit: Unplanned Vaccination - Unscheduled **Form:** VACCINATION
Form Version: 10-Dec-2020 02:26 **Form Status:** Not Started
Site No: 1149 **Site Name:** (1149) Collaborative Neuroscience Network, LLC.
Subject No: 11491313 **Subject Initials:** ---
Generated By: (b) (4) **Generated Time (GMT):** 29-Mar-2021 11:56

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?	

090177e196ae30c8\Final\Final On: 01-Apr-2021 04:16 (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: 1149 **Site Name:** (1149) Collaborative Neuroscience Network, LLC.
Subject No: 11491313 **Subject Initials:** ---
Generated By: (b) (4) **Generated Time (GMT):** 29-Mar-2021 11:56

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

090177e196ae30c8\Final\Final On: 01-Apr-2021 04:16 (GMT)

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: 1149 **Site Name:** (1149) Collaborative Neuroscience Network, LLC.
Subject No: 11491313 **Subject Initials:** ---
Generated By: (b) (4) **Generated Time (GMT):** 29-Mar-2021 11:56

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

090177e196ae30c8\Final\Final On: 01-Apr-2021 04:16 (GMT)

Header Text: c4591001

Visit: Follow-Up - Unscheduled

Form Version: 15-Sep-2020 21:53

Site No: 1149

Subject No: 11491313

Generated By: (b) (4)

Form: DISPOSITION - FOLLOW-UP

Form Status: Not Started

Site Name: (1149) Collaborative Neuroscience Network, LLC.

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:56

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: 1149

Site Name: (1149) Collaborative Neuroscience Network, LLC.

Subject No: 11491313

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

[eCRF Audit Trail History](#)

Date of Visit

1.	Date of Visit	Jan/19/2021
2.	Erroneous Visit	

Header Text: c4591001

Visit: Potential ReVax Initial Contact - Unscheduled

Form: FURTHER VACCINATION CONFIRMATION

Form Version: 10-Dec-2020 02:25

Form Status: Data Complete, Frozen, Verified

Site No: 1149

Site Name: (1149) Collaborative Neuroscience Network, LLC.

Subject No: 11491313

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

[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: 1149

Subject No: 11491313

Generated By: (b) (4)

Form: TREATMENT UNBLINDED

Form Status: Data Complete, Frozen, Verified

Site Name: (1149) Collaborative Neuroscience Network, LLC.

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:56

[eCRF Audit Trail History](#)

Treatment Unblinded

1.	Date Treatment Unblinded :	Jan/20/2021
2.	Primary Reason for Unblinding:	ASSESS ELIGIBILITY FOR ADDITIONAL VACCINATION

090177e196ae30c8\Final\Final On: 01-Apr-2021 04:16 (GMT)

Header Text: c4591001		Form: WITHDRAWAL OF CONSENT
Visit: Disposition - Unscheduled		Form Status: Not Started
Form Version: 22-Apr-2020 21:03		Site Name: (1149) Collaborative Neuroscience Network, LLC.
Site No: 1149		Subject Initials: ---
Subject No: 11491313		Generated Time (GMT): 29-Mar-2021 11:56
Generated By: (b) (4)		
Withdrawal Of Consent		
1.	Withdrawal of Consent Date :	//

Header Text: c4591001
Visit: Disposition - Unscheduled
Form Version: 22-Apr-2020 21:03
Site No: 1149
Subject No: 11491313
Generated By: (b) (4)

Form: DEATH DETAILS CODED
Form Status: Not Started
Site Name: (1149) Collaborative Neuroscience Network, LLC.
Subject Initials: ---
Generated Time (GMT): 29-Mar-2021 11:56

Death Details		
1.	Date of Collection / Notification of Death:	//
Cause of Death		
2.	Cause of Death Status:	
	Cause of Death:	[]

090177e196ae30c8\Final\Final On: 01-Apr-2021 04:16 (GMT)

Header Text: c4591001	Form: DATE OF VISIT
Visit: V101_VAX3	Form Status: Data Complete, Frozen, Verified
Form Version: 22-Apr-2020 21:02	Site Name: (1149) Collaborative Neuroscience Network, LLC.
Site No: 1149	Subject Initials: ---
Subject No: 11491313	Generated Time (GMT): 29-Mar-2021 11:56
Generated By: (b) (4)	

[eCRF Audit Trail History](#)

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

Header Text: c4591001	Form: INFORMED CONSENT - FURTHER VACCINATION
Visit: V101_VAX3	Form Status: Data Complete, Frozen, Verified
Form Version: 10-Dec-2020 02:31	Site Name: (1149) Collaborative Neuroscience Network, LLC.
Site No: 1149	Subject Initials: ---
Subject No: 11491313	Generated Time (GMT): 29-Mar-2021 11:56
Generated By: (b) (4)	

[eCRF Audit Trail History](#)

Informed Consent - Further Vaccination

1.	Consent Was:	OBTAINED Date Written Consent Obtained Jan/22/2021
----	--------------	--

090177e196ae30c8\Final\Final On: 01-Apr-2021 04:16 (GMT)

Header Text: c4591001

Visit: V101_VAX3

Form Version: 10-Dec-2020 02:30

Site No: 1149

Subject No: 11491313

Generated By: (b) (4)

Form: INCLUSION/EXCLUSION CRITERIA - FURTHER VACCINATION

Form Status: Data Complete, Frozen, Verified

Site Name: (1149) Collaborative Neuroscience Network, LLC.

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:56

Form Comments

Inclusion Criteria Not Met

1.	Description of Inclusion Criterion Not Met	Not Applicable
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Exclusion Criteria Met

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

Header Text: c4591001	Form: DISPOSITION - SCREENING FOR FURTHER VACCINATION
Visit: V101_VAX3	Form Status: Data Complete, Frozen, Verified
Form Version: 10-Dec-2020 02:31	Site Name: (1149) Collaborative Neuroscience Network, LLC.
Site No: 1149	Subject Initials: ---
Subject No: 11491313	Generated Time (GMT): 29-Mar-2021 11:56
Generated By: (b) (4)	

[eCRF Audit Trail History](#)

Disposition - Screening for Further Vaccination

1.	Date of Completion/Discontinuation /Death :	Jan/22/2021
2.	Phase of Disposition:	REPEAT SCREENING 1
3.	Status:	COMPLETED
4.	Specify Status:	[]

090177e196ae30c8\Final\Final On: 01-Apr-2021 04:16 (GMT)

Header Text: c4591001

Visit: V101_VAX3

Form Version: 14-Jan-2021 02:21

Site No: 1149

Subject No: 11491313

Generated By: (b) (4)

Form: LAB URINALYSIS - PREGNANCY TEST

Form Status: Data Complete, Frozen, Verified

Site Name: (1149) Collaborative Neuroscience Network, LLC.

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:56

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

Lab Urinalysis

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

Lab Result

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

090177e196ae30c8\Final\Final On: 01-Apr-2021 04:16 (GMT)

Header Text: c4591001

Visit: V101_VAX3

Form Version: 22-Apr-2020 21:03

Site No: 1149

Subject No: 11491313

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Status: Data Complete, Frozen, Verified

Site Name: (1149) Collaborative Neuroscience Network, LLC.

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:56

[eCRF Audit Trail History](#)

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	SERUM
3.	Sample Collected?	YES Date of Collection: Jan/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	[BR7WGZ]
5.b	Sample ID	[BSGTFS]
5.c	Sample ID	[BSGTFT]

090177e196ae30c8\Final\Final On: 01-Apr-2021 04:16 (GMT)

Header Text: c4591001

Visit: V101_VAX3

Form Version: 22-Apr-2020 21:03

Site No: 1149

Subject No: 11491313

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB

Form Status: Data Complete, Frozen, Verified

Site Name: (1149) Collaborative Neuroscience Network, LLC.

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:56

[eCRF Audit Trail History](#)

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Jan/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	[BR7WGY]
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090177e196ae30c8\Final\Final On: 01-Apr-2021 04:16 (GMT)

Header Text: c4591001
Visit: V101_VAX3
Form Version: 10-Dec-2020 02:26
Site No: 1149
Subject No: 11491313
Generated By: (b) (4)

Form: VACCINATION
Form Status: Data Complete, Frozen, Verified
Site Name: (1149) Collaborative Neuroscience Network, LLC.
Subject Initials: ---
Generated Time (GMT): 29-Mar-2021 11:56

[eCRF Audit Trail History](#)

Vaccination

1.	Was there a temporary delay of vaccination?	NO
2.	Treatment Name	[BNT162b2]
3.	Formulation:	INJECTION
4.	Dose Date Time:	Jan/22/2021 13:55
5.	Anatomical Location:	DELTOID MUSCLE
6.	Body Side:	LEFT
7.	Route:	INTRAMUSCULAR
8.	Actual Dose:	[30.0]
9.	Unit:	ug
10.	Timeframe Subject Was Observed	30 MINUTES
11.	Was the subject observed for at least the protocol specified observation period after investigational product administration?	YES

090177e196ae30c8\Final\Final On: 01-Apr-2021 04:16 (GMT)

Header Text: c4591001

Visit: V102_VAX4

Form Version: 22-Apr-2020 21:02

Site No: 1149

Subject No: 11491313

Generated By: (b) (4)

Form: DATE OF VISIT

Form Status: Data Complete, Frozen, Verified

Site Name: (1149) Collaborative Neuroscience Network, LLC.

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:56

[eCRF Audit Trail History](#)

Date of Visit

1.	Date of Visit	Feb/12/2021
2.	Erroneous Visit	

Header Text: c4591001

Visit: V102_VAX4

Form Version: 14-Jan-2021 02:21

Site No: 1149

Subject No: 11491313

Generated By: (b) (4)

Form: LAB URINALYSIS - PREGNANCY TEST

Form Status: Data Complete, Frozen, Verified

Site Name: (1149) Collaborative Neuroscience Network, LLC.

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:56

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

Lab Urinalysis

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

Lab Result

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

090177e196ae30c8\Final\Final On: 01-Apr-2021 04:16 (GMT)

Header Text: c4591001

Visit: V102_VAX4

Form Version: 22-Apr-2020 21:03

Site No: 1149

Subject No: 11491313

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB

Form Status: Data Complete, Frozen, Verified

Site Name: (1149) Collaborative Neuroscience Network, LLC.

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:56

[eCRF Audit Trail History](#)

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Feb/12/2021
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	[BR7WF6]
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Header Text: c4591001
Visit: V102_VAX4
Form Version: 10-Dec-2020 02:26
Site No: 1149
Subject No: 11491313
Generated By: (b) (4)

Form: VACCINATION
Form Status: Data Complete, Frozen, Verified
Site Name: (1149) Collaborative Neuroscience Network, LLC.
Subject Initials: ---
Generated Time (GMT): 29-Mar-2021 11:56

[eCRF Audit Trail History](#)

Vaccination		
1.	Was there a temporary delay of vaccination?	NO
2.	Treatment Name	[BNT162b2]
3.	Formulation:	INJECTION
4.	Dose Date Time:	Feb/12/2021 11:47
5.	Anatomical Location:	DELTOID MUSCLE
6.	Body Side:	LEFT
7.	Route:	INTRAMUSCULAR
8.	Actual Dose:	[30.0]
9.	Unit:	ug
10.	Timeframe Subject Was Observed	30 MINUTES
11.	Was the subject observed for at least the protocol specified observation period after investigational product administration?	YES

090177e196ae30c8\Final\Final On: 01-Apr-2021 04:16 (GMT)

Header Text: c4591001	Form: DATE OF VISIT
Visit: V103_MONTH1	Form Status: Data Complete, Verified
Form Version: 22-Apr-2020 21:02	Site Name: (1149) Collaborative Neuroscience Network, LLC.
Site No: 1149	Subject Initials: ---
Subject No: 11491313	Generated Time (GMT): 29-Mar-2021 11:56
Generated By: (b) (4)	

[eCRF Audit Trail History](#)

Date of Visit		
1.	Date of Visit	Mar/12/2021
2.	Erroneous Visit	

Header Text: c4591001	Form: CONTACT OUTCOME
Visit: V103_MONTH1	Form Status: Data Complete, Verified
Form Version: 22-Apr-2020 21:04	Site Name: (1149) Collaborative Neuroscience Network, LLC.
Site No: 1149	Subject Initials: ---
Subject No: 11491313	Generated Time (GMT): 29-Mar-2021 11:56
Generated By: (b) (4)	

[eCRF Audit Trail History](#)

Contact Outcome		
1.	Contact Type:	TELEPHONE VISIT
2.	Was contact made?	YES Date of Contact: Mar/12/2021
3.	Comments:	[]

090177e196ae30c8\Final\Final On: 01-Apr-2021 04:16 (GMT)

Header Text: c4591001

Visit: V104_MONTH6

Form Version: 22-Apr-2020 21:02

Site No: 1149

Subject No: 11491313

Generated By: (b) (4)

Form: DATE OF VISIT

Form Status: Not Started

Site Name: (1149) Collaborative Neuroscience Network, LLC.

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:56

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

Header Text: c4591001	Form: CONTACT OUTCOME
Visit: V104_MONTH6	Form Status: Not Started
Form Version: 22-Apr-2020 21:04	Site Name: (1149) Collaborative Neuroscience Network, LLC.
Site No: 1149	Subject Initials: ---
Subject No: 11491313	Generated Time (GMT): 29-Mar-2021 11:56
Generated By: (b) (4)	

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

090177e196ae30c8\Final\Final On: 01-Apr-2021 04:16 (GMT)

Header Text: c4591001

Visit: V105_MONTH18

Form Version: 22-Apr-2020 21:02

Site No: 1149

Subject No: 11491313

Generated By: (b) (4)

Form: DATE OF VISIT

Form Status: Not Started

Site Name: (1149) Collaborative Neuroscience Network, LLC.

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:56

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

Header Text: c4591001
Visit: V105_MONTH18
Form Version: 22-Apr-2020 21:04
Site No: 1149
Subject No: 11491313
Generated By: (b) (4)

Form: CONTACT OUTCOME
Form Status: Not Started
Site Name: (1149) Collaborative Neuroscience Network, LLC.
Subject Initials: ---
Generated Time (GMT): 29-Mar-2021 11:56

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

090177e196ae30c8\Final\Final On: 01-Apr-2021 04:16 (GMT)

Header Text: c4591001

Visit: FURTHER_VACCINATION_EOT -
Unscheduled

Form: DISPOSITION - TREATMENT

Form Version: 20-Feb-2021 02:26

Form Status: Not Started

Site No: 1149

Site Name: (1149) Collaborative Neuroscience Network, LLC.

Subject No: 11491313

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

Disposition - Treatment

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

Header Text: c4591001

Visit: Subject Status - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1149

Subject No: 11491313

Generated By: (b) (4)

Form: SUBJECT STATUS

Form Status: Data Complete, Verified

Site Name: (1149) Collaborative Neuroscience Network, LLC.

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:56

[eCRF Audit Trail History](#)

Subject Status

1.	Subject Status	FOLLOW-UP
2.	Subject Status Date	Dec/10/2020

Header Text: c4591001

Visit: Investigator Signature - Unscheduled

Form Version: 22-Apr-2020 21:04

Site No: 1149

Subject No: 11491313

Generated By: (b) (4)

Form: CASEBOOK SIGNATURE FORM

Form Status: Data Complete, Verified

Site Name: (1149) Collaborative Neuroscience Network, LLC.

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:56

[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: 1149

Site Name: (1149) Collaborative Neuroscience Network, LLC.

Subject No: 11491313

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

[Audit Trail](#)

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

- CRF_Sign
- CRF_Sign_1

Name	Signature Meaning	Date	Type	Action
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Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 15-Sep-2020 21:53

Site No: 1149

Subject No: 11491313

Generated By: (b) (4)

Form: INCLUSION/EXCLUSION CRITERIA - Comments

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1149) Collaborative Neuroscience Network, LLC.

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:56

[Back to Form](#)

Item	Date	User	Comment
Form	Sep-25-2020 07:50:02 (UTC-08:00) Pacific Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 15-Sep-2020 21:51

Site No: 1149

Subject No: 11491313

Generated By: (b) (4)

Form: LAB URINALYSIS - PREGNANCY TEST - Comments

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1149) Collaborative Neuroscience Network, LLC.

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:56

[Back to Form](#)

Item	Date	User	Comment
Form	Sep-25-2020 07:56:01 (UTC-08:00) Pacific Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 15-Sep-2020 21:51

Site No: 1149

Subject No: 11491313

Generated By: (b) (4)

Form: LAB URINALYSIS - PREGNANCY TEST - Comments

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1149) Collaborative Neuroscience Network, LLC.

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:56

[Back to Form](#)

Item	Date	User	Comment
1	Sep-25-2020 07:56:01 (UTC-08:00) Pacific Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 15-Sep-2020 21:51

Site No: 1149

Subject No: 11491313

Generated By: (b) (4)

Form: LAB URINALYSIS - PREGNANCY TEST - Comments

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1149) Collaborative Neuroscience Network, LLC.

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:56

[Back to Form](#)

Item	Date	User	Comment
2	Sep-25-2020 07:56:01 (UTC-08:00) Pacific Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 15-Sep-2020 21:51

Site No: 1149

Subject No: 11491313

Generated By: (b) (4)

Form: LAB URINALYSIS - PREGNANCY TEST - Comments

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1149) Collaborative Neuroscience Network, LLC.

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:56

[Back to Form](#)

Item	Date	User	Comment
3	Sep-25-2020 07:56:01 (UTC-08:00) Pacific Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 15-Sep-2020 21:51

Site No: 1149

Subject No: 11491313

Generated By: (b) (4)

Form: LAB URINALYSIS - PREGNANCY TEST - Comments

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1149) Collaborative Neuroscience Network, LLC.

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:56

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4	Sep-25-2020 07:56:01 (UTC-08:00) Pacific Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 15-Sep-2020 21:51

Site No: 1149

Subject No: 11491313

Generated By: (b) (4)

Form: LAB URINALYSIS - PREGNANCY TEST - Comments

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1149) Collaborative Neuroscience Network, LLC.

Subject Initials: ---

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Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 15-Sep-2020 21:51

Site No: 1149

Subject No: 11491313

Generated By: (b) (4)

Form: LAB URINALYSIS - PREGNANCY TEST - Comments

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Site Name: (1149) Collaborative Neuroscience Network, LLC.

Subject Initials: ---

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Item	Date	User	Comment
6.a	Sep-25-2020 07:56:01 (UTC-08:00) Pacific Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 15-Sep-2020 21:51

Site No: 1149

Subject No: 11491313

Generated By: (b) (4)

Form: LAB URINALYSIS - PREGNANCY TEST - Comments

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Site Name: (1149) Collaborative Neuroscience Network, LLC.

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Item	Date	User	Comment
6.a	Sep-25-2020 07:56:01 (UTC-08:00) Pacific Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 15-Sep-2020 21:51

Site No: 1149

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Site Name: (1149) Collaborative Neuroscience Network, LLC.

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Item	Date	User	Comment
6.a	Sep-25-2020 07:56:01 (UTC-08:00) Pacific Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

090177e196ae30c8\Final\Final On: 01-Apr-2021 04:16 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 1149

Subject No: 11491313

Generated By: (b) (4)

Form: DATE OF VISIT - Comments

Form Status: Data Complete, Frozen, Verified

Site Name: (1149) Collaborative Neuroscience Network, LLC.

Subject Initials: ---

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Item	Date	User	Comment
1	Jan-12-2021 09:27:14 (UTC-08:00) Pacific Time (US & Canada)	(b) (4), (b) (6)	
1	Nov-25-2020 10:14:45 (UTC-08:00) Pacific Time (US & Canada)	(b) (4), (b) (6)	Not Done

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/03/2020

Form: MICROBIOLOGY SPECIMEN - Comments

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen, Verified

Site No: 1149

Site Name: (1149) Collaborative Neuroscience Network, LLC.

Subject No: 11491313

Subject Initials: ---

Generated By: (b) (4)

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Item	Date	User	Comment
Form	Nov-04-2020 15:06:02 (UTC-08:00) Pacific Time (US & Canada)	(b) (4), (b) (6)	per subject got tested and it came back negative but not aware of more details. <hr/> Unknown

090177e196ae30c8\Final\Final On: 01-Apr-2021 04:16 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/03/2020

Form: MICROBIOLOGY SPECIMEN - Comments

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Form Status: Data Complete, Frozen, Verified

Site No: 1149

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Item	Date	User	Comment
1	Nov-04-2020 15:06:02 (UTC-08:00) Pacific Time (US & Canada)	(b) (4), (b) (6)	per subject got tested and it came back negative but not aware of more details. <hr/> Unknown

Header Text: c4591001

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Item	Date	User	Comment
2	Nov-04-2020 15:06:02 (UTC-08:00) Pacific Time (US & Canada)	(b) (4), (b) (6)	per subject got tested and it came back negative but not aware of more details. <hr/> Unknown

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5	Nov-04-2020 15:06:02 (UTC-08:00) Pacific Time (US & Canada)	(b) (4), (b) (6)	per subject got tested and it came back negative but not aware of more details. <hr/> Unknown

Header Text: c4591001

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Item	Date	User	Comment
6	Nov-04-2020 15:06:02 (UTC-08:00) Pacific Time (US & Canada)	(b) (4), (b) (6)	per subject got tested and it came back negative but not aware of more details. <hr/> Unknown

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/03/2020

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Form Status: Data Complete, Frozen, Verified

Site No: 1149

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Item	Date	User	Comment
7	Nov-04-2020 15:06:02 (UTC-08:00) Pacific Time (US & Canada)	(b) (4), (b) (6)	per subject got tested and it came back negative but not aware of more details. <hr/> Unknown

Header Text: c4591001

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Form Status: Data Complete, Frozen, Verified

Site No: 1149

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Item	Date	User	Comment
8	Nov-04-2020 15:06:02 (UTC-08:00) Pacific Time (US & Canada)	(b) (4), (b) (6)	per subject got tested and it came back negative but not aware of more details. <hr/> Unknown

Header Text: c4591001

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Site No: 1149

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9	Nov-04-2020 15:06:02 (UTC-08:00) Pacific Time (US & Canada)	(b) (4), (b) (6)	per subject got tested and it came back negative but not aware of more details. <hr/> Unknown

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Form Version: 06-Jul-2020 21:53

Form Status: Data Complete, Frozen, Verified

Site No: 1149

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Form	Nov-16-2020 13:35:47 (UTC-08:00) Pacific Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

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Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/03/2020

Form: RESPIRATORY TREATMENT - Comments

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Form Status: Data Complete, Frozen, Verified

Site No: 1149

Site Name: (1149) Collaborative Neuroscience Network, LLC.

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Item	Date	User	Comment
1	Nov-16-2020 13:35:47 (UTC-08:00) Pacific Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

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Site No: 1149

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Item	Date	User	Comment
2	Nov-16-2020 13:35:47 (UTC-08:00) Pacific Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/03/2020

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Item	Date	User	Comment
3	Nov-16-2020 13:35:47 (UTC-08:00) Pacific Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

Header Text: c4591001

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Item	Date	User	Comment
4	Nov-16-2020 13:35:47 (UTC-08:00) Pacific Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

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Item	Date	User	Comment
5	Nov-16-2020 13:35:47 (UTC-08:00) Pacific Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

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6	Nov-16-2020 13:35:47 (UTC-08:00) Pacific Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

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Visit: V101_VAX3

Form: INCLUSION/EXCLUSION CRITERIA - FURTHER VACCINATION - Comments

Form Version: 10-Dec-2020 02:30

Form Status: Data Complete, Frozen, Verified

Site No: 1149

Site Name: (1149) Collaborative Neuroscience Network, LLC.

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Form	Jan-25-2021 10:13:39 (UTC-08:00) Pacific Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

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Visit: V101_VAX3

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Generated By: (b) (4)

Form: LAB URINALYSIS - PREGNANCY TEST - Comments

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Form	Jan-25-2021 10:14:04 (UTC-08:00) Pacific Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

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Header Text: c4591001

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2	Jan-25-2021 10:14:04 (UTC-08:00) Pacific Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

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6.a	Jan-25-2021 10:14:04 (UTC-08:00) Pacific Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

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Header Text: c4591001

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Generated By: (b) (4)

Form: LAB URINALYSIS - PREGNANCY TEST - Comments

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Item	Date	User	Comment
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Subject Initials: ---

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Item	Date	User	Comment
5	Feb-12-2021 17:11:29 (UTC-08:00) Pacific Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

090177e196ae30c8\Final\Final On: 01-Apr-2021 04:16 (GMT)

Header Text: c4591001

Visit: V102_VAX4

Form Version: 14-Jan-2021 02:21

Site No: 1149

Subject No: 11491313

Generated By: (b) (4)

Form: LAB URINALYSIS - PREGNANCY TEST - Comments

Form Status: Data Complete, Frozen, Verified

Site Name: (1149) Collaborative Neuroscience Network, LLC.

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:56

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Item	Date	User	Comment
6.a	Feb-12-2021 17:11:29 (UTC-08:00) Pacific Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

Header Text: c4591001

Visit: V102_VAX4

Form Version: 14-Jan-2021 02:21

Site No: 1149

Subject No: 11491313

Generated By: (b) (4)

Form: LAB URINALYSIS - PREGNANCY TEST - Comments

Form Status: Data Complete, Frozen, Verified

Site Name: (1149) Collaborative Neuroscience Network, LLC.

Subject Initials: ---

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Item	Date	User	Comment
6.a	Feb-12-2021 17:11:29 (UTC-08:00) Pacific Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

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Header Text: c4591001

Visit: V102_VAX4

Form Version: 14-Jan-2021 02:21

Site No: 1149

Subject No: 11491313

Generated By: (b) (4)

Form: LAB URINALYSIS - PREGNANCY TEST - Comments

Form Status: Data Complete, Frozen, Verified

Site Name: (1149) Collaborative Neuroscience Network, LLC.

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:56

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Item	Date	User	Comment
6.a	Feb-12-2021 17:11:29 (UTC-08:00) Pacific Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

Header Text: c4591001

Visit: Investigator Signature - Unscheduled

Form: CASEBOOK SIGNATURE FORM - Signature History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Verified

Site No: 1149

Site Name: (1149) Collaborative Neuroscience Network, LLC.

Subject No: 11491313

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

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

- CRF_Sign
- CRF_Sign_1

Name	Signature Meaning	Date	Type	Action
(b) (6)	N/A	Nov-19-2020 11:24:06 (UTC-08:00) Pacific Time (US & Canada)		Edit - All signatures invalidated

Affidavit:

N/A

Steven Reynolds	Approved	Nov-17-2020 12:36:10 (UTC-08:00) Pacific Time (US & Canada)	BOOK	Signed
-----------------	----------	---	------	--------

Affidavit:

By my dated signature below, I, StevenReynolds, 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.

090177e196ae30c8\Final\Final On: 01-Apr-2021 04:16 (GMT)

Header Text: c4591001

Visit: COHORT_SELECTION

Form Version: 15-Sep-2020 21:55

Site No: 1149

Subject No: 11491313

Generated By: (b) (4)

Form: COHORT_SELECTION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1149) Collaborative Neuroscience Network, LLC.

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:56

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1. Select appropriate response - Protocol version

Date	Location	User	Value	Reason
Sep-25-2020 07:49:31 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 08 SEP 2020	Initial Entry

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

Date	Location	User	Value	Reason
Sep-25-2020 07:49:31 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: STAGE 3 COHORTS	Initial Entry

Header Text: c4591001

Visit: COHORT_SELECTION

Form Version: 22-Apr-2020 21:02

Site No: 1149

Subject No: 11491313

Generated By: (b) (4)

Form: MAIN INFORMED CONSENT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1149) Collaborative Neuroscience Network, LLC.

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:56

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I. Consent Was:

Date	Location	User	Value	Reason
Sep-25-2020 07:49:38 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: OBTAINED Date Written Consent Obtained Sep/24/2020	Initial Entry

090177e196ae30c8\Final\Final On: 01-Apr-2021 04:16 (GMT)

Header Text: c4591001

Visit: COHORT_SELECTION

Form Version: 15-Sep-2020 21:54

Site No: 1149

Subject No: 11491313

Generated By: (b) (4)

Form: DEMOGRAPHY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1149) Collaborative Neuroscience Network, LLC.

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:56

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1. Subject ID

Date	Location	User	Value	Reason
Nov-04-2020 23:23:09 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Nov-04-2020 15:00:06 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	SAE entered in CRF
Nov-04-2020 04:13:17 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	SAE RECON:AER#2020427994 Severe Cough (onset date:01Nov2020)was reported as serious in Safety database but missing in AE CRF. Please confirm and update CRF. If safety update is required, submit a follow-up SAE Form.
Sep-25-2020 07:49:25 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 11491313	Item copied from previous form

2. Birth Date:

Date	Location	User	Value	Reason
Sep-25-2020 07:49:22 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: (b) (6)/1952	Enrollment Entry

3. Sex:

Date	Location	User	Value	Reason
Sep-25-2020 07:49:47 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: FEMALE	Initial Entry

4. Ethnicity:

Date	Location	User	Value	Reason
Sep-25-2020 07:49:47 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NOT HISPANIC OR LATINO(A) OR O F SPANISH ORIGIN	Initial Entry

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

090177e196ae30c8\Final\Final On: 01-Apr-2021 04:16 (GMT)

Header Text: c4591001

Visit: COHORT_SELECTION

Form Version: 15-Sep-2020 21:54

Site No: 1149

Subject No: 11491313

Generated By: (b) (4)

Form: DEMOGRAPHY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1149) Collaborative Neuroscience Network, LLC.

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:56

Date	Location	User	Value	Reason
Sep-25-2020 07:49:47 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: WHITE	Initial Entry

090177e196ae30c8\Final\Final On: 01-Apr-2021 04:16 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:02

Site No: 1149

Subject No: 11491313

Generated By: (b) (4)

Form: DATE OF VISIT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1149) Collaborative Neuroscience Network, LLC.

Subject Initials: ---

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I. Date of Visit

Date	Location	User	Value	Reason
Sep-25-2020 07:49:56 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sep/24/2020	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 15-Sep-2020 21:52

Site No: 1149

Subject No: 11491313

Generated By: (b) (4)

Form: DISPOSITION - SCREENING - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1149) Collaborative Neuroscience Network, LLC.

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:56

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1. Date of Completion/Discontinuation/Death

Date	Location	User	Value	Reason
Sep-25-2020 07:50:11 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sep/24/2020	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Sep-25-2020 07:50:11 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SCREENING	Initial Entry

3. Status:

Date	Location	User	Value	Reason
Sep-25-2020 07:50:11 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: COMPLETED	Initial Entry

090177e196ae30c8\Final\Final On: 01-Apr-2021 04:16 (GMT)

Header Text: c4591001**Visit:** V1_DAY1_VAX1_L**Form Version:** 22-Apr-2020 21:03**Site No:** 1149**Subject No:** 11491313**Generated By:** (b) (4)**Form:** GENERAL MEDICAL HISTORY - eCRF Audit Trail History**Form Status:** Data Complete, Locked, Frozen, Verified**Site Name:** (1149) Collaborative Neuroscience Network, LLC.**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 11:56[Back to Form](#)**I.a**

Date	Location	User	Value	Reason
Sep-25-2020 07:50:50 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 1 Medical History Term lyrica allergy : Start Date: UNK/UNK/201 2 Ongoing: YES	Initial Entry

I.a Line/MH Number:

Date	Location	User	Value	Reason
Sep-25-2020 07:50:50 (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-25-2020 07:50:50 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: lyrica allergy	Initial Entry

I.a Start Date:

Date	Location	User	Value	Reason
Sep-25-2020 07:50:50 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNK/UNK/2012	Initial Entry

I.a Ongoing:

Date	Location	User	Value	Reason
Sep-25-2020 07:50:50 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

I.b

Date	Location	User	Value	Reason
Sep-25-2020 07:51:10 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 2 Medical History Term gabapentin allerg m: y	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1149

Subject No: 11491313

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1149) Collaborative Neuroscience Network, LLC.

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:56

			Start Date:	UNK/UNK/2012
			Ongoing:	YES

1.b Line/MH Number:

Date	Location	User	Value	Reason
Sep-25-2020 07:51:10 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 2	Initial Entry

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

Date	Location	User	Value	Reason
Sep-25-2020 07:51:10 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: gabapentin allergy	Initial Entry

1.b Start Date:

Date	Location	User	Value	Reason
Sep-25-2020 07:51:10 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNK/UNK/2012	Initial Entry

1.b Ongoing:

Date	Location	User	Value	Reason
Sep-25-2020 07:51:10 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

1.c

Date	Location	User	Value	Reason
Sep-25-2020 12:34:19 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Data Entry: Line/MH Number: 3 r: Medical History Term: partial denture - WE ARER Start Date: UNK/UNK/2016 Ongoing: YES	updated per query
Sep-25-2020 07:51:32 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 3 Medical History Term: partial denture Start Date: UNK/UNK/2016	Initial Entry

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Header Text: c4591001

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Subject No: 11491313

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1149) Collaborative Neuroscience Network, LLC.

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			Ongoing:	YES	
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Header Text: c4591001

Visit: V1_DAY1_VAX1_L

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Site No: 1149

Subject No: 11491313

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1149) Collaborative Neuroscience Network, LLC.

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:56

I.c Line/MH Number:

Date	Location	User	Value	Reason
Sep-25-2020 07:51:32 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> 3	Initial Entry

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

Date	Location	User	Value	Reason
Sep-25-2020 15:59:47 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	PFETMS Oracle (b) (4)	Query 1: Closed	Discrepancy has been closed.
Sep-25-2020 12:34:19 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	updated per query
Sep-25-2020 12:34:19 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> partial denture - WEA RER	updated per query
Sep-25-2020 09:37:11 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	PFETMS Oracle (b) (4)	Query 1: Opened	Clarify the term PARTIAL DENTURE as follows. This is a device. Please specify are you reporting PARTIAL DENTURE - WEARER? or PARTIAL DENTURE - PLACEMENT? or Other? If so, edit to such. Otherwise please clarify the term further. Thank you.
Sep-25-2020 07:51:32 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> partial denture	Initial Entry

I.c Start Date:

Date	Location	User	Value	Reason
Sep-25-2020 07:51:32 (UTC-08:00) Pacific Time	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> UNK/UNK/2016	Initial Entry

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Header Text: c4591001

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Form Version: 22-Apr-2020 21:03

Site No: 1149

Subject No: 11491313

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1149) Collaborative Neuroscience Network, LLC.

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:56

(US & Canada)				
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I.c Ongoing:

Date	Location	User	Value	Reason
Sep-25-2020 07:51:32 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

I.d

Date	Location	User	Value	Reason
Sep-25-2020 07:51:50 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 4 Medical History Term: hypertension Start Date: Jan/UNK/2020 Ongoing: YES	Initial Entry

I.d Line/MH Number:

Date	Location	User	Value	Reason
Sep-25-2020 07:51:50 (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-25-2020 07:51:50 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: hypertension	Initial Entry

I.d Start Date:

Date	Location	User	Value	Reason
Sep-25-2020 07:51:50 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Jan/UNK/2020	Initial Entry

I.d Ongoing:

Date	Location	User	Value	Reason
Sep-25-2020 07:51:50 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

I.e

Date	Location	User	Value	Reason
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090177e196ae30c8\Final\Final On: 01-Apr-2021 04:16 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1149

Subject No: 11491313

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1149) Collaborative Neuroscience Network, LLC.

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:56

Sep-25-2020 07:52:12 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number 5 : Medical History Term: intermittent heart murmur Start Date: UNK/UNK/1954 Ongoing: YES	Initial Entry
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I.e Line/MH Number:

Date	Location	User	Value	Reason
Sep-25-2020 07:52:12 (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-25-2020 07:52:12 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: intermittent heart murmur	Initial Entry

I.e Start Date:

Date	Location	User	Value	Reason
Sep-25-2020 07:52:12 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNK/UNK/1954	Initial Entry

I.e Ongoing:

Date	Location	User	Value	Reason
Sep-25-2020 07:52:12 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

I.f

Date	Location	User	Value	Reason
Sep-25-2020 07:52:33 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 6 Medical History Term: hyperlipidemia Start Date: Jan/UNK/2020 Ongoing: YES	Initial Entry

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Header Text: c4591001

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Site No: 1149

Subject No: 11491313

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1149) Collaborative Neuroscience Network, LLC.

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:56

If Line/MH Number:

Date	Location	User	Value	Reason
Sep-25-2020 07:52:33 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 6	Initial Entry

If Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:

Date	Location	User	Value	Reason
Sep-25-2020 07:52:33 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: hyperlipidemia	Initial Entry

If Start Date:

Date	Location	User	Value	Reason
Sep-25-2020 07:52:33 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Jan/UNK/2020	Initial Entry

If Ongoing:

Date	Location	User	Value	Reason
Sep-25-2020 07:52:33 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

I.g

Date	Location	User	Value	Reason
Sep-25-2020 07:53:00 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 7 Medical History Term type 2 diabetes : Start Date: UNK/UNK/201 9 Ongoing: YES	Initial Entry

090177e196ae30c8\Final\Final On: 01-Apr-2021 04:16 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1149

Subject No: 11491313

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1149) Collaborative Neuroscience Network, LLC.

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:56

I.g Line/MH Number:

Date	Location	User	Value	Reason
Sep-25-2020 07:53:00 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> 7	Initial Entry

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

Date	Location	User	Value	Reason
Sep-25-2020 07:53:00 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> type 2 diabetes	Initial Entry

I.g Start Date:

Date	Location	User	Value	Reason
Sep-25-2020 07:53:00 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> UNK/UNK/2019	Initial Entry

I.g Ongoing:

Date	Location	User	Value	Reason
Sep-25-2020 07:53:00 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> YES	Initial Entry

I.h

Date	Location	User	Value	Reason
Sep-25-2020 07:53:39 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> Line/MH Number: 8 Medical History Term: left thumb osteoarthritis Start Date: UNK/UNK/2018 Ongoing: YES	Initial Entry

090177e196ae30c8\Final\Final On: 01-Apr-2021 04:16 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1149

Subject No: 11491313

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1149) Collaborative Neuroscience Network, LLC.

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:56

I.h Line/MH Number:

Date	Location	User	Value	Reason
Sep-25-2020 07:53:39 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> 8	Initial Entry

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

Date	Location	User	Value	Reason
Sep-25-2020 07:53:39 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> left thumb osteoarthritis	Initial Entry

I.h Start Date:

Date	Location	User	Value	Reason
Sep-25-2020 07:53:39 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> UNK/UNK/2018	Initial Entry

I.h Ongoing:

Date	Location	User	Value	Reason
Sep-25-2020 07:53:39 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> YES	Initial Entry

I.i

Date	Location	User	Value	Reason
Sep-25-2020 07:54:09 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> Line/MH Number: 9 Medical History Term: right knee osteoarthritis Start Date: UNK/UNK/2018 Ongoing: YES	Initial Entry

090177e196ae30c8\Final\Final On: 01-Apr-2021 04:16 (GMT)

Header Text: c4591001
 Visit: V1_DAY1_VAX1_L
 Form Version: 22-Apr-2020 21:03
 Site No: 1149
 Subject No: 11491313
 Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History
 Form Status: Data Complete, Locked, Frozen, Verified
 Site Name: (1149) Collaborative Neuroscience Network, LLC.
 Subject Initials: ---
 Generated Time (GMT): 29-Mar-2021 11:56

I.i Line/MH Number:

Date	Location	User	Value	Reason
Sep-25-2020 07:54:09 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 9	Initial Entry

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

Date	Location	User	Value	Reason
Sep-25-2020 07:54:09 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: right knee osteoarthritis	Initial Entry

I.i Start Date:

Date	Location	User	Value	Reason
Sep-25-2020 07:54:09 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNK/UNK/2018	Initial Entry

I.i Ongoing:

Date	Location	User	Value	Reason
Sep-25-2020 07:54:09 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

090177e196ae30c8\Final\Final On: 01-Apr-2021 04:16 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1149

Subject No: 11491313

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1149) Collaborative Neuroscience Network, LLC.

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:56

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<i>I.j</i>				
Date	Location	User	Value	Reason
Oct-13-2020 10:54:50 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Data Entry: Line/MH Number: 10 er: Medical History Term: lumbar degenerative disc disease Start Date: UNK/UNK/2013 Ongoing: YES	Updated per query
Sep-25-2020 12:14:41 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Data Entry: Line/MH Number: 10 Medical History Term: lumbar DDD Start Date: UNK/UNK/2013 Ongoing: YES	Updated per query
Sep-25-2020 07:54:29 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 10 Medical History Term: lumbar DDD hernia Start Date: UNK/UNK/2013 Ongoing: YES	Initial Entry

090177e196ae30c8\Final\Final On: 01-Apr-2021 04:16 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1149

Subject No: 11491313

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1149) Collaborative Neuroscience Network, LLC.

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:56

L.j Line/MH Number:

Date	Location	User	Value	Reason
Sep-25-2020 07:54:29 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 10	Initial Entry

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

Date	Location	User	Value	Reason
Oct-16-2020 11:08:56 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Query 2: Closed	Response satisfies query
Oct-13-2020 10:54:50 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Answered	Updated per query
Oct-13-2020 10:54:50 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: lumbar degenerative di sc disease	Updated per query
Oct-06-2020 15:56:11 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Opened	Please spell out degenerative disc disease
Sep-25-2020 16:00:00 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	PFETMS Oracle (b) (4)	Query 1: Closed	Discrepancy has been closed.
Sep-25-2020 12:14:41 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Updated per query
Sep-25-2020 12:14:41 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: lumbar DDD	Updated per query
Sep-25-2020 11:11:56 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	PFETMS Oracle (b) (4)	Query 1: Opened	Multiple concepts in the term LUMBAR DDD HERNIA. Split the term into LUMBAR DDD and LUMBAR DISC HERNIA and report as

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Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1149

Subject No: 11491313

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1149) Collaborative Neuroscience Network, LLC.

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:56

				separate entries. Thank you.
Sep-25-2020 07:54:29 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: lumbar DDD hernia	Initial Entry

I.j Start Date:

Date	Location	User	Value	Reason
Sep-25-2020 07:54:29 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNK/UNK/2013	Initial Entry

I.j Ongoing:

Date	Location	User	Value	Reason
Sep-25-2020 07:54:29 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

I.k

Date	Location	User	Value	Reason
Nov-03-2020 14:48:57 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Data Entry: Line/MH Number: 11 Medical History Te femoral hernia rm: Start Date: Jan/UNK/2020 Ongoing: NO End Date: UNK/UNK/2020	Changed Information
Sep-25-2020 07:55:07 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 11 Medical History Te hernia repair rm: Start Date: Jan/UNK/2020 Ongoing: NO End Date: UNK/UNK/2020	Initial Entry

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Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1149

Subject No: 11491313

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1149) Collaborative Neuroscience Network, LLC.

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:56

I.k Line/MH Number:

Date	Location	User	Value	Reason
Sep-25-2020 07:55:07 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 11	Initial Entry

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

Date	Location	User	Value	Reason
Nov-04-2020 09:22:12 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Query 1: Closed	Response satisfies query
Nov-03-2020 14:48:57 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Changed Information
Nov-03-2020 14:48:57 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: femoral hernia	Changed Information
Oct-25-2020 10:16:58 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Query 1: Reissued:Opened	Please list the condition and not the procedure.
Oct-23-2020 18:18:14 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Hernia added
Oct-06-2020 15:57:01 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Query 1: Opened	Hernia repair is a procedure, please list the reason (Hernia) as the diagnosis/condition.
Sep-25-2020 07:55:07 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: hernia repair	Initial Entry

I.k Start Date:

Date	Location	User	Value	Reason
Sep-25-2020 07:55:07 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Jan/UNK/2020	Initial Entry

I.k Ongoing:

Date	Location	User	Value	Reason
Sep-25-2020 07:55:07	ACV0PFEINFP6000	(b) (6)	Data Entry:	Initial Entry

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Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1149

Subject No: 11491313

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1149) Collaborative Neuroscience Network, LLC.

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:56

(UTC-08:00) Pacific Time (US & Canada)		(b) (4)	NO End Date: UNK/UNK/2020	
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1.1

Date	Location	User	Value	Reason
Oct-23-2020 18:17:40 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 12 Medical History Term hernia : Start Date: UNK/UNK/2013 Ongoing: YES	Initial Entry

1.1 Line/MH Number:

Date	Location	User	Value	Reason
Oct-23-2020 18:17:40 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 12	Initial Entry

1.1 Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:

Date	Location	User	Value	Reason
Oct-23-2020 18:17:40 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Data Entry: hernia	Initial Entry

1.1 Start Date:

Date	Location	User	Value	Reason
Oct-23-2020 18:17:40 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Data Entry: UNK/UNK/2013	Initial Entry

1.1 Ongoing:

Date	Location	User	Value	Reason
Oct-23-2020 18:17:40 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Data Entry: YES	Initial Entry

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Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 15-Sep-2020 21:57

Site No: 1149

Subject No: 11491313

Generated By: (b) (4)

Form: HIV STATUS - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1149) Collaborative Neuroscience Network, LLC.

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:56

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

Date	Location	User	Value	Reason
Sep-25-2020 07:55:18 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: The subject is NOT known to be HIV POSITIVE	Initial Entry

Header Text: c4591001
 Visit: V1_DAY1_VAX1_L
 Form Version: 15-Sep-2020 21:56
 Site No: 1149
 Subject No: 11491313
 Generated By: (b) (4)

Form: VITAL SIGNS - BASELINE - eCRF Audit Trail History
 Form Status: Data Complete, Locked, Frozen, Verified
 Site Name: (1149) Collaborative Neuroscience Network, LLC.
 Subject Initials: ---
 Generated Time (GMT): 29-Mar-2021 11:56

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1. Date:

Date	Location	User	Value	Reason
Sep-25-2020 07:55:41 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Sep/24/2020	Initial Entry

2. Weight:

Date	Location	User	Value	Reason
Sep-25-2020 07:55:41 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> 72.8	Initial Entry

3. Unit:

Date	Location	User	Value	Reason
Sep-25-2020 07:55:41 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> kg	Initial Entry

4. Height:

Date	Location	User	Value	Reason
Sep-25-2020 07:55:41 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> 152.0	Initial Entry

5. Unit:

Date	Location	User	Value	Reason
Sep-25-2020 07:55:41 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> cm	Initial Entry

6. Body Mass Index:

Date	Location	User	Value	Reason
Sep-25-2020 07:55:41 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> 31.5	Initial Entry

7.a

Date	Location	User	Value	Reason
Sep-25-2020 07:55:41	ACV0PFEINFP6000	(b) (6)	<u>Data Entry:</u>	Initial Entry

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Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 15-Sep-2020 21:56

Site No: 1149

Subject No: 11491313

Generated By: (b) (4)

Form: VITAL SIGNS - BASELINE - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1149) Collaborative Neuroscience Network, LLC.

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:56

(UTC-08:00) Pacific Time (US & Canada)		(b) (4)	Record Identifier:: 1 Temperature: 36.2 Temperature Unit: C Temperature Location:: FOREHEAD
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7.a Record Identifier:

Date	Location	User	Value	Reason
Sep-25-2020 07:55:41 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 1	Initial Entry

7.a Temperature:

Date	Location	User	Value	Reason
Sep-25-2020 07:55:41 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 36.2	Initial Entry

7.a Unit:

Date	Location	User	Value	Reason
Sep-25-2020 07:55:41 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: C	Initial Entry

7.a Temperature Location:

Date	Location	User	Value	Reason
Sep-25-2020 07:55:41 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: FOREHEAD	Initial Entry

090177e196ae30c8\Final\Final On: 01-Apr-2021 04:16 (GMT)

Header Text: c4591001**Visit:** V1_DAY1_VAX1_L**Form Version:** 15-Sep-2020 21:51**Site No:** 1149**Subject No:** 11491313**Generated By:** (b) (4)**Form:** LAB URINALYSIS - PREGNANCY TEST - eCRF Audit Trail History**Form Status:** Data Complete, Locked, Frozen, Verified**Site Name:** (1149) Collaborative Neuroscience Network, LLC.**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 11:56[Back to Form](#)**1. Lab Panel:**

Date	Location	User	Value	Reason
Sep-25-2020 07:56:01 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

2. Lab Sub-Panel:

Date	Location	User	Value	Reason
Sep-25-2020 07:56:01 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

3. Collection Date:

Date	Location	User	Value	Reason
Sep-25-2020 07:56:01 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

4. Laboratory Name and Address (Derived)

Date	Location	User	Value	Reason
Sep-25-2020 07:56:01 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5. Specimen Type:

Date	Location	User	Value	Reason
Sep-25-2020 07:56:01 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

6.a

Date	Location	User	Value	Reason
Sep-25-2020 07:56:01 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sponsor-Defined Identifier: Not Applicable Test:: Not Applicable Result:: Not Applicable	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 15-Sep-2020 21:51

Site No: 1149

Subject No: 11491313

Generated By: (b) (4)

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

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1149) Collaborative Neuroscience Network, LLC.

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:56

			Not Done::	Not Applicable
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6.a Sponsor ID:

Date	Location	User	Value	Reason
Sep-25-2020 07:56:01 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

6.a Test:

Date	Location	User	Value	Reason
Sep-25-2020 07:56:01 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

6.a Result:

Date	Location	User	Value	Reason
Sep-25-2020 07:56:01 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

6.a Not Done:

Date	Location	User	Value	Reason
Sep-25-2020 07:56:01 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

090177e196ae30c8\Final\Final On: 01-Apr-2021 04:16 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1149

Subject No: 11491313

Generated By: (b) (4)

Form: RANDOMIZATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1149) Collaborative Neuroscience Network, LLC.

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:56

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1. Randomization Date :

Date	Location	User	Value	Reason
Sep-25-2020 07:56:37 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sep/24/2020	Initial Entry

2. Randomization Number:

Date	Location	User	Value	Reason
Sep-30-2020 23:43:19 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Sep-30-2020 12:25:16 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Transcription Error
Sep-30-2020 12:25:16 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 265035	Transcription Error
Sep-28-2020 02:42:52 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	PFE SDQ PROD (b) (4)	Query 1: Opened	As per Impala, Randomization Number is 265035 . Please review and update as appropriate. (b) (4)
Sep-25-2020 07:56:37 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 263035	Initial Entry

090177e196ae30c8\Final\Final On: 01-Apr-2021 04:16 (GMT)

Header Text: c4591001
Visit: V1_DAY1_VAX1_L
Form Version: 22-Apr-2020 21:03
Site No: 1149
Subject No: 11491313
Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF
 Audit Trail History
Form Status: Data Complete, Locked, Frozen, Verified
Site Name: (1149) Collaborative Neuroscience Network, LLC.
Subject Initials: ---
Generated Time (GMT): 29-Mar-2021 11:56

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1. Data Origin

Date	Location	User	Value	Reason
Sep-25-2020 07:56:44 (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-25-2020 07:56:44 (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-25-2020 08:45:28 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Sep-25-2020 07:56:44 (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-25-2020 07:56:44 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Collection: Sep/24/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Sep-25-2020 08:45:28 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Data Entry: Sample ID: BLCBTS	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Sep-25-2020 08:45:28 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Data Entry: BLCBTS	Initial Entry

Header Text: c4591001
Visit: V1_DAY1_VAX1_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1149

Site Name: (1149) Collaborative Neuroscience Network, LLC.

Subject No: 11491313

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

5.b

Date	Location	User	Value	Reason
Sep-25-2020 08:45:35 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	<u>Data Entry:</u> Sample ID: BLCBTT	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Sep-25-2020 08:45:35 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	<u>Data Entry:</u> BLCBTT	Initial Entry

5.c

Date	Location	User	Value	Reason
Sep-25-2020 08:45:43 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	<u>Data Entry:</u> Sample ID: BR7WBB	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Sep-25-2020 08:45:43 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	<u>Data Entry:</u> BR7WBB	Initial Entry

5.d

Date	Location	User	Value	Reason
Sep-25-2020 08:45:51 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	<u>Data Entry:</u> Sample ID: BR7WBC	Initial Entry

5.d Sample ID

Date	Location	User	Value	Reason
Sep-25-2020 08:45:51 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	<u>Data Entry:</u> BR7WBC	Initial Entry

090177e196ae30c8\Final\Final On: 01-Apr-2021 04:16 (GMT)

Header Text: c4591001
Visit: V1_DAY1_VAX1_L
Form Version: 22-Apr-2020 21:03
Site No: 1149
Subject No: 11491313
Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB - eCRF Audit Trail History
Form Status: Data Complete, Locked, Frozen, Verified
Site Name: (1149) Collaborative Neuroscience Network, LLC.
Subject Initials: ---
Generated Time (GMT): 29-Mar-2021 11:56

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1. Data Origin

Date	Location	User	Value	Reason
Sep-25-2020 07:56:50 (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-25-2020 07:56:50 (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-25-2020 09:06:18 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Sep-25-2020 07:56:50 (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-25-2020 07:56:50 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Collection: Sep/24/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Sep-25-2020 09:06:18 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Data Entry: Sample ID: BR7WB9	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Sep-25-2020 09:06:18 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Data Entry: BR7WB9	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:04

Site No: 1149

Subject No: 11491313

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1149) Collaborative Neuroscience Network, LLC.

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:56

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1. Was there a temporary delay of vaccination?

Date	Location	User	Value	Reason
Sep-25-2020 07:57:03 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2. Treatment Name

Date	Location	User	Value	Reason
Sep-25-2020 07:57:03 (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-25-2020 07:57:03 (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-25-2020 07:57:03 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sep/24/2020 13:20	Initial Entry

5. Anatomical Location:

Date	Location	User	Value	Reason
Sep-25-2020 07:57:03 (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-25-2020 07:57:03 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: LEFT	Initial Entry

7. Route:

Date	Location	User	Value	Reason
Sep-25-2020 07:57:03	ACV0PFEINFP6000	auto calc	Data Entry:	Initial Entry

090177e196ae30c8\Final\Final On: 01-Apr-2021 04:16 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:04

Site No: 1149

Subject No: 11491313

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1149) Collaborative Neuroscience Network, LLC.

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:56

(UTC-08:00) Pacific Time (US & Canada)		(autocalc)	INTRAMUSCULAR	
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10. Timeframe Subject Was Observed

Date	Location	User	Value	Reason
Sep-25-2020 07:57:03 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: THE PROTOCOL SPECIFIED OBSERVATION PERIOD	Initial Entry

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

Date	Location	User	Value	Reason
Sep-25-2020 07:57:03 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

090177e196ae30c8\Final\Final On: 01-Apr-2021 04:16 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 06-Jul-2020 21:53

Site No: 1149

Subject No: 11491313

Generated By: (b) (4)

Form: REACTOGENICITY DIARY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1149) Collaborative Neuroscience Network, LLC.

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:56

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1. Select appropriate response - Reactogenicity diary collection

Date	Location	User	Value	Reason
Sep-25-2020 07:57:09 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO - REACTOGENICITY E-DIARY NOT COLLECTED FOR THIS SUBJECT	Initial Entry

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 1149

Subject No: 11491313

Generated By: (b) (4)

Form: DATE OF VISIT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1149) Collaborative Neuroscience Network, LLC.

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:56

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I. Date of Visit

Date	Location	User	Value	Reason
Oct-19-2020 14:03:21 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: Oct/15/2020	Initial Entry

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 10-Oct-2020 16:01

Site No: 1149

Subject No: 11491313

Generated By: (b) (4)

Form: VITAL SIGNS - TEMP - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1149) Collaborative Neuroscience Network, LLC.

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:56

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1. Date:

Date	Location	User	Value	Reason
Oct-19-2020 14:06:18 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: Oct/15/2020	Initial Entry

2.a

Date	Location	User	Value	Reason
Oct-19-2020 14:06:18 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: Record Identifier:: 1 Temperature: 35.8 Temperature Unit: C Temperature Location:: FOREHEAD	Initial Entry

2.a Record Identifier:

Date	Location	User	Value	Reason
Oct-19-2020 14:06:18 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: 1	Initial Entry

2.a Temperature:

Date	Location	User	Value	Reason
Oct-23-2020 23:43:09 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Sandip Namdeorao Suryawanshi (b) (4)	Query 1: Closed	Response satisfies query
Oct-23-2020 18:09:14 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	NCS per MD
Oct-19-2020 14:06:18 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	Temperature 35.8 C is outside of Normal Range 36.1 - 37.5 C.
Oct-19-2020 14:06:18 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 35.8	Initial Entry

2.a Unit:

Date	Location	User	Value	Reason
Oct-19-2020 14:06:18 (UTC-08:00) Pacific Time	ACV0PFEINFP6000	(b) (6)	Data Entry: C	Initial Entry

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Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 10-Oct-2020 16:01

Site No: 1149

Subject No: 11491313

Generated By: (b) (4)

Form: VITAL SIGNS - TEMP - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1149) Collaborative Neuroscience Network, LLC.

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:56

(US & Canada)

(b) (4)

2.a Temperature Location:

Date	Location	User	Value	Reason
Oct-19-2020 14:06:18 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: FOREHEAD	Initial Entry

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 15-Sep-2020 21:51

Site No: 1149

Subject No: 11491313

Generated By: (b) (4)

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

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1149) Collaborative Neuroscience Network, LLC.

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:56

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1. Lab Panel:

Date	Location	User	Value	Reason
Oct-19-2020 14:09:31 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: URINALYSIS	Initial Entry

2. Lab Sub-Panel:

Date	Location	User	Value	Reason
Oct-19-2020 14:09:31 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: PREGNANCY	Initial Entry

3. Collection Date:

Date	Location	User	Value	Reason
Oct-19-2020 14:09:31 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: Oct/15/2020	Initial Entry

4. Laboratory Name and Address (Derived)

Date	Location	User	Value	Reason
Oct-19-2020 14:09:31 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: STUDY SITE	Initial Entry

5. Specimen Type:

Date	Location	User	Value	Reason
Oct-19-2020 14:09:31 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: URINE	Initial Entry

6.a

Date	Location	User	Value	Reason
Oct-19-2020 14:09:31 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sponsor-Defined 113 Identifier: Test:: Choriogonadotropin Beta_PX113 Result:: Not Done:: NOT DONE	Initial Entry

090177e196ae30c8\Final\Final On: 01-Apr-2021 04:16 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 15-Sep-2020 21:51

Site No: 1149

Subject No: 11491313

Generated By: (b) (4)

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

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1149) Collaborative Neuroscience Network, LLC.

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:56

6.a Sponsor ID:

Date	Location	User	Value	Reason
Oct-19-2020 14:09:31 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> 113	Initial Entry

6.a Test:

Date	Location	User	Value	Reason
Oct-19-2020 14:09:31 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	<u>Data Entry:</u> Choriogonadotropin Beta_PX113	Initial Entry

6.a Not Done:

Date	Location	User	Value	Reason
Oct-19-2020 14:09:31 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	<u>Data Entry:</u> NOT DONE	Initial Entry

090177e196ae30c8\Final\Final On: 01-Apr-2021 04:16 (GMT)

Header Text: c4591001**Visit:** V2_VAX2_L**Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB - eCRF Audit Trail History**Form Version:** 22-Apr-2020 21:03**Form Status:** Data Complete, Locked, Frozen, Verified**Site No:** 1149**Site Name:** (1149) Collaborative Neuroscience Network, LLC.**Subject No:** 11491313**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 11:56[Back to Form](#)**1. Data Origin**

Date	Location	User	Value	Reason
Oct-19-2020 14:11:04 (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-19-2020 14:11:04 (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 08:14:34 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Oct-19-2020 14:11:04 (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-19-2020 14:11:04 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: YES Date of Collection: Oct/15/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Oct-20-2020 08:14:34 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Data Entry: Sample ID: BR7WR8	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Oct-20-2020 08:14:34 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Data Entry: BR7WR8	Initial Entry

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1149

Subject No: 11491313

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1149) Collaborative Neuroscience Network, LLC.

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:56

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1. Was there a temporary delay of vaccination?

Date	Location	User	Value	Reason
Oct-19-2020 14:11:57 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: NO	Initial Entry

2. Treatment Name

Date	Location	User	Value	Reason
Oct-19-2020 14:11:57 (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-19-2020 14:11:57 (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-19-2020 14:11:57 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: Oct/15/2020 12:31	Initial Entry

5. Anatomical Location:

Date	Location	User	Value	Reason
Oct-19-2020 14:11:57 (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-19-2020 14:11:57 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: LEFT	Initial Entry

7. Route:

Date	Location	User	Value	Reason
Oct-19-2020 14:11:57	ACV0PFEINFP6000	auto calc	Data Entry:	Initial Entry

090177e196ae30c8\Final\Final On: 01-Apr-2021 04:16 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1149

Subject No: 11491313

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1149) Collaborative Neuroscience Network, LLC.

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:56

(UTC-08:00) Pacific Time (US & Canada)		(autocalc)	INTRAMUSCULAR	
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10. Timeframe Subject Was Observed

Date	Location	User	Value	Reason
Oct-19-2020 14:11:57 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: THE PROTOCOL SPECIFIED OBSERVATION PERIOD	Initial Entry

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

Date	Location	User	Value	Reason
Oct-19-2020 14:11:57 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: YES	Initial Entry

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form: DATE OF VISIT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen, Verified

Site No: 1149

Site Name: (1149) Collaborative Neuroscience Network, LLC.

Subject No: 11491313

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

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I. Date of Visit

Date	Location	User	Value	Reason
Jan-26-2021 06:52:48 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Closed	Response satisfies query
Jan-24-2021 21:07:59 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Closed	Per site confirmation_Updated PD tracker
Jan-22-2021 09:15:13 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Answered	Original entry is correct. Subject was unable to conduct visit 3 within window.
Jan-22-2021 09:12:51 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Answered	EOT form has been updated.
Jan-13-2021 02:39:40 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Opened	DM: The treatment period is defined as 1st vaccination visit through the 1-month post vaccination visit after the 2nd vaccination. Please complete treatment disposition CRF and update date of EOT to match date of visit at visit 3.
Jan-13-2021 00:11:40 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Jan-12-2021 21:55:59 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	PFE SDQ PROD (b) (4)	Query 2: Opened	PDQ: Date of visit at V3_MONTH1_POSTVAX2_L is out of window for 21 days from V2_VAX2_L DOV or V2 Vaccination date. Please verify and update. Else, confirm in query response appropriately. (b) (4)

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Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 1149

Subject No: 11491313

Generated By: (b) (4)

Form: DATE OF VISIT - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1149) Collaborative Neuroscience Network, LLC.

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:56

Jan-12-2021 09:27:41 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Initial Entry
Jan-12-2021 09:27:41 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Dec/10/20 20	Initial Entry
Jan-12-2021 09:27:14 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Initial Entry
Jan-11-2021 23:53:48 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Balaji Prabu R (b) (4)	Query 1: Opened	Please remove comment and enter date of visit when the sample is collected for visit 3.
Nov-25-2020 10:14:45 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

090177e196ae30c8\Final\Final On: 01-Apr-2021 04:16 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1149

Site Name: (1149) Collaborative Neuroscience Network, LLC.

Subject No: 11491313

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

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1. Data Origin

Date	Location	User	Value	Reason
Dec-10-2020 13:49:33 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Dec-10-2020 13:49:33 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SERUM	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Jan-13-2021 03:44:11 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Closed as data updated.
Jan-13-2021 00:27:13 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Closed	Response satisfies query
Jan-12-2021 09:21:47 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Answered	Transcription Error
Jan-12-2021 09:21:47 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Answer Auto Query
Jan-12-2021 09:21:47 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Transcription Error
Jan-11-2021 23:57:52 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Balaji Prabu R (b) (4)	Query 2: Opened	Per CCG, If blood sample is combined with convalescent visit, then answer this item to NO. Please review and update as necessary. Else clarify.
Dec-13-2020 21:45:59 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued:Opened	DMI: Thank you for response, Barcode at convalescent visit were missing. Please review and provide the

090177e196ae30c8\Final\Final On: 01-Apr-2021 04:16 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1149

Site Name: (1149) Collaborative Neuroscience Network, LLC.

Subject No: 11491313

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

				missing data or else clarify.
Dec-11-2020 15:20:55 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	this was a combined with convalescent visit. Blood sample was collected and barcoded in Convalescent visit.
Dec-11-2020 09:33:38 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Dec-10-2020 13:49:33 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Dec-10-2020 13:49:33 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Collection: Dec/10/2020	Initial Entry

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

Date	Location	User	Value	Reason
Jan-12-2021 21:01:57 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Jan-12-2021 09:25:19 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Query 1: Answered	'Sample collected' response has been changed to No
Dec-13-2020 22:50:29 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued:Opened	DM: Response to 'Sample Collected' is marked as Yes and sample collection date provided. However, reason for sample not collected is not blank. Please review and consider to update the data accordingly else clarify.
Dec-10-2020 13:50:05 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Please unfreeze DOV to update ecrf

090177e196ae30c8\Final\Final On: 01-Apr-2021 04:16 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1149

Site Name: (1149) Collaborative Neuroscience Network, LLC.

Subject No: 11491313

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

Dec-10-2020 13:49:33 (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 without adding extra spaces or using enter or tab keys.
Dec-10-2020 13:49:33 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: this was a combined with convalescent visit. Blood sample was collected and b arcoded in Convalescent visit.	Initial Entry

Header Text: c4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit on
Nov/03/2020**Form:** DATE OF VISIT - ILLNESS ONSET - eCRF Audit Trail History**Form Version:** 22-Apr-2020 21:03**Form Status:** Data Complete, Frozen, Verified**Site No:** 1149**Site Name:** (1149) Collaborative Neuroscience Network, LLC.**Subject No:** 11491313**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 11:56[Back to Form](#)**I. Date of Visit**

Date	Location	User	Value	Reason
Nov-16-2020 16:46:41 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 4: Closed	Response satisfies query
Nov-16-2020 12:38:25 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 4: Answered	entered
Nov-09-2020 21:51:17 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 4: Opened	DM: Kindly review and complete 'Illness Details form' at this visit. Thank you.
Nov-05-2020 08:15:25 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Query closed as per site response
Nov-05-2020 01:15:23 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Deleted	Duplicate
Nov-04-2020 15:01:28 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 3: 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.
Nov-04-2020 09:19:15 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Nasal swab not complete due to subject having an SAE and currently in the hospital. Site to follow up once subject is available.
Nov-04-2020 04:19:24 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Query 1: Opened	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.
Nov-03-2020 15:11:00	ACV0PFEINFP6000	auto query	Query 2: Deleted	Close Auto Query

Header Text: c4591001
Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/03/2020
Form: DATE OF VISIT - ILLNESS ONSET - eCRF Audit Trail History
Form Version: 22-Apr-2020 21:03
Form Status: Data Complete, Frozen, Verified
Site No: 1149
Site Name: (1149) Collaborative Neuroscience Network, LLC.
Subject No: 11491313
Subject Initials: ---
Generated By: (b) (4)
Generated Time (GMT): 29-Mar-2021 11:56

(UTC-08:00) Pacific Time (US & Canada)		(autoquery)		
Nov-03-2020 15:10:15 (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.
Nov-03-2020 15:10:15 (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.
Nov-03-2020 15:10:15 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Nov/3/2020	Initial Entry

3. COVID-19 Illness Visit:

Date	Location	User	Value	Reason
Nov-03-2020 15:10:15 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: COVID_A	Initial Entry

Header Text: c4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit on Nov/03/2020**Form Version:** 10-Oct-2020 16:02**Site No:** 1149**Subject No:** 11491313**Generated By:** (b) (4)**Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF Audit Trail History**Form Status:** Data Complete, Frozen, Not Complete**Site Name:** (1149) Collaborative Neuroscience Network, LLC.**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 11:56[Back to Form](#)**1. Date of Assessment:**

Date	Location	User	Value	Reason
Nov-03-2020 15:11:00 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Nov/3/2020	Initial Entry

2. Date of First Symptom Started:

Date	Location	User	Value	Reason
Nov-03-2020 15:11:00 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Nov/1/2020	Initial Entry

3. Symptoms Ongoing?

Date	Location	User	Value	Reason
Jan-22-2021 11:47:19 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Query 1: Closed	Response satisfies query
Jan-22-2021 10:37:57 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	New Information
Jan-22-2021 10:37:57 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: NO Date of Last Symptom Resolved: Nov/5/2020	New Information
Dec-14-2020 05:46:26 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	CLINQUERY: Please clarify whether the reported symptoms are still ongoing? If symptoms have ended, please update 'Symptoms Ongoing' on to 'NO' and add Date of Last Symptom Resolved on the CRF.
Nov-03-2020 15:11:00 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

4.a

Date	Location	User	Value	Reason
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Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/03/2020

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

Form Version: 10-Oct-2020 16:02

Form Status: Data Complete, Frozen, Not Complete

Site No: 1149

Site Name: (1149) Collaborative Neuroscience Network, LLC.

Subject No: 11491313

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

Nov-03-2020 15:11:00 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptoms: FEVER Symptom Present: NO	Initial Entry
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4.a Symptoms:

Date	Location	User	Value	Reason
Nov-03-2020 15:11:00 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: FEVER	Initial Entry

4.a Was symptom present?

Date	Location	User	Value	Reason
Nov-03-2020 15:11:00 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

4.b

Date	Location	User	Value	Reason
Nov-03-2020 15:11:00 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptoms: NEW OR INCREASED COUGH Symptom Present: YES	Initial Entry

4.b Symptoms:

Date	Location	User	Value	Reason
Nov-03-2020 15:11:00 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NEW OR INCREASED COUGH	Initial Entry

4.b Was symptom present?

Date	Location	User	Value	Reason
Nov-03-2020 15:11:00 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

4.c

Date	Location	User	Value	Reason
Nov-03-2020 15:11:00 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptoms: NEW OR INCREASED S HORTNESS OF BREATH	Initial Entry

090177e196ae30c8\Final\Final On: 01-Apr-2021 04:16 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/03/2020

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

Form Version: 10-Oct-2020 16:02

Form Status: Data Complete, Frozen, Not Complete

Site No: 1149

Site Name: (1149) Collaborative Neuroscience Network, LLC.

Subject No: 11491313

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

			Symptom NO Present:	
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4.c Symptoms:

Date	Location	User	Value	Reason
Nov-03-2020 15:11:00 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NEW OR INCREASED SHORTNESS OF BREATH	Initial Entry

4.c Was symptom present?

Date	Location	User	Value	Reason
Nov-03-2020 15:11:00 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

4.d

Date	Location	User	Value	Reason
Nov-03-2020 15:11:00 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Symptoms: CHILLS Symptom Present: NO	Initial Entry

4.d Symptoms:

Date	Location	User	Value	Reason
Nov-03-2020 15:11:00 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> CHILLS	Initial Entry

4.d Was symptom present?

Date	Location	User	Value	Reason
Nov-03-2020 15:11:00 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

4.e

Date	Location	User	Value	Reason
Nov-03-2020 15:11:00 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Symptoms: NEW OR INCREASED MUSCLE PAIN Symptom Present: NO	Initial Entry

090177e196ae30c8\Final\Final On: 01-Apr-2021 04:16 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/03/2020

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

Form Version: 10-Oct-2020 16:02

Form Status: Data Complete, Frozen, Not Complete

Site No: 1149

Site Name: (1149) Collaborative Neuroscience Network, LLC.

Subject No: 11491313

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

4.e Symptoms:

Date	Location	User	Value	Reason
Nov-03-2020 15:11:00 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NEW OR INCREASED MUSCLE PAI N	Initial Entry

4.e Was symptom present?

Date	Location	User	Value	Reason
Nov-03-2020 15:11:00 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

4.f

Date	Location	User	Value	Reason
Nov-03-2020 15:11:00 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptoms: NEW LOSS OF TASTE OR SMELL Symptom Pr NO esent:	Initial Entry

4.f Symptoms:

Date	Location	User	Value	Reason
Nov-03-2020 15:11:00 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NEW LOSS OF TASTE OR SMELL	Initial Entry

4.f Was symptom present?

Date	Location	User	Value	Reason
Nov-03-2020 15:11:00 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

4.g

Date	Location	User	Value	Reason
Nov-03-2020 15:11:00 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptoms: NEW OR INCREASED SORE THROAT Symptom P NO resent:	Initial Entry

090177e196ae30c8\Final\Final On: 01-Apr-2021 04:16 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/03/2020

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

Form Version: 10-Oct-2020 16:02

Form Status: Data Complete, Frozen, Not Complete

Site No: 1149

Site Name: (1149) Collaborative Neuroscience Network, LLC.

Subject No: 11491313

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

4.g Symptoms:

Date	Location	User	Value	Reason
Nov-03-2020 15:11:00 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NEW OR INCREASED SORE THROAT	Initial Entry

4.g Was symptom present?

Date	Location	User	Value	Reason
Nov-03-2020 15:11:00 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

4.h

Date	Location	User	Value	Reason
Nov-03-2020 15:11:00 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptoms: DIARRHEA Symptom Present: NO	Initial Entry

4.h Symptoms:

Date	Location	User	Value	Reason
Nov-03-2020 15:11:00 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: DIARRHEA	Initial Entry

4.h Was symptom present?

Date	Location	User	Value	Reason
Nov-03-2020 15:11:00 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

4.i

Date	Location	User	Value	Reason
Nov-03-2020 15:11:00 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptoms: VOMITING Symptom Present: NO	Initial Entry

090177e196ae30c8\Final\Final On: 01-Apr-2021 04:16 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/03/2020

Form Version: 10-Oct-2020 16:02

Site No: 1149

Subject No: 11491313

Generated By: (b) (4)

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

Form Status: Data Complete, Frozen, Not Complete

Site Name: (1149) Collaborative Neuroscience Network, LLC.

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:56

4.i Symptoms:

Date	Location	User	Value	Reason
Nov-03-2020 15:11:00 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> VOMITING	Initial Entry

4.i Was symptom present?

Date	Location	User	Value	Reason
Nov-03-2020 15:11:00 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

Header Text: c4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit on
Nov/03/2020**Form:** MICROBIOLOGY SPECIMEN - eCRF Audit Trail History**Form Version:** 06-Jul-2020 21:54**Form Status:** Data Complete, Frozen, Verified**Site No:** 1149**Site Name:** (1149) Collaborative Neuroscience Network, LLC.**Subject No:** 11491313**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 11:56[Back to Form](#)**1. Actual Date of Collection:**

Date	Location	User	Value	Reason
Nov-08-2020 22:06:27 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Nov-06-2020 16:06:23 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Original value is correct
Nov-06-2020 02:28:32 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	DM: Please confirm if Comment entered needs to be recorded in appropriate data point. Please confirm and correct else clarify, thank you.
Nov-04-2020 15:06:02 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Unknown	Initial Entry

2. Specimen Type:

Date	Location	User	Value	Reason
Nov-04-2020 15:06:02 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Unknown	Initial Entry

3. Specimen Collection Location:

Date	Location	User	Value	Reason
Nov-04-2020 15:06:02 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Unknown	Initial Entry

4. Assay Code and Description:

Date	Location	User	Value	Reason
Nov-04-2020 15:06:02 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Unknown	Initial Entry

5. Device Type:

Date	Location	User	Value	Reason
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Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/03/2020

Form: MICROBIOLOGY SPECIMEN - eCRF Audit Trail History

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen, Verified

Site No: 1149

Site Name: (1149) Collaborative Neuroscience Network, LLC.

Subject No: 11491313

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

Nov-04-2020 15:06:02 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Unknown	Initial Entry
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6. Trade Name:

Date	Location	User	Value	Reason
Nov-04-2020 15:06:02 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Unknown	Initial Entry

7. Test Result:

Date	Location	User	Value	Reason
Nov-04-2020 15:06:02 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Unknown	Initial Entry

8. Comments/Findings/Details:

Date	Location	User	Value	Reason
Nov-04-2020 15:06:02 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Unknown	Initial Entry

9. Trade Name Other, Specify:

Date	Location	User	Value	Reason
Nov-04-2020 15:06:02 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Unknown	Initial Entry

090177e196ae30c8\Final\Final On: 01-Apr-2021 04:16 (GMT)

Header Text: c4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit on
Nov/03/2020**Form Version:** 22-Apr-2020 21:03**Site No:** 1149**Subject No:** 11491313**Generated By:** (b) (4)**Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB SELF - eCRF
Audit Trail History**Form Status:** Data Complete, Frozen, Verified**Site Name:** (1149) Collaborative Neuroscience Network, LLC.**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 11:56[Back to Form](#)**1. Data Origin**

Date	Location	User	Value	Reason
Nov-04-2020 15:05:00 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Nov-04-2020 15:05:00 (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
Nov-15-2020 13:52:55 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Query 1: Closed	Response satisfies query
Nov-15-2020 12:39:22 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	subject has no more symptoms
Nov-08-2020 08:35:21 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Query 1: Opened	Clinical Query: Swab must be collected. Please make arrangements to collect swab.
Nov-04-2020 15:05:00 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	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
Nov-04-2020 15:05:00 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Subject is admitted to the hospital and doesn't have self swab kit with her.	Initial Entry

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/03/2020

Form Version: 22-Apr-2020 21:03

Site No: 1149

Subject No: 11491313

Generated By: (b) (4)

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

Form Status: Data Complete, Frozen, Verified

Site Name: (1149) Collaborative Neuroscience Network, LLC.

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:56

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1. Data Origin

Date	Location	User	Value	Reason
Nov-04-2020 15:01:28 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Nov-04-2020 15:01:28 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: NASAL_SWAB	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Nov-04-2020 15:01:28 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	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
Nov-04-2020 15:01:28 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Subject is admitted to the hospital and d oesn't have self swab kit with her.	Initial Entry

090177e196ae30c8\Final\Final On: 01-Apr-2021 04:16 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/03/2020

Form: HEALTH CARE UTILIZATION - eCRF Audit Trail History

Form Version: 10-Oct-2020 15:59

Form Status: Data Complete, Frozen, Verified

Site No: 1149

Site Name: (1149) Collaborative Neuroscience Network, LLC.

Subject No: 11491313

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

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I.a

Date	Location	User	Value	Reason
Nov-04-2020 15:03:24 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Type of Practitioner: SPECIALIST Occurrence of Visits or Contacts: NO	Initial Entry

I.a Physician or Healthcare Professional:

Date	Location	User	Value	Reason
Nov-04-2020 15:03:24 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: SPECIALIST	Initial Entry

I.a Occurrence of Visits or Contacts:

Date	Location	User	Value	Reason
Nov-04-2020 15:03:24 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

I.b

Date	Location	User	Value	Reason
Nov-04-2020 15:03:24 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Type of Practitioner: EMERGENCY ROOM Occurrence of Visits or Contacts: YES <i>Number of Visits or Contacts:</i> 1	Initial Entry

090177e196ae30c8\Final\Final On: 01-Apr-2021 04:16 (GMT)

Header Text: c4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit on
Nov/03/2020**Form:** HEALTH CARE UTILIZATION - eCRF Audit Trail History**Form Version:** 10-Oct-2020 15:59**Form Status:** Data Complete, Frozen, Verified**Site No:** 1149**Site Name:** (1149) Collaborative Neuroscience Network, LLC.**Subject No:** 11491313**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 11:56**I.b Physician or Healthcare Professional:**

Date	Location	User	Value	Reason
Nov-04-2020 15:03:24 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: EMERGENCY ROOM	Initial Entry

I.b Occurrence of Visits or Contacts:

Date	Location	User	Value	Reason
Nov-04-2020 15:03:24 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES <i>Number of Visits or Contacts:</i> 1	Initial Entry

I.c

Date	Location	User	Value	Reason
Nov-04-2020 15:03:24 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	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
Nov-04-2020 15:03:24 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: PRIMARY CARE PHYSICIAN	Initial Entry

I.c Occurrence of Visits or Contacts:

Date	Location	User	Value	Reason
Nov-04-2020 15:03:24 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

I.d

Date	Location	User	Value	Reason
Nov-04-2020 15:03:24 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Type of Practitioner: URGENT CARE Occurrence of Visits or Contacts: NO	Initial Entry

Header Text: c4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit on
Nov/03/2020**Form:** HEALTH CARE UTILIZATION - eCRF Audit Trail History**Form Version:** 10-Oct-2020 15:59**Form Status:** Data Complete, Frozen, Verified**Site No:** 1149**Site Name:** (1149) Collaborative Neuroscience Network, LLC.**Subject No:** 11491313**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 11:56***I.d Physician or Healthcare Professional:***

Date	Location	User	Value	Reason
Nov-04-2020 15:03:24 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: URGENT CARE	Initial Entry

I.d Occurrence of Visits or Contacts:

Date	Location	User	Value	Reason
Nov-04-2020 15:03:24 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

I.e

Date	Location	User	Value	Reason
Nov-04-2020 15:03:24 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Type of Practitioner: TELEPHONE CO NSULTATION Occurrence of Visits or Contacts: NO	Initial Entry

I.e Physician or Healthcare Professional:

Date	Location	User	Value	Reason
Nov-04-2020 15:03:24 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: TELEPHONE CONSULTATION	Initial Entry

I.e Occurrence of Visits or Contacts:

Date	Location	User	Value	Reason
Nov-04-2020 15:03:24 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

I.f

Date	Location	User	Value	Reason
Nov-04-2020 15:03:24 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Type of Practitioner: OTHE R Occurrence of Visits or Contacts: NO	Initial Entry

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/03/2020

Form: HEALTH CARE UTILIZATION - eCRF Audit Trail History

Form Version: 10-Oct-2020 15:59

Form Status: Data Complete, Frozen, Verified

Site No: 1149

Site Name: (1149) Collaborative Neuroscience Network, LLC.

Subject No: 11491313

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

If Physician or Healthcare Professional:

Date	Location	User	Value	Reason
Nov-04-2020 15:03:24 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: OTHER	Initial Entry

If Occurrence of Visits or Contacts:

Date	Location	User	Value	Reason
Nov-04-2020 15:03:24 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

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

Date	Location	User	Value	Reason
Nov-16-2020 13:40:22 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Query 1: Closed	Response satisfies query
Nov-16-2020 13:36:57 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	entered
Nov-16-2020 12:52:26 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Query 1: Reissued:Opened	Clin: Thank you. Please also enter ILL POTEN, CHEM/HEM, RESP TX and any other applicable forms.
Nov-16-2020 12:38:10 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	entered
Nov-08-2020 08:39:46 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	Clinical Query: This subject was hospitalized. Please enter on the CRF form any available information (vital signs, pulse oxymet, respiratory treatment, lab results, imaging...). Please make every effort to obtain these information.
Nov-04-2020 15:03:24 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Has the subject been in intensive care	Initial Entry

090177e196ae30c8\Final\Final On: 01-Apr-2021 04:16 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/03/2020

Form: HEALTH CARE UTILIZATION - eCRF Audit Trail History

Form Version: 10-Oct-2020 15:59

Form Status: Data Complete, Frozen, Verified

Site No: 1149

Site Name: (1149) Collaborative Neuroscience Network, LLC.

Subject No: 11491313

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

			due to potential COVID-19 illness?	
			NO	

Header Text: c4591001
Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/03/2020 **Form:** HOSPITALIZATION DETAILS - Audit Trail
Form Version: 22-Apr-2020 21:02 **Form Status:**
Site No: 1149 **Site Name:** (1149) Collaborative Neuroscience Network, LLC.
Subject No: 11491313 **Subject Initials:** ---
Generated By: (b) (4) **Generated Time (GMT):** 29-Mar-2021 11:56

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Date	Location	User	Value	Reason
Nov-04-2020 15:04:22 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/03/2020

Form: HOSPITALIZATION DETAILS - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen, Not Complete

Site No: 1149

Site Name: (1149) Collaborative Neuroscience Network, LLC.

Subject No: 11491313

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

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1. Hospitalization Category:

Date	Location	User	Value	Reason
Nov-04-2020 15:04:22 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: HOSPITALIZATION STATUS	Initial Entry

2. Hospitalization Term:

Date	Location	User	Value	Reason
Nov-04-2020 15:04:22 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: HOSPITAL	Initial Entry

3. Admission Date:

Date	Location	User	Value	Reason
Nov-04-2020 15:04:22 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Nov/1/2020	Initial Entry

4. Ongoing?

Date	Location	User	Value	Reason
Jan-22-2021 09:33:43 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Query 1: Closed	Response satisfies query
Jan-22-2021 09:32:08 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	New Information
Jan-22-2021 09:32:08 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: NO Discharge Date: Nov/13/2020	New Information
Dec-23-2020 09:14:35 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Query 1: Opened	Clin: Please enter end date for hospitalization.
Nov-04-2020 15:04:22 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

090177e196ae30c8\Final\Final On: 01-Apr-2021 04:16 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/03/2020

Form: RESPIRATORY TREATMENT - eCRF Audit Trail History

Form Version: 06-Jul-2020 21:53

Form Status: Data Complete, Frozen, Verified

Site No: 1149

Site Name: (1149) Collaborative Neuroscience Network, LLC.

Subject No: 11491313

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

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1. What is the treatment Identifier?

Date	Location	User	Value	Reason
Nov-16-2020 13:35:47 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

2. Concomitant Non-drug Treatment Pre-specified:

Date	Location	User	Value	Reason
Nov-16-2020 13:35:47 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

3. Treatment:

Date	Location	User	Value	Reason
Nov-16-2020 13:35:47 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

4. Treatment:

Date	Location	User	Value	Reason
Nov-16-2020 13:35:47 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5. Start Date:

Date	Location	User	Value	Reason
Nov-16-2020 13:35:47 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

6. Ongoing?

Date	Location	User	Value	Reason
Nov-16-2020 13:35:47 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

090177e196ae30c8\Final\Final On: 01-Apr-2021 04:16 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/03/2020

Form: ILLNESS DETAILS - eCRF Audit Trail History

Form Version: 06-Jul-2020 21:52

Form Status: Data Complete, Frozen, Verified

Site No: 1149

Site Name: (1149) Collaborative Neuroscience Network, LLC.

Subject No: 11491313

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

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1. Category of Clinical Event:

Date	Location	User	Value	Reason
Nov-16-2020 13:32:42 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: POTENTIAL COVID-19 ILLNESS	Initial Entry

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

Date	Location	User	Value	Reason
Nov-16-2020 13:32:42 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Data Entry: NO	Initial Entry

3. Toxicity Grade:

Date	Location	User	Value	Reason
Dec-02-2020 18:21:25 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Closed	Response satisfies query
Dec-02-2020 17:27:56 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Answered	New Information
Dec-02-2020 17:27:56 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 1	New Information
Dec-01-2020 22:15:04 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Query 2: Opened	Clin: Per CRF CRs Section 8.33.5, please enter worst toxicity grade (1 to 5) as it relates to reported symptom(s) on SOD CRF.
Dec-01-2020 17:34:25 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Candidate	Clin: DM, please unfreeze. Per CRF CRs Section 8.33.5, please enter worst toxicity grade (1 to 5) as it relates to reported symptom(s) on SOD CRF.
Nov-16-2020 15:32:36 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query

090177e196ae30c8\Final\Final On: 01-Apr-2021 04:16 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/03/2020

Form: ILLNESS DETAILS - eCRF Audit Trail History

Form Version: 06-Jul-2020 21:52

Form Status: Data Complete, Frozen, Verified

Site No: 1149

Site Name: (1149) Collaborative Neuroscience Network, LLC.

Subject No: 11491313

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

Nov-16-2020 13:33:07 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	pt was not diagnosed with COVID-19
Nov-16-2020 13:32:42 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	Per CRF CRs Section 8.33.5, please enter worst toxicity grade (1 to 5) as it relates to reported symptom(s) on SOD CRF. Please review and update as appropriate.
Nov-16-2020 13:32:42 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 0	Initial Entry

090177e196ae30c8\Final\Final On: 01-Apr-2021 04:16 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on
Nov/03/2020

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - Audit Trail

Form Version: 15-Sep-2020 21:51

Form Status:

Site No: 1149

Site Name: (1149) Collaborative Neuroscience Network, LLC.

Subject No: 11491313

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

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Date	Location	User	Value	Reason
Nov-16-2020 12:56:42 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/03/2020

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: 1149

Site Name: (1149) Collaborative Neuroscience Network, LLC.

Subject No: 11491313

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

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1. Lab Panel:

Date	Location	User	Value	Reason
Nov-16-2020 12:56:42 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: CLINICAL CHEMISTRY	Initial Entry

2. Laboratory Name and Address

Date	Location	User	Value	Reason
Nov-19-2020 21:24:06 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Nov-19-2020 11:24:06 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Fixing formatting of data entered.
Nov-19-2020 11:24:06 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Los Alamitos Medical Center,3751 Katella Avenue, Los Alamitos, CA 90720	Fixing formatting of data entered.
Nov-19-2020 08:19:58 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	DM :A carriage return is identified, please do not press enter key, just type lab name all in single line with comma separated.
Nov-16-2020 12:56:42 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Los Alamitos Medical Center 3751 Katella Avenue Los Alamitos, CA 90720	Initial Entry

3. Collection Date:

Date	Location	User	Value	Reason
Nov-16-2020 12:56:42 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Nov/1/2020	Initial Entry

4. Specimen Type:

Date	Location	User	Value	Reason
Nov-16-2020 12:56:42 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: BLOOD	Initial Entry

5.a

090177e196ae30c8\Final\Final On: 01-Apr-2021 04:16 (GMT)

Header Text: c4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit on Nov/03/2020**Form Version:** 15-Sep-2020 21:51**Site No:** 1149**Subject No:** 11491313**Generated By:** (b) (4)**Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History**Form Status:** Data Complete, Frozen, Verified**Site Name:** (1149) Collaborative Neuroscience Network, LLC.**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 11:56

Date	Location	User	Value	Reason
Nov-16-2020 12:57:22 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sponsor-Defined Identifier: 329 Test:: C Reactive Protein_PX329 Result:: Not Done:: NOT DONE Lab Normal Range:	Initial Entry
Nov-16-2020 12:56:42 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sponsor-Defined Identifier: Test:: C Reactive Protein_PX329 Result:: Not Done:: Lab Normal Range:	Initial Entry

5.a Sponsor ID:

Date	Location	User	Value	Reason
Nov-16-2020 12:57:22 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 329	Initial Entry

5.a Test:

Date	Location	User	Value	Reason
Nov-16-2020 12:56:42 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: C Reactive Protein_PX329	Initial Entry

5.a Not Done:

Date	Location	User	Value	Reason
Nov-16-2020 12:57:22 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NOT DONE	Initial Entry

5.b

Date	Location	User	Value	Reason
Nov-16-2020 12:56:42 (UTC-08:00) Pacific Time	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sponsor-Defined 30	Initial Entry

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/03/2020

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: 1149

Site Name: (1149) Collaborative Neuroscience Network, LLC.

Subject No: 11491313

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

(US & Canada)			Identifier: Test:: Alanine Aminotransf erase_PX30 Result:: 23 Not Done:: Lab Normal Ran <i>Low</i> ge: 7 <i>High</i> 35 <i>Unit</i> U/L
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5.b Sponsor ID:

Date	Location	User	Value	Reason
Nov-16-2020 12:56:42 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 30	Initial Entry

5.b Test:

Date	Location	User	Value	Reason
Nov-16-2020 12:56:42 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Alanine Aminotransferase_PX30	Initial Entry

5.b Result:

Date	Location	User	Value	Reason
Nov-16-2020 12:56:42 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 23	Initial Entry

5.b LNMT

Date	Location	User	Value	Reason
Nov-16-2020 12:56:42 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: <i>Low</i> 7 <i>High</i> 35 <i>Unit</i> U/L	Initial Entry

5.c

090177e196ae30c8\Final\Final On: 01-Apr-2021 04:16 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/03/2020

Form Version: 15-Sep-2020 21:51

Site No: 1149

Subject No: 11491313

Generated By: (b) (4)

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

Form Status: Data Complete, Frozen, Verified

Site Name: (1149) Collaborative Neuroscience Network, LLC.

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:56

Date	Location	User	Value	Reason
Nov-16-2020 12:56:42 (UTC-08:00) Pacific Time (US & Canada)	ACVOPFEINFP6000	auto calc (autocalc)	Data Entry: Sponsor-Defined Identifier: 28 Test:: Aspartate Aminotransferase_PX28 Result:: 20 Not Done:: Lab Normal Range: <i>Low</i> 8 <i>High</i> 20 <i>Unit</i> U/L	Initial Entry

090177e196ae30c8\Final\Final On: 01-Apr-2021 04:16 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/03/2020

Form Version: 15-Sep-2020 21:51

Site No: 1149

Subject No: 11491313

Generated By: (b) (4)

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

Form Status: Data Complete, Frozen, Verified

Site Name: (1149) Collaborative Neuroscience Network, LLC.

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:56

5.c Sponsor ID:

Date	Location	User	Value	Reason
Nov-16-2020 12:56:42 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 28	Initial Entry

5.c Test:

Date	Location	User	Value	Reason
Nov-16-2020 12:56:42 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Aspartate Aminotransferase_PX28	Initial Entry

5.c Result:

Date	Location	User	Value	Reason
Nov-16-2020 12:56:42 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 20	Initial Entry

5.c LNMT

Date	Location	User	Value	Reason
Nov-16-2020 12:56:42 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Low 8 High 20 Unit U/L	Initial Entry

5.d

Date	Location	User	Value	Reason
Nov-16-2020 12:56:42 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sponsor-Defined I 35 dentifier: Test:: Alkaline Phosphata se_PX35 Result:: 68 Not Done::	Initial Entry

090177e196ae30c8\Final\Final On: 01-Apr-2021 04:16 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/03/2020

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: 1149

Site Name: (1149) Collaborative Neuroscience Network, LLC.

Subject No: 11491313

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

			Lab Normal Range <i>Low</i> : 38 <i>High</i> 136 <i>Unit</i> U/L	
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5.d Sponsor ID:

Date	Location	User	Value	Reason
Nov-16-2020 12:56:42 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 35	Initial Entry

5.d Test:

Date	Location	User	Value	Reason
Nov-16-2020 12:56:42 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Alkaline Phosphatase_PX35	Initial Entry

5.d Result:

Date	Location	User	Value	Reason
Nov-16-2020 12:56:42 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 68	Initial Entry

5.d LNMT

Date	Location	User	Value	Reason
Nov-16-2020 12:56:42 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: <i>Low</i> 38 <i>High</i> 136 <i>Unit</i> U/L	Initial Entry

5.e

Date	Location	User	Value	Reason
Nov-16-2020 12:56:42 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sponsor-Defined Identifier: 21	Initial Entry

090177e196ae30c8\Final\Final On: 01-Apr-2021 04:16 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/03/2020

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: 1149

Site Name: (1149) Collaborative Neuroscience Network, LLC.

Subject No: 11491313

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

			Test:: Bilirubin_PX 21 Result:: Not Done:: NOT DONE Lab Normal Range:
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5.e Sponsor ID:

Date	Location	User	Value	Reason
Nov-16-2020 12:56:42 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 21	Initial Entry

5.e Test:

Date	Location	User	Value	Reason
Nov-16-2020 12:56:42 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Bilirubin_PX21	Initial Entry

5.e Not Done:

Date	Location	User	Value	Reason
Nov-16-2020 12:56:42 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NOT DONE	Initial Entry

5.f

Date	Location	User	Value	Reason
Nov-16-2020 13:17:17 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sponsor-Defined I 47 dentifier: Test:: Blood Urea Nitrogen_PX47 Result:: 18 Not Done:: Lab Normal Range: <i>Low</i> 6 <i>High</i> 20 <i>Unit</i> mg/dL	Initial Entry
Nov-16-2020 12:56:42 (UTC-08:00) Pacific Time	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sponsor-Defined I 47	Initial Entry

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Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/03/2020

Form Version: 15-Sep-2020 21:51

Site No: 1149

Subject No: 11491313

Generated By: (b) (4)

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Form Status: Data Complete, Frozen, Verified

Site Name: (1149) Collaborative Neuroscience Network, LLC.

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:56

(US & Canada)			dentifier:	
			Test::	Blood Urea Nitrogen_PX47
			Result::	18
			Not Done::	
			Lab Normal Range:	

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/03/2020

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Form Status: Data Complete, Frozen, Verified

Site No: 1149

Site Name: (1149) Collaborative Neuroscience Network, LLC.

Subject No: 11491313

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

5.f Sponsor ID:

Date	Location	User	Value	Reason
Nov-16-2020 12:56:42 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 47	Initial Entry

5.f Test:

Date	Location	User	Value	Reason
Nov-16-2020 12:56:42 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Blood Urea Nitrogen_PX47	Initial Entry

5.f Result:

Date	Location	User	Value	Reason
Nov-16-2020 13:17:17 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Nov-16-2020 12:56:42 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	Result is present, but lab normal range (Low, high or Unit) is missing. Please correct or confirm.
Nov-16-2020 12:56:42 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 18	Initial Entry

5.f LNMT

Date	Location	User	Value	Reason
Nov-16-2020 13:17:17 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: <i>Low</i> 6 <i>High</i> 20 <i>Unit</i> mg/dL	Initial Entry

5.g

Date	Location	User	Value	Reason
Nov-16-2020 12:58:41 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sponsor-Defined Ident 48 ifier:	Initial Entry

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Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/03/2020

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Site No: 1149

Subject No: 11491313

Generated By: (b) (4)

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

Form Status: Data Complete, Frozen, Verified

Site Name: (1149) Collaborative Neuroscience Network, LLC.

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:56

			Test:: Creatinine_P X48 Result:: 1.0 Not Done:: Lab Normal Range: <i>Low</i> 0.6 <i>High</i> 20 <i>Unit</i> mg/dL	
Nov-16-2020 12:56:42 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sponsor-Defined Identifier: 48 Test:: Creatinine_P X48 Result:: 1.0 Not Done:: Lab Normal Range:	Initial Entry

090177e196ae30c8\Final\Final On: 01-Apr-2021 04:16 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/03/2020

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: 1149

Site Name: (1149) Collaborative Neuroscience Network, LLC.

Subject No: 11491313

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

5.g Sponsor ID:

Date	Location	User	Value	Reason
Nov-16-2020 12:56:42 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 48	Initial Entry

5.g Test:

Date	Location	User	Value	Reason
Nov-16-2020 12:56:42 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Creatinine_PX48	Initial Entry

5.g Result:

Date	Location	User	Value	Reason
Nov-16-2020 12:58:41 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Nov-16-2020 12:56:42 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	Result is present, but lab normal range (Low, high or Unit) is missing. Please correct or confirm.
Nov-16-2020 12:56:42 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 1.0	Initial Entry

5.g LNMT

Date	Location	User	Value	Reason
Nov-16-2020 12:58:41 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: <i>Low</i> 0.6 <i>High</i> 20 <i>Unit</i> mg/dL	Initial Entry

090177e196ae30c8\Final\Final On: 01-Apr-2021 04:16 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on
Nov/03/2020

Form: LOCAL LABORATORY DATA - REPEATING Hematology - Audit Trail

Form Version: 15-Sep-2020 21:55

Form Status:

Site No: 1149

Site Name: (1149) Collaborative Neuroscience Network, LLC.

Subject No: 11491313

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

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Date	Location	User	Value	Reason
Nov-16-2020 14:41:50 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

Header Text: c4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit on Nov/03/2020**Form Version:** 15-Sep-2020 21:55**Site No:** 1149**Subject No:** 11491313**Generated By:** (b) (4)**Form:** LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History**Form Status:** Data Complete, Frozen, Verified**Site Name:** (1149) Collaborative Neuroscience Network, LLC.**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 11:56[Back to Form](#)**1. Lab Panel:**

Date	Location	User	Value	Reason
Nov-16-2020 14:41:50 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: HEMATOLOGY	Initial Entry

2. Laboratory Name and Address

Date	Location	User	Value	Reason
Nov-19-2020 21:24:41 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Nov-19-2020 11:24:42 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Fixing formatting of data entered.
Nov-19-2020 11:24:42 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Los Alamitos Medical Center, 3751 Katella Avenue CA, 90720	Fixing formatting of data entered.
Nov-19-2020 08:20:14 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	DM :A carriage return is identified, please do not press enter key, just type lab name all in single line with comma separated.
Nov-16-2020 14:41:50 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Los Alamitos Medical Center 3751 Katella Avenue CA, 90720	Initial Entry

3. Collection Date:

Date	Location	User	Value	Reason
Nov-16-2020 14:41:50 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Nov/1/2020	Initial Entry

4. Specimen Type:

Date	Location	User	Value	Reason
Nov-16-2020 14:41:50 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: BLOOD	Initial Entry

5.a

Date	Location	User	Value	Reason
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Header Text: c4591001
Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/03/2020
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: 1149
Site Name: (1149) Collaborative Neuroscience Network, LLC.
Subject No: 11491313
Subject Initials: ---
Generated By: (b) (4)
Generated Time (GMT): 29-Mar-2021 11:56

Nov-16-2020 14:47:38 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sponsor-Defined Identifier: Test:: Hemoglobin_PX1 Result:: 12.1 Not Done:: Lab Normal Range: <i>Low</i> 12.0 <i>High</i> 15.6 <i>Unit</i> 10 ³ /uL	Initial Entry
Nov-16-2020 14:41:50 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sponsor-Defined Identifier: Test:: Hemoglobin_PX1 Result:: Not Done:: Lab Normal Range:	Initial Entry

5.a Sponsor ID:

Date	Location	User	Value	Reason
Nov-16-2020 14:47:38 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 1	Initial Entry

5.a Test:

Date	Location	User	Value	Reason
Nov-16-2020 14:41:50 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Hemoglobin_PX1	Initial Entry

5.a Result:

Date	Location	User	Value	Reason
Nov-16-2020 14:47:38 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 12.1	Initial Entry

5.a LNMT

Date	Location	User	Value	Reason
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Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/03/2020

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

Form Version: 15-Sep-2020 21:55

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Site No: 1149

Site Name: (1149) Collaborative Neuroscience Network, LLC.

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Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

Nov-16-2020 14:47:38 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: <i>Low</i> 12.0 <i>High</i> 15.6 <i>Unit</i> 10^3/uL	Initial Entry
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5.b

Date	Location	User	Value	Reason
Nov-16-2020 14:47:38 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sponsor-Defined Identifier: Test:: Hematocrit_P X2 Result:: 36.6 Not Done:: Lab Normal Range: <i>Low</i> 35.0 <i>High</i> 46.0 <i>Unit</i> 10^3/uL	Initial Entry
Nov-16-2020 14:41:50 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sponsor-Defined Identifier: Test:: Hematocrit_P X2 Result:: Not Done:: Lab Normal Range:	Initial Entry

090177e196ae30c8\Final\Final On: 01-Apr-2021 04:16 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/03/2020

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: 1149

Site Name: (1149) Collaborative Neuroscience Network, LLC.

Subject No: 11491313

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

5.b Sponsor ID:

Date	Location	User	Value	Reason
Nov-16-2020 14:47:38 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> 2	Initial Entry

5.b Test:

Date	Location	User	Value	Reason
Nov-16-2020 14:41:50 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Hematocrit_PX2	Initial Entry

5.b Result:

Date	Location	User	Value	Reason
Nov-16-2020 14:47:38 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> 36.6	Initial Entry

5.b LNMT

Date	Location	User	Value	Reason
Nov-16-2020 14:47:38 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> <i>Low</i> 35.0 <i>High</i> 46.0 <i>Unit</i> 10^3/uL	Initial Entry

5.c

Date	Location	User	Value	Reason
Nov-16-2020 14:47:38 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> Sponsor-Defined Identifier: Test:: Erythrocytes_PX3 Result:: Not Done:: NOT DONE Lab Normal Range:	Initial Entry
Nov-16-2020 14:41:50 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Sponsor-Defined Identifier:	Initial Entry

090177e196ae30c8\Final\Final On: 01-Apr-2021 04:16 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/03/2020

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: 1149

Site Name: (1149) Collaborative Neuroscience Network, LLC.

Subject No: 11491313

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

			tifier: Test:: Erythrocytes_PX3 Result:: Not Done:: Lab Normal Range:
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5.c Sponsor ID:

Date	Location	User	Value	Reason
Nov-16-2020 14:47:38 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 3	Initial Entry

5.c Test:

Date	Location	User	Value	Reason
Nov-16-2020 14:41:50 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Erythrocytes_PX3	Initial Entry

5.c Not Done:

Date	Location	User	Value	Reason
Nov-16-2020 14:47:38 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NOT DONE	Initial Entry

5.d

Date	Location	User	Value	Reason
Nov-16-2020 14:47:38 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sponsor-Defined Identifier: Test:: Platelets_PX5 Result:: 221 Not Done:: Lab Normal Range: Low 130 High 400 Unit 10^3/uL	Initial Entry

090177e196ae30c8\Final\Final On: 01-Apr-2021 04:16 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/03/2020

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: 1149

Site Name: (1149) Collaborative Neuroscience Network, LLC.

Subject No: 11491313

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

Nov-16-2020 14:41:50 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sponsor-Defined Identifier: Test:: Platelets_P X5 Result:: Not Done:: Lab Normal Range:	Initial Entry
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5.d Sponsor ID:

Date	Location	User	Value	Reason
Nov-16-2020 14:47:38 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 5	Initial Entry

5.d Test:

Date	Location	User	Value	Reason
Nov-16-2020 14:41:50 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Platelets_PX5	Initial Entry

5.d Result:

Date	Location	User	Value	Reason
Nov-16-2020 14:47:38 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 221	Initial Entry

5.d LNMT

Date	Location	User	Value	Reason
Nov-16-2020 14:47:38 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: <i>Low</i> 130 <i>High</i> 400 <i>Unit</i> 10^3/uL	Initial Entry

5.e

Date	Location	User	Value	Reason
Nov-16-2020 14:47:38 (UTC-08:00) Pacific Time	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sponsor-Defined Ident 7	Initial Entry

090177e196ae30c8\Final\Final On: 01-Apr-2021 04:16 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/03/2020

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Form Version: 15-Sep-2020 21:55

Form Status: Data Complete, Frozen, Verified

Site No: 1149

Site Name: (1149) Collaborative Neuroscience Network, LLC.

Subject No: 11491313

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

(US & Canada)			ifier: Test:: Leukocytes_P X7 Result:: Not Done:: NOT DONE Lab Normal Range:	
Nov-16-2020 14:41:50 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sponsor-Defined Identifier: Test:: Leukocytes_P X7 Result:: Not Done:: Lab Normal Range:	Initial Entry

5.e Sponsor ID:

Date	Location	User	Value	Reason
Nov-16-2020 14:47:38 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 7	Initial Entry

5.e Test:

Date	Location	User	Value	Reason
Nov-16-2020 14:41:50 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Leukocytes_PX7	Initial Entry

5.e Not Done:

Date	Location	User	Value	Reason
Nov-16-2020 14:47:38 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NOT DONE	Initial Entry

5.f

Date	Location	User	Value	Reason
Nov-16-2020 14:41:50 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sponsor-Defined Identifier: 608 Test:: Neutrophils_PX 608 Result:: 2.4 Not Done::	Initial Entry

090177e196ae30c8\Final\Final On: 01-Apr-2021 04:16 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/03/2020

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: 1149

Site Name: (1149) Collaborative Neuroscience Network, LLC.

Subject No: 11491313

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

			Lab Normal Range: <i>Low</i> 1.0 <i>High</i> 7.8 <i>Unit</i> 10 ³ /uL	
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5.f Sponsor ID:

Date	Location	User	Value	Reason
Nov-16-2020 14:41:50 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 608	Initial Entry

5.f Test:

Date	Location	User	Value	Reason
Nov-16-2020 14:41:50 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Neutrophils_PX608	Initial Entry

5.f Result:

Date	Location	User	Value	Reason
Nov-16-2020 14:41:50 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 2.4	Initial Entry

5.f LNMT

Date	Location	User	Value	Reason
Nov-16-2020 14:41:50 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: <i>Low</i> 1.0 <i>High</i> 7.8 <i>Unit</i> 10 ³ /uL	Initial Entry

5.g

Date	Location	User	Value	Reason
Nov-16-2020 14:41:50 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sponsor-Defined Identifier: 609	Initial Entry

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Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/03/2020

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: 1149

Site Name: (1149) Collaborative Neuroscience Network, LLC.

Subject No: 11491313

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

			Test:: Eosinophils_PX 609 Result:: 0.2 Not Done:: Lab Normal Range: <i>Low</i> 0.0 <i>High</i> 0.6 <i>Unit</i> 10^3/uL	
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5.g Sponsor ID:

Date	Location	User	Value	Reason
Nov-16-2020 14:41:50 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 609	Initial Entry

5.g Test:

Date	Location	User	Value	Reason
Nov-16-2020 14:41:50 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Eosinophils_PX609	Initial Entry

5.g Result:

Date	Location	User	Value	Reason
Nov-16-2020 14:41:50 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 0.2	Initial Entry

5.g LNMT

Date	Location	User	Value	Reason
Nov-16-2020 14:41:50 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: <i>Low</i> 0.0 <i>High</i> 0.6 <i>Unit</i> 10^3/uL	Initial Entry

5.h

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Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/03/2020

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Form Status: Data Complete, Frozen, Verified

Site No: 1149

Site Name: (1149) Collaborative Neuroscience Network, LLC.

Subject No: 11491313

Subject Initials: ---

Generated By: (b) (4)

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Date	Location	User	Value	Reason
Nov-16-2020 14:41:50 (UTC-08:00) Pacific Time (US & Canada)	ACVOPFEINFP6000	auto calc (autocalc)	Data Entry: Sponsor-Defined Identifier: 612 Test:: Monocytes_PX 612 Result:: 0.5 Not Done:: Lab Normal Range: <i>Low</i> 0.2 <i>High</i> 1.1 <i>Unit</i> 10 ³ /uL	Initial Entry

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Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/03/2020

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Form Status: Data Complete, Frozen, Verified

Site No: 1149

Site Name: (1149) Collaborative Neuroscience Network, LLC.

Subject No: 11491313

Subject Initials: ---

Generated By: (b) (4)

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5.h Sponsor ID:

Date	Location	User	Value	Reason
Nov-16-2020 14:41:50 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 612	Initial Entry

5.h Test:

Date	Location	User	Value	Reason
Nov-16-2020 14:41:50 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Monocytes_PX612	Initial Entry

5.h Result:

Date	Location	User	Value	Reason
Nov-16-2020 14:41:50 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 0.5	Initial Entry

5.h LNMT

Date	Location	User	Value	Reason
Nov-16-2020 14:41:50 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: <i>Low</i> 0.2 <i>High</i> 1.1 <i>Unit</i> 10^3/uL	Initial Entry

5.i

Date	Location	User	Value	Reason
Nov-16-2020 14:41:50 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sponsor-Defined Identifier: 610 Test:: Basophils_PX6 10 Result:: 0.1 Not Done::	Initial Entry

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Header Text: c4591001

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Form Status: Data Complete, Frozen, Verified

Site No: 1149

Site Name: (1149) Collaborative Neuroscience Network, LLC.

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Subject Initials: ---

Generated By: (b) (4)

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			Lab Normal Range: <i>Low</i> 0.0 <i>High</i> 0.2 <i>Unit</i> 10^3/uL	
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5.i Sponsor ID:

Date	Location	User	Value	Reason
Nov-16-2020 14:41:50 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 610	Initial Entry

5.i Test:

Date	Location	User	Value	Reason
Nov-16-2020 14:41:50 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Basophils_PX610	Initial Entry

5.i Result:

Date	Location	User	Value	Reason
Nov-16-2020 14:41:50 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 0.1	Initial Entry

5.i LNMT

Date	Location	User	Value	Reason
Nov-16-2020 14:41:50 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: <i>Low</i> 0.0 <i>High</i> 0.2 <i>Unit</i> 10^3/uL	Initial Entry

5.j

Date	Location	User	Value	Reason
Nov-16-2020 14:41:50 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sponsor-Defined Iden 611 tifier:	Initial Entry

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Header Text: c4591001

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Subject No: 11491313

Generated By: (b) (4)

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			Test:: Lymphocytes_P X611	
			Result:: 2.2	
			Not Done::	
			Lab Normal Range: <i>Low</i> 0.8	
			<i>High</i> 4.1	
			<i>Unit</i> 10 ³ /uL	

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5.j Sponsor ID:

Date	Location	User	Value	Reason
Nov-16-2020 14:41:50 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 611	Initial Entry

5.j Test:

Date	Location	User	Value	Reason
Nov-16-2020 14:41:50 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Lymphocytes_PX611	Initial Entry

5.j Result:

Date	Location	User	Value	Reason
Nov-16-2020 14:41:50 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 2.2	Initial Entry

5.j LNMT

Date	Location	User	Value	Reason
Nov-16-2020 14:41:50 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: <i>Low</i> 0.8 <i>High</i> 4.1 <i>Unit</i> 10 ³ /uL	Initial Entry

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Header Text: c4591001
Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/03/2020 **Form:** VITAL SIGNS - COVID - Audit Trail
Form Version: 15-Sep-2020 21:52 **Form Status:**
Site No: 1149 **Site Name:** (1149) Collaborative Neuroscience Network, LLC.
Subject No: 11491313 **Subject Initials:** ---
Generated By: (b) (4) **Generated Time (GMT):** 29-Mar-2021 11:56

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Date	Location	User	Value	Reason
Nov-16-2020 12:24:48 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/03/2020

Form: VITAL SIGNS - COVID - eCRF Audit Trail History

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Form Status: Data Complete, Frozen, Verified

Site No: 1149

Site Name: (1149) Collaborative Neuroscience Network, LLC.

Subject No: 11491313

Subject Initials: ---

Generated By: (b) (4)

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I. Date:

Date	Location	User	Value	Reason
Nov-16-2020 12:25:23 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Nov-16-2020 12:25:23 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Nov/3/2020	Transcription Error
Nov-16-2020 12:24:48 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	Date is before Date of First Symptom Started on the Signs and Symptoms form in the same visit. Please review and update as appropriate.
Nov-16-2020 12:24:48 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Oct/30/2020	Initial Entry

2.a

Date	Location	User	Value	Reason
Nov-16-2020 12:24:48 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Record Identifier:: 1 Systolic:: 18 0 Diastolic:: 85 Respiratory Rate in respirations/ minute: 20 Heart Rate in beats/minute: 11 0	Initial Entry

2.a Record Identifier:

Date	Location	User	Value	Reason
Nov-16-2020 12:24:48 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 1	Initial Entry

2.a Systolic:

Date	Location	User	Value	Reason
Nov-16-2020 15:44:58 (UTC-08:00) Pacific Time	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query

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Header Text: c4591001

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Form Status: Data Complete, Frozen, Verified

Site No: 1149

Site Name: (1149) Collaborative Neuroscience Network, LLC.

Subject No: 11491313

Subject Initials: ---

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(US & Canada)				
Nov-16-2020 12:25:04 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Original value is correct
Nov-16-2020 12:24:48 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	Systolic BP 180 is outside of Normal Range 90 - 140.
Nov-16-2020 12:24:48 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 180	Initial Entry

2.a Diastolic:

Date	Location	User	Value	Reason
Nov-16-2020 12:24:48 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 85	Initial Entry

2.a Respiratory Rate in respirations/minute:

Date	Location	User	Value	Reason
Nov-16-2020 12:24:48 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 20	Initial Entry

2.a Heart Rate in beats/minute:

Date	Location	User	Value	Reason
Nov-16-2020 12:24:48 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 110	Initial Entry

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Form: VITAL SIGNS - COVID - Audit Trail

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Form Status:

Site No: 1149

Site Name: (1149) Collaborative Neuroscience Network, LLC.

Subject No: 11491313

Subject Initials: ---

Generated By: (b) (4)

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Date	Location	User	Value	Reason
Nov-16-2020 12:25:42 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Deleted	Transcription Error
Nov-16-2020 12:23:13 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/03/2020

Form: VITAL SIGNS - COVID - eCRF Audit Trail History

Form Version: 10-Oct-2020 15:59

Form Status: Data Complete, Deleted, Frozen, Verified

Site No: 1149

Site Name: (1149) Collaborative Neuroscience Network, LLC.

Subject No: 11491313

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

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

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1. Date:

Date	Location	User	Value	Reason
Nov-16-2020 12:23:13 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Nov/3/2020	Initial Entry

2.a

Date	Location	User	Value	Reason
Nov-16-2020 12:23:13 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Record Identifier:: 1 Systolic:: 18 0 Diastolic:: 85 Respiratory Rate in respirations/ minute: 20 Heart Rate in beats/minute: 11 0	Initial Entry

2.a Record Identifier:

Date	Location	User	Value	Reason
Nov-16-2020 12:23:13 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> 1	Initial Entry

2.a Systolic:

Date	Location	User	Value	Reason
Nov-16-2020 15:46:01 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Nov-16-2020 12:23:28 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Original value is correct
Nov-16-2020 12:23:13 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	Systolic BP 180 is outside of Normal Range 90 - 140.
Nov-16-2020 12:23:13 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> 180	Initial Entry

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Header Text: c4591001

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Form Status: Data Complete, Deleted, Frozen, Verified

Site No: 1149

Site Name: (1149) Collaborative Neuroscience Network, LLC.

Subject No: 11491313

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Generated By: (b) (4)

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

2.a Diastolic:

Date	Location	User	Value	Reason
Nov-16-2020 12:23:13 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> 85	Initial Entry

2.a Respiratory Rate in respirations/minute:

Date	Location	User	Value	Reason
Nov-16-2020 12:23:13 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> 20	Initial Entry

2.a Heart Rate in beats/minute:

Date	Location	User	Value	Reason
Nov-16-2020 12:23:13 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> 110	Initial Entry

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Header Text: c4591001

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Form: VITAL SIGNS - PULSE OX ROOM AIR - Audit Trail

Form Version: 15-Sep-2020 21:54

Form Status:

Site No: 1149

Site Name: (1149) Collaborative Neuroscience Network, LLC.

Subject No: 11491313

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

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Date	Location	User	Value	Reason
Nov-16-2020 12:26:12 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/03/2020

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: 1149

Site Name: (1149) Collaborative Neuroscience Network, LLC.

Subject No: 11491313

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1. Date:

Date	Location	User	Value	Reason
Nov-16-2020 12:26:12 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Nov/3/2020	Initial Entry

2.a

Date	Location	User	Value	Reason
Nov-16-2020 12:26:12 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Record Identifier:: 1 Oxygen Saturation: 97.0	Initial Entry

2.a Record Identifier:

Date	Location	User	Value	Reason
Nov-16-2020 12:26:12 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> 1	Initial Entry

2.a SPO2 Pulse Oximetry %

Date	Location	User	Value	Reason
Nov-16-2020 12:26:12 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> 97.0	Initial Entry

090177e196ae30c8\Final\Final On: 01-Apr-2021 04:16 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on
Nov/03/2020

Form: VITAL SIGNS - PULSE OX ROOM AIR - Audit Trail

Form Version: 10-Oct-2020 16:04

Form Status:

Site No: 1149

Site Name: (1149) Collaborative Neuroscience Network, LLC.

Subject No: 11491313

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

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

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Date	Location	User	Value	Reason
Nov-16-2020 12:26:48 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Deleted	New Information
Nov-16-2020 12:23:52 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

090177e196ae30c8\Final\Final On: 01-Apr-2021 04:16 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/03/2020

Form: VITAL SIGNS - PULSE OX ROOM AIR - eCRF Audit Trail History

Form Version: 10-Oct-2020 16:04

Form Status: Data Complete, Deleted, Frozen, Verified

Site No: 1149

Site Name: (1149) Collaborative Neuroscience Network, LLC.

Subject No: 11491313

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

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

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I. Date:

Date	Location	User	Value	Reason
Nov-16-2020 12:23:52 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Nov/3/2020	Initial Entry

2.a

Date	Location	User	Value	Reason
Nov-16-2020 12:23:52 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Record Identifier:: 1 Oxygen Saturation: 97.0	Initial Entry

2.a Record Identifier:

Date	Location	User	Value	Reason
Nov-16-2020 12:23:52 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> 1	Initial Entry

2.a SPO2 Pulse Oximetry %

Date	Location	User	Value	Reason
Nov-16-2020 12:23:52 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> 97.0	Initial Entry

090177e196ae30c8\Final\Final On: 01-Apr-2021 04:16 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on
Nov/03/2020

Form: IMAGING - Audit Trail

Form Version: 06-Jul-2020 21:53

Form Status:

Site No: 1149

Site Name: (1149) Collaborative Neuroscience Network, LLC.

Subject No: 11491313

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

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Date	Location	User	Value	Reason
Nov-16-2020 12:35:28 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on
Nov/03/2020

Form: IMAGING - Audit Trail

Form Version: 06-Jul-2020 21:53

Form Status:

Site No: 1149

Site Name: (1149) Collaborative Neuroscience Network, LLC.

Subject No: 11491313

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

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Date	Location	User	Value	Reason
Nov-16-2020 12:36:28 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/03/2020

Form: IMAGING - eCRF Audit Trail History

Form Version: 06-Jul-2020 21:53

Form Status: Data Complete, Frozen, Verified

Site No: 1149

Site Name: (1149) Collaborative Neuroscience Network, LLC.

Subject No: 11491313

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

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1. Date of Assessment:

Date	Location	User	Value	Reason
Nov-16-2020 15:46:23 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Nov-16-2020 12:35:39 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Original value is correct
Nov-16-2020 12:35:28 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	Date of Assessment is before Date of First Symptom Started on the Signs and Symptoms form in the same visit. Please review and update as appropriate.
Nov-16-2020 12:35:28 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Oct/30/2020	Initial Entry

2. Location of Assessment:

Date	Location	User	Value	Reason
Nov-16-2020 12:35:28 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: HEAD	Initial Entry

3. Type of Imaging Exam:

Date	Location	User	Value	Reason
Nov-16-2020 12:35:28 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: CT SCAN	Initial Entry

4. Assessment:

Date	Location	User	Value	Reason
Nov-16-2020 12:35:28 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NORMAL	Initial Entry

090177e196ae30c8\Final\Final On: 01-Apr-2021 04:16 (GMT)

Header Text: c4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit on
Nov/03/2020**Form:** IMAGING - eCRF Audit Trail History**Form Version:** 06-Jul-2020 21:53**Form Status:** Data Complete, Frozen, Verified**Site No:** 1149**Site Name:** (1149) Collaborative Neuroscience Network, LLC.**Subject No:** 11491313**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 11:56[Back to Form](#)**1. Date of Assessment:**

Date	Location	User	Value	Reason
Nov-16-2020 15:46:40 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Nov-16-2020 12:37:49 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Original value is correct
Nov-16-2020 12:36:28 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	Date of Assessment is before Date of First Symptom Started on the Signs and Symptoms form in the same visit. Please review and update as appropriate.
Nov-16-2020 12:36:28 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Oct/31/2020	Initial Entry

2. Location of Assessment:

Date	Location	User	Value	Reason
Nov-16-2020 12:36:28 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: OTHER <i>If other, specify:</i> Neck	Initial Entry

3. Type of Imaging Exam:

Date	Location	User	Value	Reason
Nov-16-2020 12:36:28 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: MRI	Initial Entry

4. Assessment:

Date	Location	User	Value	Reason
Nov-16-2020 12:36:28 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NORMAL	Initial Entry

Header Text: c4591001

Visit: POT_COVID_CONVA 1 - Unscheduled Visit on Dec/10/2020 **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: 1149

Site Name: (1149) Collaborative Neuroscience Network, LLC.

Subject No: 11491313

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

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1. Date of Visit

Date	Location	User	Value	Reason
Dec-10-2020 13:47:12 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Dec/10/2020	Initial Entry

3. COVID-19 Illness Visit:

Date	Location	User	Value	Reason
Dec-10-2020 13:47:12 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> COVID_A1	Initial Entry

Header Text: c4591001**Visit:** POT_COVID_CONVA 1 - Unscheduled Visit on Dec/10/2020 **Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF Audit Trail History**Form Version:** 22-Apr-2020 21:03**Form Status:** Data Complete, Frozen, Verified**Site No:** 1149**Site Name:** (1149) Collaborative Neuroscience Network, LLC.**Subject No:** 11491313**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 11:56[Back to Form](#)**1. Data Origin**

Date	Location	User	Value	Reason
Dec-10-2020 13:47:27 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Dec-10-2020 13:47:27 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SERUM	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Dec-14-2020 12:43:47 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Dec-11-2020 09:33:38 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Dec-10-2020 13:47:27 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Dec-10-2020 13:47:27 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Collection: Dec/10/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Dec-14-2020 12:43:47 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BRJ947	Initial Entry

5.a Sample ID

Header Text: c4591001

Visit: POT_COVID_CONVA 1 - Unscheduled Visit on Dec/10/2020 Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1149

Site Name: (1149) Collaborative Neuroscience Network, LLC.

Subject No: 11491313

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

Date	Location	User	Value	Reason
Dec-14-2020 12:43:47 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	<u>Data Entry:</u> BRJ947	Initial Entry

5.b

Date	Location	User	Value	Reason
Dec-14-2020 12:43:57 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	<u>Data Entry:</u> Sample ID: BRVJYJ	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Dec-14-2020 12:43:57 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	<u>Data Entry:</u> BRVJYJ	Initial Entry

5.c

Date	Location	User	Value	Reason
Dec-14-2020 12:44:04 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	<u>Data Entry:</u> Sample ID: BRVJYK	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Dec-14-2020 12:44:04 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	<u>Data Entry:</u> BRVJYK	Initial Entry

090177e196ae30c8\Final\Final On: 01-Apr-2021 04:16 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1149

Subject No: 11491313

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - Audit Trail

Form Status:

Site Name: (1149) Collaborative Neuroscience Network, LLC.

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:56

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Date	Location	User	Value	Reason
Nov-13-2020 13:41:45 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Undeleted	Transcription Error
Nov-12-2020 15:46:00 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Form Deleted	Symptom deleted from AE log. Symptom entered on COVID Illness Visit SOD CRF.
Nov-04-2020 14:58:44 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1149

Subject No: 11491313

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - Audit Trail

Form Status:

Site Name: (1149) Collaborative Neuroscience Network, LLC.

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:56

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Date	Location	User	Value	Reason
Dec-01-2020 16:17:28 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

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Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1149

Subject No: 11491313

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - Audit Trail

Form Status:

Site Name: (1149) Collaborative Neuroscience Network, LLC.

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:56

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Date	Location	User	Value	Reason
Jan-22-2021 10:56:13 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1149

Subject No: 11491313

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - Audit Trail

Form Status:

Site Name: (1149) Collaborative Neuroscience Network, LLC.

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:56

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Date	Location	User	Value	Reason
Jan-22-2021 10:57:09 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

090177e196ae30c8\Final\Final On: 01-Apr-2021 04:16 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

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Site No: 1149

Subject No: 11491313

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - Audit Trail

Form Status:

Site Name: (1149) Collaborative Neuroscience Network, LLC.

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:56

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Date	Location	User	Value	Reason
Jan-22-2021 10:59:12 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1149

Subject No: 11491313

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Not Complete

Site Name: (1149) Collaborative Neuroscience Network, LLC.

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:56

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1. Category:

Date	Location	User	Value	Reason
Nov-04-2020 14:58:44 (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-14-2020 09:14:51 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Nov-12-2020 15:46:00 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Symptom deleted from AE log. Symptom entered on COVID Illness Visit SOD CRF.
Nov-12-2020 15:12:41 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Query 1: Opened	Since the COVID Illness Visit supersedes the SAEs, should this be deleted from here?
Nov-04-2020 14:58:44 (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
Jan-25-2021 08:59:02 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Giselle Castillo (b) (4)	Query 5: Closed	Response satisfies query
Jan-22-2021 10:53:47 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 5: Answered	entered
Jan-05-2021 10:18:12 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Giselle Castillo (b) (4)	Query 5: Opened	Per report, the subject had head injury "after sustaining 3 falls". Per CRF completion guidelines 8.50.2.2., the fall needs to be reported as an additional AEs as well, even if an injury did not result. Thank you.
Jan-05-2021 10:17:43 (UTC-08:00) Pacific Time	ACV0PFEINFP6000	Giselle Castillo (b) (4)	Query 4: Closed	the query will be issued again.

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Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1149

Subject No: 11491313

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Not Complete

Site Name: (1149) Collaborative Neuroscience Network, LLC.

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:56

(US & Canada)				
Dec-13-2020 22:31:28 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 4: Reissued:Opened	Unfrozen. Thank you.
Dec-13-2020 17:39:17 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Giselle Castillo (b) (4)	Query 4: Reissued:Candidate	Unfrozen. Thank you.
Dec-11-2020 15:20:02 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 4: Answered	please unfreeze to add fall
Dec-09-2020 05:37:59 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Giselle Castillo (b) (4)	Query 4: Opened	Per report, the subject had head injury "after sustaining 3 falls". Per CRF completion guidelines 8.50.2.2., the fall needs to be reported as AEs as well, even if an injury did not result. Thank you.
Dec-04-2020 13:02:04 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Giselle Castillo (b) (4)	Query 1: Closed	The previous response was sent in error. Apologies. Thank you.
Dec-03-2020 16:28:44 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	please clarify
Dec-02-2020 23:33:19 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Query 1: Reissued:Opened	Response does not satisfy query
Dec-02-2020 15:59:44 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Giselle Castillo (b) (4)	Query 1: Reissued:Candidate	Response does not satisfy query
Dec-02-2020 03:52:05 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Closed	query issued for seriousness
Dec-01-2020 23:41:30 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Reissued:Opened	Response does not satisfy query
Dec-01-2020 23:39:58 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Closed	Response satisfies query
Dec-01-2020 12:15:30 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 3: Answered	New Information
Dec-01-2020 12:15:30 (UTC-08:00) Pacific Time	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Answered	New Information

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Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1149

Subject No: 11491313

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Not Complete

Site Name: (1149) Collaborative Neuroscience Network, LLC.

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:56

(US & Canada)				
Dec-01-2020 12:15:30 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Acute Trauma Head Injury	New Information
Dec-01-2020 04:31:45 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Opened	SAE RECON:AER#2020427994 Cervicogenic headache(onset date:30Oct2020)was reported as serious in Safety database but missing in AE CRF. Please confirm and update CRF. If safety update is required, submit a follow-up SAE Form.
Dec-01-2020 04:29:44 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Opened	SAE RECON: AER#2020427994,the term was updated to 'Acute Trauma Head injury' in Safety database while recorded as 'severe cough' in AE CRF. Please confirm correct term.If safety update is required, please submit a follow-up form.
Nov-30-2020 16:27:19 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Will re-fax follow-up
Nov-30-2020 12:12:21 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Giselle Castillo (b) (4)	Query 1: Opened	Kindly provide information on the discharge summary (work-up and treatment received). Please submit FU report with the information. Thank you.
Nov-04-2020 14:58:44 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: severe cough	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason
Dec-03-2020 21:27:44 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Dec-02-2020 17:25:07 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Transcription Error

090177e196ae30c8\Final\Final On: 01-Apr-2021 04:16 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1149

Subject No: 11491313

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Not Complete

Site Name: (1149) Collaborative Neuroscience Network, LLC.

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:56

Dec-02-2020 17:25:07 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Oct/30/2020 08:00	Transcription Error
Dec-02-2020 03:51:33 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	SAE RECON: AER#2020427994 onset date was recorded as 30Oct2020 in Safety database however, recorded as 01Nov2020 on AE CRF. Please confirm correct Onset Date. If safety update is required, please submit a follow-up SAE form.
Nov-04-2020 14:58:44 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Nov/1/2020 08:00	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Dec-03-2020 16:26:05 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO End Date Time: Nov/3/2020 UNK:UNK	New Information
Nov-04-2020 14:58:44 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
Nov-06-2020 17:46:16 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Quan Jason Gong (b) (4)	Query 1: Closed	Response satisfies query
Nov-06-2020 16:04:56 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Transcription Error
Nov-06-2020 16:04:56 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 3	Transcription Error
Nov-05-2020 18:51:08 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Quan Jason Gong (b) (4)	Query 1: Opened	GPDClin: Please clarify the grade for the severe cough.
Nov-04-2020 14:58:44 (UTC-08:00) Pacific Time	ACV0PFEINFP6000	(b) (6)	Data Entry: 1	Initial Entry

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Site No: 1149

Subject No: 11491313

Generated By: (b) (4)

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(US & Canada)

(b) (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).

Date	Location	User	Value	Reason
Nov-04-2020 23:21:40 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Nov-04-2020 14:58:44 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	For AE severe cough: Response to "Is the adverse event serious?" is 'Yes' but "Serious Adverse Event Number" is blank.
Nov-04-2020 14:58:44 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> YES Is this serious event associated with co ngenital anomaly or birth defect? NO Did this serious event result in death? NO Did this serious event require or prolo ng hospitalization? YES Did this serious event result in persiste nt or significant disability/incapacity? NO Is this serious event life threatening? NO Other medically important serious eve nt NO	Initial Entry

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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-04-2020 14:58:44 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Feb-07-2021 18:20:03 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Quan Jason Gong (b) (4)	Query 1: Closed	Response satisfies query
Feb-05-2021 09:10:47 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Transcription Error
Feb-05-2021 09:10:47 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: NOT RELATED If Not Related to study treatment(s), t his event is due to: OTHER <i>If Other, specify:</i> 3 subsequent falls	Transcription Error
Feb-01-2021 07:59:49 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Quan Jason Gong (b) (4)	Query 1: Opened	GPDClin: Per SAE report, the cause of the SAE was falls (x3). If yes, please make the corresponding change.
Nov-04-2020 14:58:44 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NOT RELATED If Not Related to study treatment(s), t his event is due to: OTHER <i>If Other, specify:</i> medical	Initial Entry

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Nov-04-2020 14:58:44 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NOT APPLICABLE	Initial Entry

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11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
Nov-04-2020 14:58:44 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Nov-04-2020 14:58:44 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

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

Date	Location	User	Value	Reason
Dec-04-2020 00:53:34 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (b) (4)	Query 2: Closed	Auto closed by Validation Check: VC_AE001_35
Dec-03-2020 21:26:37 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Dec-03-2020 16:26:49 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Answered	entered
Dec-03-2020 00:50:43 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (b) (4)	Query 2: Opened	DMW6303254;Response to "What was the outcome of this adverse event?" is 'Recovered/Resolved' or 'Recovered/Resolved with Sequelae' but End Date/Time is missing. Please review and update as appropriate.
Dec-02-2020 17:25:27 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Transcription Error

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Canada)				
Dec-02-2020 17:25:27 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry : RECO VERE D/RE SOLV ED	Transcription Error
Dec-02-2020 03:52:46 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Op ened	SAE RECON:AER#2020427994,outcome was reported as RECOVERED/RESOLVED to Safety DB however, recorded as RECOVERING/RESOLVING on AE CRF. Please confirm correct outcome. If safety update is required, please submit a follow-up form.
Nov-04-2020 14:58:44 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry : RECO VERI NG/R ESOL VING	Initial Entry

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

Date	Location	User	Value	Reason
Nov-04-2020 14:58:44 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

15. Serious Adverse Event Number: For Pfizer Use Only

Date	Location	User	Value	Reason
Nov-04-2020 23:21:40 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 2020427994	Initial Entry

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1. Category:

Date	Location	User	Value	Reason
Dec-01-2020 16:17:28 (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-01-2020 16:17:28 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 2	Initial Entry

3. Adverse Event:

(If possible specify diagnosis, not individual symptoms)

Date	Location	User	Value	Reason
Dec-01-2020 16:17:28 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Cervicogenic headache	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason
Dec-01-2020 16:17:28 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Oct/30/2020 UNK:UNK	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Dec-01-2020 16:17:28 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO End Date Time: Nov/3/2020 UNK:UNK	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
Feb-07-2021 18:21:00 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Quan Jason Gong (b) (4)	Query 1: Closed	Response satisfies query
Feb-05-2021 11:21:32 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Transcription Error

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Feb-05-2021 11:21:32 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: 3	Transcription Error
Feb-01-2021 11:56:26 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Quan Jason Gong (b) (4)	Query 1: Opened	GPDClin: Please clarify if the SAE was more severe than "mild" per protocol 10.3.3. If no, no change needed. If yes, please make the corresponding change.
Dec-01-2020 16:17:28 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 1	Initial Entry

7. Is the adverse event serious?

If Yes, NOTIFY PFIZER IMMEDIATELY.

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

Date	Location	User	Value	Reason
Dec-03-2020 21:28:23 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Closed	Response satisfies query
Dec-02-2020 17:27:11 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 3: Closed	Close Auto Query
Dec-02-2020 17:27:11 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Is this serious event associated with congenital anomaly or birth defect? NO Did this serious event result in death? NO Did this serious event require or prolong hospitalization? YES Did this serious event result in persistent or significant disability/incapacity?	New Information

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			acuity? NO Is this serious event life threatening ? NO Other medically important serious event NO	
Dec-02-2020 17:26:37 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 3: Opened	'Is the adverse event serious?' is marked as YES, but responses to all of the seriousness criteria are NO. At least one seriousness criterion is expected to be YES for serious events. Please review and update as appropriate.
Dec-02-2020 17:26:37 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Answered	New Information
Dec-02-2020 17:26:37 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Is this serious event associated with congenital anomaly or birth defect? NO Did this serious event result in death? NO Did this serious event require or prolong hospitalization? NO Did this serious event result in persistent or significant disability/incapacity? NO Is this serious event life threatening ?	New Information

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			NO Other medically important serious event NO	
Dec-01-2020 23:46:54 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Opened	SAE RECON:AER#2020427994 Cervicogenic headache(onset date:30Oct2020)was reported as serious in Safety database but nonserious in AE CRF. Please confirm and update CRF. If safety update is required, submit a follow-up SAE Form.
Dec-01-2020 23:42:25 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Deleted	Query can be addressed internally
Dec-01-2020 23:41:43 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	For AE Cervicogenic headache : Response to "Is the adverse event serious?" is 'No' but "Serious Adverse Event Number" is present.
Dec-01-2020 16:17:28 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	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-01-2020 16:17:28 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Dec-01-2020 16:17:58 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NOT RELATED If Not Related to study treatment(s), this event is due to: OTHER	Transcription Error

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			<i>If Other, specify:</i> Head Trauma	
Dec-01-2020 16:17:28 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NOT RELATED	Initial Entry

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Dec-01-2020 16:17:28 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NOT APPLICABLE	Initial Entry

11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
Dec-01-2020 16:17:28 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Dec-01-2020 16:17:28 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

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

Date	Location	User	Value	Reason
Dec-01-2020 16:17:28 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: RECOVERED/RESOLVED	Initial Entry

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

Date	Location	User	Value	Reason
Dec-01-2020 16:17:28 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

15. Serious Adverse Event Number: For Pfizer Use Only

Date	Location	User	Value	Reason
Dec-01-2020 23:41:43 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 2020427994	Initial Entry

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1. Category:

Date	Location	User	Value	Reason
Jan-22-2021 10:56:13 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: ADVERSE EVENT	Initial Entry

2. AE ID:

Date	Location	User	Value	Reason
Jan-22-2021 10:56:13 (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
Feb-08-2021 00:26:00 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Query 1: Closed	Response satisfies query
Feb-05-2021 09:07:39 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	The falls recorded are three separate incidences.
Feb-03-2021 22:57:20 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Balaji Prabu R (b) (4)	Query 1: Opened	AE fall is reported thrice (AE # 3,4 AND 5). Please review and delete the duplicate entries. Else clarify.
Jan-22-2021 10:56:13 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: fall	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason
Jan-22-2021 10:56:13 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Oct/UNK/2020 UNK:UNK	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Jan-22-2021 10:56:13 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO End Date Time:	Initial Entry

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6. Toxicity Grade:

Date	Location	User	Value	Reason
Jan-22-2021 10:56:13 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> 1	Initial Entry

7. Is the adverse event serious?

If Yes, NOTIFY PFIZER IMMEDIATELY.

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

Date	Location	User	Value	Reason
Jan-22-2021 10:56:13 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> 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
Jan-22-2021 10:56:13 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Jan-22-2021 10:56:13 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NOT RELATED If Not Related to study treatment(s), th is event is due to: OTHER If Other, specify: unknown	Initial Entry

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Jan-22-2021 10:56:13 (UTC-08:00) Pacific Time	ACV0PFEINFP6000	(b) (6)	<u>Data Entry:</u> NOT APPLICABLE	Initial Entry

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Subject Initials: ---

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

Date	Location	User	Value	Reason
Jan-22-2021 10:56:13 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Jan-22-2021 10:56:13 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

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

Date	Location	User	Value	Reason
Jan-22-2021 10:56:13 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<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
Jan-22-2021 10:56:13 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

090177e196ae30c8\Final\Final On: 01-Apr-2021 04:16 (GMT)

Header Text: c4591001**Visit:** Logs - Unscheduled**Form Version:** 22-Apr-2020 21:02**Site No:** 1149**Subject No:** 11491313**Generated By:** (b) (4)**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History**Form Status:** Data Complete, Frozen**Site Name:** (1149) Collaborative Neuroscience Network, LLC.**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 11:56[Back to Form](#)**1. Category:**

Date	Location	User	Value	Reason
Jan-22-2021 10:57:09 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: ADVERSE EVENT	Initial Entry

2. AE ID:

Date	Location	User	Value	Reason
Jan-22-2021 10:57:09 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 4	Initial Entry

3. Adverse Event:*(If possible specify diagnosis, not individual symptoms)*

Date	Location	User	Value	Reason
Jan-28-2021 18:31:20 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Quan Jason Gong (b) (4)	Query 1: Closed	Response satisfies query
Jan-27-2021 11:26:16 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Query 1: Answered	This is a separate incident from AE #4 and AE #6
Jan-26-2021 09:57:18 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Quan Jason Gong (b) (4)	Query 1: Opened	GPDClin: If this repeat of AE #4, please remove it.
Jan-22-2021 10:57:09 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: fall	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason
Jan-22-2021 10:57:09 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Oct/UNK/2020 UNK:UNK	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Jan-22-2021 10:57:09 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO End Date Time: Oct/UNK/2020 UNK:UNK	Initial Entry

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1149

Subject No: 11491313

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Frozen

Site Name: (1149) Collaborative Neuroscience Network, LLC.

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:56

6. Toxicity Grade:

Date	Location	User	Value	Reason
Jan-22-2021 10:57:09 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> 1	Initial Entry

7. Is the adverse event serious?

If Yes, NOTIFY PFIZER IMMEDIATELY.

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

Date	Location	User	Value	Reason
Jan-22-2021 10:57:09 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> 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
Jan-22-2021 10:57:09 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Jan-22-2021 10:57:09 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NOT RELATED If Not Related to study treatment(s), th is event is due to: OTHER If Other, specify: unk	Initial Entry

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Jan-22-2021 10:57:09 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NOT APPLICABLE	Initial Entry

11. Was a Concomitant Medication given?

090177e196ae30c8\Final\Final On: 01-Apr-2021 04:16 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1149

Subject No: 11491313

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Frozen

Site Name: (1149) Collaborative Neuroscience Network, LLC.

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:56

Date	Location	User	Value	Reason
Jan-22-2021 10:57:09 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Jan-22-2021 10:57:09 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

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

Date	Location	User	Value	Reason
Jan-22-2021 10:57:09 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<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
Jan-22-2021 10:57:09 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

090177e196ae30c8\Final\Final On: 01-Apr-2021 04:16 (GMT)

Header Text: c4591001**Visit:** Logs - Unscheduled**Form Version:** 22-Apr-2020 21:02**Site No:** 1149**Subject No:** 11491313**Generated By:** (b) (4)**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History**Form Status:** Data Complete, Frozen**Site Name:** (1149) Collaborative Neuroscience Network, LLC.**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 11:56[Back to Form](#)**1. Category:**

Date	Location	User	Value	Reason
Jan-22-2021 10:59:12 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: ADVERSE EVENT	Initial Entry

2. AE ID:

Date	Location	User	Value	Reason
Jan-22-2021 10:59:12 (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
Jan-28-2021 18:31:56 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Quan Jason Gong (b) (4)	Query 1: Closed	Response satisfies query
Jan-27-2021 11:27:22 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Query 1: Answered	This is a separate incident from AE #4 and AE #6
Jan-26-2021 09:58:05 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Quan Jason Gong (b) (4)	Query 1: Opened	GPDClin: If this is a repeat entry of AE #3, please remove it.
Jan-22-2021 10:59:12 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: fall	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason
Jan-22-2021 10:59:12 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Oct/UNK/2020 UNK:UNK	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Jan-22-2021 10:59:12 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO End Date Time: Oct/UNK/2020 UNK:UNK	Initial Entry

Header Text: c4591001

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Site No: 1149

Subject No: 11491313

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Frozen

Site Name: (1149) Collaborative Neuroscience Network, LLC.

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:56

6. Toxicity Grade:

Date	Location	User	Value	Reason
Jan-22-2021 10:59:12 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> 1	Initial Entry

7. Is the adverse event serious?

If Yes, NOTIFY PFIZER IMMEDIATELY.

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

Date	Location	User	Value	Reason
Jan-22-2021 10:59:12 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> 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
Jan-22-2021 10:59:12 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Jan-22-2021 10:59:12 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NOT RELATED If Not Related to study treatment(s), th is event is due to: OTHER If Other, specify: unk	Initial Entry

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Jan-22-2021 10:59:12 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NOT APPLICABLE	Initial Entry

11. Was a Concomitant Medication given?

090177e196ae30c8\Final\Final On: 01-Apr-2021 04:16 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1149

Subject No: 11491313

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Frozen

Site Name: (1149) Collaborative Neuroscience Network, LLC.

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:56

Date	Location	User	Value	Reason
Jan-22-2021 10:59:12 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Jan-22-2021 10:59:12 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

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

Date	Location	User	Value	Reason
Jan-22-2021 10:59:12 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<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
Jan-22-2021 10:59:12 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

090177e196ae30c8\Final\Final On: 01-Apr-2021 04:16 (GMT)

Header Text: c4591001

Visit: End of Treatment - Unscheduled

Form: DISPOSITION - TREATMENT - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:29

Form Status: Data Complete, Frozen, Verified

Site No: 1149

Site Name: (1149) Collaborative Neuroscience Network, LLC.

Subject No: 11491313

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

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1. Date of Completion/Discontinuation/Death :

Date	Location	User	Value	Reason
Jan-22-2021 09:12:22 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: Dec/10/2020	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Jan-22-2021 09:12:22 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: VACCINATION	Initial Entry

3. Status:

Date	Location	User	Value	Reason
Jan-22-2021 09:12:22 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: COMPLETED	Initial Entry

090177e196ae30c8\Final\Final On: 01-Apr-2021 04:16 (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: 1149

Site Name: (1149) Collaborative Neuroscience Network, LLC.

Subject No: 11491313

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

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I. Date of Visit

Date	Location	User	Value	Reason
Jan-25-2021 10:12:37 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: Jan/19/2021	Initial Entry

Header Text: c4591001

Visit: Potential ReVax Initial Contact - Unscheduled

Form: FURTHER VACCINATION CONFIRMATION - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:25

Form Status: Data Complete, Frozen, Verified

Site No: 1149

Site Name: (1149) Collaborative Neuroscience Network, LLC.

Subject No: 11491313

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

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

Date	Location	User	Value	Reason
Jan-25-2021 10:13:00 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Jan-25-2021 10:12:45 (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.
Jan-25-2021 10:12:45 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: Participant is willing to return for Vaccination 3 Participant is: eligible per local/national recommendations and confirmed to have received only placebo at Vaccination 1/2	Initial Entry

090177e196ae30c8\Final\Final On: 01-Apr-2021 04:16 (GMT)

Header Text: c4591001

Visit: Disposition - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1149

Subject No: 11491313

Generated By: (b) (4)

Form: TREATMENT UNBLINDED - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1149) Collaborative Neuroscience Network, LLC.

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:56

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1. Date Treatment Unblinded :

Date	Location	User	Value	Reason
Jan-25-2021 10:13:00 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: Jan/20/2021	Initial Entry

2. Primary Reason for Unblinding:

Date	Location	User	Value	Reason
Jan-25-2021 10:13:00 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: ASSESS ELIGIBILITY FOR ADDITIO NAL VACCINATION	Initial Entry

Header Text: c4591001

Visit: V101_VAX3

Form Version: 22-Apr-2020 21:02

Site No: 1149

Subject No: 11491313

Generated By: (b) (4)

Form: DATE OF VISIT - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1149) Collaborative Neuroscience Network, LLC.

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:56

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I. Date of Visit

Date	Location	User	Value	Reason
Jan-25-2021 10:13:19 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: Jan/22/2021	Initial Entry

Header Text: c4591001

Visit: V101_VAX3

Form Version: 10-Dec-2020 02:31

Site No: 1149

Subject No: 11491313

Generated By: (b) (4)

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

Form Status: Data Complete, Frozen, Verified

Site Name: (1149) Collaborative Neuroscience Network, LLC.

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:56

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I. Consent Was:

Date	Location	User	Value	Reason
Jan-25-2021 10:13:33 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: OBTAINED Date Written Consent Obtained Jan/22/2021	Initial Entry

Header Text: c4591001

Visit: V101_VAX3

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

Form Version: 10-Dec-2020 02:31

Form Status: Data Complete, Frozen, Verified

Site No: 1149

Site Name: (1149) Collaborative Neuroscience Network, LLC.

Subject No: 11491313

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

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1. Date of Completion/Discontinuation/Death :

Date	Location	User	Value	Reason
Jan-25-2021 10:13:54 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: Jan/22/2021	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Jan-25-2021 10:13:54 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: REPEAT SCREENING 1	Initial Entry

3. Status:

Date	Location	User	Value	Reason
Jan-25-2021 10:13:54 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: COMPLETED	Initial Entry

090177e196ae30c8\Final\Final On: 01-Apr-2021 04:16 (GMT)

Header Text: c4591001

Visit: V101_VAX3

Form Version: 14-Jan-2021 02:21

Site No: 1149

Subject No: 11491313

Generated By: (b) (4)

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

Form Status: Data Complete, Frozen, Verified

Site Name: (1149) Collaborative Neuroscience Network, LLC.

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:56

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1. Lab Panel:

Date	Location	User	Value	Reason
Jan-25-2021 10:14:04 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: Not Applicable	Initial Entry

2. Lab Sub-Panel:

Date	Location	User	Value	Reason
Jan-25-2021 10:14:04 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: Not Applicable	Initial Entry

3. Collection Date:

Date	Location	User	Value	Reason
Jan-25-2021 10:14:04 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: Not Applicable	Initial Entry

4. Laboratory Name and Address (Derived)

Date	Location	User	Value	Reason
Jan-25-2021 10:14:04 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: Not Applicable	Initial Entry

5. Specimen Type:

Date	Location	User	Value	Reason
Jan-25-2021 10:14:04 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: Not Applicable	Initial Entry

6.a

Date	Location	User	Value	Reason
Jan-25-2021 10:14:04 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: Sponsor-Defined Identifier: Not Applicable Test:: Not Applicable Result:: Not Applicable	Initial Entry

090177e196ae30c8\Final\Final On: 01-Apr-2021 04:16 (GMT)

Header Text: c4591001

Visit: V101_VAX3

Form Version: 14-Jan-2021 02:21

Site No: 1149

Subject No: 11491313

Generated By: (b) (4)

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

Form Status: Data Complete, Frozen, Verified

Site Name: (1149) Collaborative Neuroscience Network, LLC.

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:56

			Not Done::	Not Applicable
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6.a Sponsor ID:

Date	Location	User	Value	Reason
Jan-25-2021 10:14:04 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: Not Applicable	Initial Entry

6.a Test:

Date	Location	User	Value	Reason
Jan-25-2021 10:14:04 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: Not Applicable	Initial Entry

6.a Result:

Date	Location	User	Value	Reason
Jan-25-2021 10:14:04 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: Not Applicable	Initial Entry

6.a Not Done:

Date	Location	User	Value	Reason
Jan-25-2021 10:14:04 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: Not Applicable	Initial Entry

090177e196ae30c8\Final\Final On: 01-Apr-2021 04:16 (GMT)

Header Text: c4591001

Visit: V101_VAX3

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1149

Site Name: (1149) Collaborative Neuroscience Network, LLC.

Subject No: 11491313

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

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1. Data Origin

Date	Location	User	Value	Reason
Jan-25-2021 10:14:21 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Jan-25-2021 10:14:21 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SERUM	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Jan-26-2021 11:40:31 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Jan-25-2021 19:16:27 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Jan-25-2021 10:14:21 (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.
Jan-25-2021 10:14:21 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: YES Date of Collection: Jan/22/2021	Initial Entry

5.a

Date	Location	User	Value	Reason
Jan-26-2021 11:40:31 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Data Entry: Sample ID: BR7WGZ	Initial Entry

5.a Sample ID

090177e196ae30c8\Final\Final On: 01-Apr-2021 04:16 (GMT)

Header Text: c4591001

Visit: V101_VAX3

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1149

Site Name: (1149) Collaborative Neuroscience Network, LLC.

Subject No: 11491313

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

Date	Location	User	Value	Reason
Jan-26-2021 11:40:31 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	<u>Data Entry:</u> BR7WGZ	Initial Entry

5.b

Date	Location	User	Value	Reason
Jan-26-2021 11:40:52 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	<u>Data Entry:</u> Sample ID: BSGTFS	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Jan-26-2021 11:40:52 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	<u>Data Entry:</u> BSGTFS	Initial Entry

5.c

Date	Location	User	Value	Reason
Jan-26-2021 11:41:00 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	<u>Data Entry:</u> Sample ID: BSGTFT	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Jan-26-2021 11:41:00 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	<u>Data Entry:</u> BSGTFT	Initial Entry

090177e196ae30c8\Final\Final On: 01-Apr-2021 04:16 (GMT)

Header Text: c4591001**Visit:** V101_VAX3**Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB - eCRF Audit Trail History**Form Version:** 22-Apr-2020 21:03**Form Status:** Data Complete, Frozen, Verified**Site No:** 1149**Site Name:** (1149) Collaborative Neuroscience Network, LLC.**Subject No:** 11491313**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 11:56[Back to Form](#)**1. Data Origin**

Date	Location	User	Value	Reason
Jan-25-2021 10:14:31 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Jan-25-2021 10:14:31 (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
Jan-26-2021 11:41:45 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Jan-25-2021 19:16:27 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Jan-25-2021 10:14:31 (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.
Jan-25-2021 10:14:31 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: YES Date of Collection: Jan/22/2021	Initial Entry

5.a

Date	Location	User	Value	Reason
Jan-26-2021 11:41:45 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Data Entry: Sample ID: BR7WGY	Initial Entry

5.a Sample ID

Header Text: c4591001

Visit: V101_VAX3

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1149

Site Name: (1149) Collaborative Neuroscience Network, LLC.

Subject No: 11491313

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

Date	Location	User	Value	Reason
Jan-26-2021 11:41:45 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	<u>Data Entry:</u> BR7WGY	Initial Entry

090177e196ae30c8\Final\Final On: 01-Apr-2021 04:16 (GMT)

Header Text: c4591001

Visit: V101_VAX3

Form Version: 10-Dec-2020 02:26

Site No: 1149

Subject No: 11491313

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1149) Collaborative Neuroscience Network, LLC.

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:56

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1. Was there a temporary delay of vaccination?

Date	Location	User	Value	Reason
Jan-25-2021 10:14:58 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: NO	Initial Entry

2. Treatment Name

Date	Location	User	Value	Reason
Jan-25-2021 10:14:58 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: BNT162b2	Initial Entry

3. Formulation:

Date	Location	User	Value	Reason
Jan-25-2021 10:14:58 (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
Jan-25-2021 10:14:58 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: Jan/22/2021 13:55	Initial Entry

5. Anatomical Location:

Date	Location	User	Value	Reason
Jan-25-2021 10:14:58 (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
Jan-25-2021 10:14:58 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: LEFT	Initial Entry

7. Route:

Date	Location	User	Value	Reason
Jan-25-2021 10:14:58	ACV0PFEINFP6000	auto calc	Data Entry:	Initial Entry

090177e196ae30c8\Final\Final On: 01-Apr-2021 04:16 (GMT)

Header Text: c4591001

Visit: V101_VAX3

Form Version: 10-Dec-2020 02:26

Site No: 1149

Subject No: 11491313

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1149) Collaborative Neuroscience Network, LLC.

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:56

(UTC-08:00) Pacific Time (US & Canada)		(autocalc)	INTRAMUSCULAR	
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8. Actual Dose:

Date	Location	User	Value	Reason
Jan-25-2021 10:14:58 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 30.0	Initial Entry

9. Unit:

Date	Location	User	Value	Reason
Jan-25-2021 10:14:58 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: ug	Initial Entry

10. Timeframe Subject Was Observed

Date	Location	User	Value	Reason
Jan-25-2021 10:14:58 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 30 MINUTES	Initial Entry

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

Date	Location	User	Value	Reason
Jan-25-2021 10:14:58 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: YES	Initial Entry

090177e196ae30c8\Final\Final On: 01-Apr-2021 04:16 (GMT)

Header Text: c4591001

Visit: V102_VAX4

Form Version: 22-Apr-2020 21:02

Site No: 1149

Subject No: 11491313

Generated By: (b) (4)

Form: DATE OF VISIT - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1149) Collaborative Neuroscience Network, LLC.

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:56

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I. Date of Visit

Date	Location	User	Value	Reason
Feb-12-2021 17:11:19 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: Feb/12/2021	Initial Entry

Header Text: c4591001

Visit: V102_VAX4

Form Version: 14-Jan-2021 02:21

Site No: 1149

Subject No: 11491313

Generated By: (b) (4)

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

Form Status: Data Complete, Frozen, Verified

Site Name: (1149) Collaborative Neuroscience Network, LLC.

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:56

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1. Lab Panel:

Date	Location	User	Value	Reason
Feb-12-2021 17:11:29 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: Not Applicable	Initial Entry

2. Lab Sub-Panel:

Date	Location	User	Value	Reason
Feb-12-2021 17:11:29 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: Not Applicable	Initial Entry

3. Collection Date:

Date	Location	User	Value	Reason
Feb-12-2021 17:11:29 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: Not Applicable	Initial Entry

4. Laboratory Name and Address (Derived)

Date	Location	User	Value	Reason
Feb-12-2021 17:11:29 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: Not Applicable	Initial Entry

5. Specimen Type:

Date	Location	User	Value	Reason
Feb-12-2021 17:11:29 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

6.a

Date	Location	User	Value	Reason
Feb-12-2021 17:11:29 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: Sponsor-Defined Identifier: Not Applicable Test:: Not Applicable Result:: Not Applicable	Initial Entry

090177e196ae30c8\Final\Final On: 01-Apr-2021 04:16 (GMT)

Header Text: c4591001

Visit: V102_VAX4

Form Version: 14-Jan-2021 02:21

Site No: 1149

Subject No: 11491313

Generated By: (b) (4)

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

Form Status: Data Complete, Frozen, Verified

Site Name: (1149) Collaborative Neuroscience Network, LLC.

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:56

			Not Done::	Not Applicable
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6.a Sponsor ID:

Date	Location	User	Value	Reason
Feb-12-2021 17:11:29 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: Not Applicable	Initial Entry

6.a Test:

Date	Location	User	Value	Reason
Feb-12-2021 17:11:29 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: Not Applicable	Initial Entry

6.a Result:

Date	Location	User	Value	Reason
Feb-12-2021 17:11:29 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: Not Applicable	Initial Entry

6.a Not Done:

Date	Location	User	Value	Reason
Feb-12-2021 17:11:29 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: Not Applicable	Initial Entry

090177e196ae30c8\Final\Final On: 01-Apr-2021 04:16 (GMT)

Header Text: c4591001**Visit:** V102_VAX4**Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB - eCRF Audit Trail History**Form Version:** 22-Apr-2020 21:03**Form Status:** Data Complete, Frozen, Verified**Site No:** 1149**Site Name:** (1149) Collaborative Neuroscience Network, LLC.**Subject No:** 11491313**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 11:56[Back to Form](#)**1. Data Origin**

Date	Location	User	Value	Reason
Feb-12-2021 17:11:46 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Feb-12-2021 17:11:46 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: NASAL_SWAB	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Feb-17-2021 08:56:49 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Feb-15-2021 03:34:58 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Feb-12-2021 17:11:46 (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-12-2021 17:11:46 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: YES Date of Collection: Feb/12/2021	Initial Entry

5.a

Date	Location	User	Value	Reason
Feb-17-2021 08:56:49 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Data Entry: Sample ID: BR7WF6	Initial Entry

5.a Sample ID

Header Text: c4591001

Visit: V102_VAX4

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1149

Site Name: (1149) Collaborative Neuroscience Network, LLC.

Subject No: 11491313

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

Date	Location	User	Value	Reason
Feb-17-2021 08:56:49 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	<u>Data Entry:</u> BR7WF6	Initial Entry

Header Text: c4591001

Visit: V102_VAX4

Form Version: 10-Dec-2020 02:26

Site No: 1149

Subject No: 11491313

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1149) Collaborative Neuroscience Network, LLC.

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:56

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1. Was there a temporary delay of vaccination?

Date	Location	User	Value	Reason
Feb-12-2021 17:12:07 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: NO	Initial Entry

2. Treatment Name

Date	Location	User	Value	Reason
Feb-12-2021 17:12:07 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: BNT162b2	Initial Entry

3. Formulation:

Date	Location	User	Value	Reason
Feb-12-2021 17:12:07 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INJECTION	Initial Entry

4. Dose Date Time:

Date	Location	User	Value	Reason
Feb-12-2021 17:12:07 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: Feb/12/2021 11:47	Initial Entry

5. Anatomical Location:

Date	Location	User	Value	Reason
Feb-12-2021 17:12:07 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: DELTOID MUSCLE	Initial Entry

6. Body Side:

Date	Location	User	Value	Reason
Feb-12-2021 17:12:07 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: LEFT	Initial Entry

7. Route:

Date	Location	User	Value	Reason
Feb-12-2021 17:12:07	ACV0PFEINFP6000	auto calc	Data Entry:	Initial Entry

090177e196ae30c8\Final\Final On: 01-Apr-2021 04:16 (GMT)

Header Text: c4591001

Visit: V102_VAX4

Form Version: 10-Dec-2020 02:26

Site No: 1149

Subject No: 11491313

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1149) Collaborative Neuroscience Network, LLC.

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:56

(UTC-08:00) Pacific Time (US & Canada)		(autocalc)	INTRAMUSCULAR	
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8. Actual Dose:

Date	Location	User	Value	Reason
Feb-12-2021 17:12:07 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 30.0	Initial Entry

9. Unit:

Date	Location	User	Value	Reason
Feb-12-2021 17:12:07 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: ug	Initial Entry

10. Timeframe Subject Was Observed

Date	Location	User	Value	Reason
Feb-12-2021 17:12:07 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 30 MINUTES	Initial Entry

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

Date	Location	User	Value	Reason
Feb-12-2021 17:12:07 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: YES	Initial Entry

090177e196ae30c8\Final\Final On: 01-Apr-2021 04:16 (GMT)

Header Text: c4591001

Visit: V103_MONTH1

Form Version: 22-Apr-2020 21:02

Site No: 1149

Subject No: 11491313

Generated By: (b) (4)

Form: DATE OF VISIT - eCRF Audit Trail History

Form Status: Data Complete, Verified

Site Name: (1149) Collaborative Neuroscience Network, LLC.

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:56

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I. Date of Visit

Date	Location	User	Value	Reason
Mar-12-2021 16:40:41 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Mar/12/2021	Initial Entry

Header Text: c4591001

Visit: V103_MONTH1

Form Version: 22-Apr-2020 21:04

Site No: 1149

Subject No: 11491313

Generated By: (b) (4)

Form: CONTACT OUTCOME - eCRF Audit Trail History

Form Status: Data Complete, Verified

Site Name: (1149) Collaborative Neuroscience Network, LLC.

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:56

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1. Contact Type:

Date	Location	User	Value	Reason
Mar-12-2021 16:40:51 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: TELEPHONE VISIT	Initial Entry

2. Was contact made?

Date	Location	User	Value	Reason
Mar-12-2021 16:40:51 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Contact: Mar/12/2021	Initial Entry

Header Text: c4591001

Visit: Subject Status - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1149

Subject No: 11491313

Generated By: (b) (4)

Form: SUBJECT STATUS - eCRF Audit Trail History

Form Status: Data Complete, Verified

Site Name: (1149) Collaborative Neuroscience Network, LLC.

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:56

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1. Subject Status

Date	Location	User	Value	Reason
Jan-22-2021 09:12:22 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: FOLLOW-UP	Initial Entry
Nov-25-2020 23:07:37 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Nov-25-2020 10:15:11 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	V3 has been changed to "not done"
Nov-24-2020 05:18:16 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued:Opened	Please consider to update V3 as Not done. Or confirm date to which visit has been rescheduled.
Nov-23-2020 16:36:34 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	has not occurred. Subject missed appointment
Nov-23-2020 08:06:52 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	DM: Please confirm if visit 3 occurred and if so, please enter data.
Sep-25-2020 07:56:37 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: ENROLLED/RANDOMIZED	Initial Entry
Sep-25-2020 07:50:11 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SCREENED	Initial Entry

2. Subject Status Date

Date	Location	User	Value	Reason
Jan-22-2021 09:12:22 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Dec/10/2020	Initial Entry
Sep-25-2020 07:56:37 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sep/24/2020	Initial Entry
Sep-25-2020 07:50:11 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sep/24/2020	Initial Entry

090177e196ae30c8\Final\Final On: 01-Apr-2021 04:16 (GMT)

Header Text: c4591001

Visit: Investigator Signature - Unscheduled

Form Version: 22-Apr-2020 21:04

Site No: 1149

Subject No: 11491313

Generated By: (b) (4)

Form: CASEBOOK SIGNATURE FORM - eCRF Audit Trail History

Form Status: Data Complete, Verified

Site Name: (1149) Collaborative Neuroscience Network, LLC.

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:56

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I. Casebook Signature

Date	Location	User	Value	Reason
Nov-10-2020 11:01:38 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Click Here to Enable	Initial Entry