

Header Text: c4591001
Visit: COHORT_SELECTION **Form:** COHORT SELECTION
Form Version: 15-Sep-2020 21:55 **Form Status:** Data Complete, Locked, Frozen, Verified
Site No: 1149 **Site Name:** (1149) Collaborative Neuroscience Network, LLC.
Subject No: 11491239 **Subject Initials:** ---
Generated By: (b) (4) **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	24 JUL 2020
2.	Select appropriate response - What cohort does the subject belong to?	STAGE 3 COHORTS

Header Text: c4591001

Visit: COHORT_SELECTION

Form: MAIN INFORMED CONSENT

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1149

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

Subject No: 11491239

Subject Initials: ---

Generated By: (b) (4)

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

[eCRF Audit Trail History](#)

Informed Consent

1.	Consent Was:	OBTAINED Date Written Consent Obtained Sep/15/2020
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Header Text: c4591001

Visit: COHORT_SELECTION

Form: DEMOGRAPHY

Form Version: 15-Sep-2020 21:54

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1149

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

Subject No: 11491239

Subject Initials: ---

Generated By: (b) (4)

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

[eCRF Audit Trail History](#)

Demography

1.	Subject ID	[11491239]
2.	Birth Date:	(b) (6)/1953
3.	Sex:	MALE
4.	Ethnicity:	NOT HISPANIC OR LATINO(A) OR OF SPANISH ORIGIN
5.	Race: (Check X all that apply):	WHITE
6.	Racial Designation:	

090177e196ae30c7\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: 11491239

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/15/2020
2.	Erroneous Visit	

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 15-Sep-2020 21:53

Site No: 1149

Subject No: 11491239

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 _____
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Exclusion Criteria Met

2.	Description of Exclusion Criterion Met	Not Applicable _____
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Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 15-Sep-2020 21:52

Site No: 1149

Subject No: 11491239

Generated By: (b) (4)

Form: DISPOSITION - SCREENING

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 - Screening

1.	Date of Completion/Discontinuation /Death	Sep/15/2020
2.	Phase of Disposition:	SCREENING
3.	Status:	COMPLETED
4.	Specify Status:	[]

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: GENERAL MEDICAL 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: 11491239

Subject Initials: ---

Generated By: (b) (4)

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:	[High blood pressure]
	Start Date:	UNK/UNK/2018
	Ongoing:	YES
1.b	Line/MH Number:	[2]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Lumbar fusion surgery (L1)]
	Start Date:	UNK/UNK/2018
	Ongoing:	NO End Date: UNK/UNK/2018
1.c	Line/MH Number:	[]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[]
	Start Date:	//
	Ongoing:	

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Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1149

Subject No: 11491239

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY

Form Status: Data Complete, Frozen, Verified

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

Subject Initials: ---

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

1.d	Line/MH Number:	[]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[]
	Start Date:	//
	Ongoing:	

1.e	Line/MH Number:	[]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[]
	Start Date:	//
	Ongoing:	

1.f	Line/MH Number:	[]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[]
	Start Date:	//
	Ongoing:	

1.g	Line/MH Number:	[]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[]
	Start Date:	//
	Ongoing:	

090177e196ae30c7\Final\Final On: 01-Apr-2021 04:16 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: VITAL SIGNS - BASELINE

Form Version: 15-Sep-2020 21:56

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1149

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

Subject No: 11491239

Subject Initials: ---

Generated By: (b) (4)

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

[eCRF Audit Trail History](#)

Vital Signs

1.	Date:	Sep/15/2020
2.	Weight:	[96.7]
3.	Unit:	kg
4.	Height:	[182.0]
5.	Unit:	cm
6.	Body Mass Index:	[29.2]

Vital Signs Details

7.a	Record Identifier:	1
	Temperature:	[36.5]
	Unit:	C
	Temperature Location:	FOREHEAD

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Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1149

Subject No: 11491239

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/15/2020
2.	Randomization Number:	[259243]
3.	Randomization Group:	[]

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1149

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

Subject No: 11491239

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: Sep/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	[BPV0ZG]
5.b	Sample ID	[BPV0ZH]
5.c	Sample ID	[BRVJSX]
5.d	Sample ID	[BRVJSY]

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Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1149

Subject No: 11491239

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/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	[BPV0ZJ]
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090177e196ae30c7\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: 11491239

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/15/2020 12:25
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

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Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 06-Jul-2020 21:53

Site No: 1149

Subject No: 11491239

Generated By: (b) (4)

Form: REACTOGENICITY DIARY

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](#)

Reactogenicity Diary

1.	Select appropriate response - Reactogenicity diary collection	NO - REACTOGENICITY E-DIARY NOT COLLECTED FOR THIS SUBJECT
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090177e196ae30c7\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: 11491239

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

[Form Comments](#)

[eCRF Audit Trail History](#)

Date of Visit

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

Header Text: c4591001

Visit: V2_VAX2_L

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: 11491239

Subject Initials: ---

Generated By: (b) (4)

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

Vital Signs

1.	Date:	//
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Vital Signs Details

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

Header Text: c4591001

Visit: V2_VAX2_L

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1149

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

Subject No: 11491239

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	[]
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090177e196ae30c7\Final\Final On: 01-Apr-2021 04:16 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 10-Dec-2020 02:26

Site No: 1149

Subject No: 11491239

Generated By: (b) (4)

Form: VACCINATION

Form Status: Not Started

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

Subject Initials: ---

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?	

090177e196ae30c7\Final\Final On: 01-Apr-2021 04:16 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form: DATE OF VISIT

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen, Verified

Site No: 1149

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

Subject No: 11491239

Subject Initials: ---

Generated By: (b) (4)

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

[Form Comments](#)

[eCRF Audit Trail History](#)

Date of Visit

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

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1149

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

Subject No: 11491239

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	[]
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090177e196ae30c7\Final\Final On: 01-Apr-2021 04:16 (GMT)

Header Text: c4591001

Visit: V4_MONTH6_L

Form Version: 22-Apr-2020 21:02

Site No: 1149

Subject No: 11491239

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: V4_MONTH6_L

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1149

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

Subject No: 11491239

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	[]
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090177e196ae30c7\Final\Final On: 01-Apr-2021 04:16 (GMT)

Header Text: c4591001

Visit: V5_MONTH12_L

Form Version: 22-Apr-2020 21:02

Site No: 1149

Subject No: 11491239

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: V5_MONTH12_L

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1149

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

Subject No: 11491239

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	[]
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090177e196ae30c7\Final\Final On: 01-Apr-2021 04:16 (GMT)

Header Text: c4591001

Visit: V6_MONTH24_L

Form Version: 22-Apr-2020 21:02

Site No: 1149

Subject No: 11491239

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: V6_MONTH24_L

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1149

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

Subject No: 11491239

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	[]
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090177e196ae30c7\Final\Final On: 01-Apr-2021 04:16 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL - New
Unscheduled Visit

Form: DATE OF VISIT - ILLNESS ONSET

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1149

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

Subject No: 11491239

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 Illness Visit

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

Visit: POT_COVID_ILL - New
Unscheduled Visit

Form: SIGNS AND SYMPTOMS OF POTENTIAL COVID-19

Form Version: 20-Feb-2021 02:17

Form Status: Not Started

Site No: 1149

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

Subject No: 11491239

Subject Initials: ---

Generated By: (b) (4)

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

Signs and Symptoms

1.	Date of Assessment:	//
2.	Date of First Symptom Started:	//
3.	Symptoms Ongoing?	

Symptoms

4.	Symptoms:	
	Was symptom present?	

Symptoms - Other

5.	Symptoms - Other Text:	[]
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090177e196ae30c7\Final\Final On: 01-Apr-2021 04:16 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL - New
Unscheduled Visit

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB
SELF

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1149

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

Subject No: 11491239

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	[]
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090177e196ae30c7\Final\Final On: 01-Apr-2021 04:16 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL - New
Unscheduled Visit

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1149

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

Subject No: 11491239

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	[]
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090177e196ae30c7\Final\Final On: 01-Apr-2021 04:16 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL - New
Unscheduled Visit

Form: HEALTH CARE UTILIZATION

Form Version: 20-Feb-2021 02:19

Form Status: Not Started

Site No: 1149

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

Subject No: 11491239

Subject Initials: ---

Generated By: (b) (4)

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

Health Care Utilization

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

Health Care Utilization Other

2.	Other Type of Practitioner Specify:	[]
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Health Care Utilization

3.	Has the subject been hospitalized due to potential COVID-19 illness?	
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090177e196ae30c7\Final\Final On: 01-Apr-2021 04:16 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL - New
Unscheduled Visit

Form: ILLNESS DETAILS

Form Version: 06-Jul-2020 21:52

Form Status: Not Started

Site No: 1149

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

Subject No: 11491239

Subject Initials: ---

Generated By: (b) (4)

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

Illness Details

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

Header Text: c4591001

Visit: POT_COVID_CONVA - New
Unscheduled Visit

Form: DATE OF VISIT - ILLNESS CONVALESCENT

Form Version: 22-Apr-2020 21:04

Form Status: Not Started

Site No: 1149

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

Subject No: 11491239

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 Illness Visit

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

Visit: POT_COVID_CONVA - New
Unscheduled Visit

Form: ELECTRONIC SAMPLE TRACKING -
IMMUNOGENICITY

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1149

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

Subject No: 11491239

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	[]
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090177e196ae30c7\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: 11491239

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:	
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Header Text: c4591001

Visit: POT_COVID_REPEAT_SWAB -
New Unscheduled Visit

Form: ELECTRONIC SAMPLE TRACKING - REPEAT
SWAB

Form Version: 10-Oct-2020 15:57

Form Status: Not Started

Site No: 1149

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

Subject No: 11491239

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	[]
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090177e196ae30c7\Final\Final On: 01-Apr-2021 04:16 (GMT)

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: 11491239

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 - New Unscheduled Visit **Form:** UNPLANNED VISIT

Form Version: 22-Apr-2020 21:04

Form Status: Not Started

Site No: 1149

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

Subject No: 11491239

Subject Initials: ---

Generated By: (b) (4)

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

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: 11491239

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 Ongoing	Form Instance
1.	ADVERSE EVENT	1	Opioid dependence withdrawal	Jan/21/2021 U NK:UNK	NO End Date Time: Jan/26/2021 UNK: UNK	Repeating Pages
2.	ADVERSE EVENT	2	swollen lymph node in right axilla	Oct/5/2020 08:00	NO End Date Time: Oct/12/2020 08:00	Repeating Pages
3.	ADVERSE EVENT	3	Right arm pain with motion	Sep/22/2020 18:00	NO End Date Time: Sep/25/2020 20:00	Repeating Pages

090177e196ae30c7\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: 11491239

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Queries, Frozen

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

Subject Initials: ---

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

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

Adverse Event Report

1.	Category:	ADVERSE EVENT
2.	AE ID:	[1]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[Opioid dependence withdrawal]
4.	Start Date Time:	Jan/21/2021 UNK:UNK
5.	Is the adverse event still ongoing?	NO End Date Time: Jan/26/2021 UNK:UNK
6.	Toxicity Grade:	4
7.	Is the adverse event serious? If Yes, NOTIFY PFIZER IMMEDIATELY. Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).	YES Is this serious event associated with congenital anomaly or birth defect? NO Did this serious event result in death? NO Did this serious event require or prolong hospitalization? YES Did this serious event result in persistent or significant disability/incapacity? NO Is this serious event life threatening? YES Other medically important serious event NO

090177e196ae30c7\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: 11491239

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Queries, Frozen

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

Subject Initials: ---

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

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: [medical]
10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE
11.	Was a Concomitant Medication given?	NO
12.	Was a Non-Drug Treatment given?	NO
13.	What was the outcome of this adverse event?:	RECOVERED/RESOLVED
14.	Did the adverse event cause the subject to be discontinued from the study?	NO
15.	Serious Adverse Event Number: For Pfizer Use Only	[2021037695]

090177e196ae30c7\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: 11491239

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

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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[Form Audit Trail](#)

Adverse Event Report

1.	Category:	ADVERSE EVENT
2.	AE ID:	[2]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[swollen lymph node in right axilla]
4.	Start Date Time:	Oct/5/2020 08:00
5.	Is the adverse event still ongoing?	NO End Date Time: Oct/12/2020 08:00
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

090177e196ae30c7\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: 11491239

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Frozen, Verified

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

Subject Initials: ---

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

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

090177e196ae30c7\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: 11491239

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

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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Adverse Event Report

1.	Category:	ADVERSE EVENT
2.	AE ID:	[3]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[Right arm pain with motion]
4.	Start Date Time:	Sep/22/2020 18:00
5.	Is the adverse event still ongoing?	NO End Date Time: Sep/25/2020 20:00
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

090177e196ae30c7\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: 11491239

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Frozen, Verified

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

Subject Initials: ---

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

8.	Is this adverse event the result of a study Medication Error? If Yes, record the type of medication error on the Medication Error Log.	NO
9.	Is this event related to study treatment:	RELATED
10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE
11.	Was a Concomitant Medication given?	NO
12.	Was a Non-Drug Treatment given?	NO
13.	What was the outcome of this adverse event?:	RECOVERED/RESOLVED
14.	Did the adverse event cause the subject to be discontinued from the study?	NO
15.	Serious Adverse Event Number: For Pfizer Use Only	[]

090177e196ae30c7\Final\Final On: 01-Apr-2021 04:16 (GMT)

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: 11491239

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

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 17-Jul-2020 21:54

Site No: 1149

Subject No: 11491239

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	[]

090177e196ae30c7\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: 11491239

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

Header Text: c4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - NON STUDY VACCINATIONS

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1149

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

Subject No: 11491239

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.	Date:	//

090177e196ae30c7\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: 11491239

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. DELETED		CORTICOSTEROIDS			25	Repeating Pages

090177e196ae30c7\Final\Final On: 01-Apr-2021 04:16 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:03

Form: CONCOMITANT MEDICATIONS - PROHIBITED

Form Status: Incomplete, Data Complete, Deleted, Frozen, Verified

Site No: 1149

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

Subject No: 11491239

Subject Initials: ---

Generated By: (b) (4)

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

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

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

Concomitant Medications

1.	What is the medication identifier?	[]
2.	Category:	CORTICOSTEROIDS
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:	[25]
6.	Dose Unit:	mg
7.	Dose Frequency:	QD
8.	Route:	ORAL
9.	Start Date:	Oct/1/2020
10.	Ongoing?	NO End Date: Oct/6/2020

090177e196ae30c7\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: 11491239

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

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1149

Subject No: 11491239

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?	

090177e196ae30c7\Final\Final On: 01-Apr-2021 04:16 (GMT)

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: 11491239

Subject Initials: ---

Generated By: (b) (4)

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

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

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1149

Subject No: 11491239

Generated By: (b) (4)

Form: TRANSFUSIONS

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

Header Text: c4591001

Visit: End of Treatment - 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: 11491239

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: 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: 11491239

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: 11491239

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: VACCINATION

Form Version: 10-Dec-2020 02:26

Form Status: Not Started

Site No: 1149

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

Subject No: 11491239

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?	

090177e196ae30c7\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: 11491239

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:	[]

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: 11491239

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:	[]

Header Text: c4591001

Visit: V201_SURVEIL_CONSENT -
Unscheduled

Form: DATE OF VISIT

Form Version: 22-Apr-2020 21:02

Form Status: Not Started

Site No: 1149

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

Subject No: 11491239

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: V201_SURVEIL_CONSENT -
Unscheduled

Form: INFORMED CONSENT - ASYMPTOMATIC
SURVEILLANCE

Form Version: 14-Jan-2021 02:29

Form Status: Not Started

Site No: 1149

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

Subject No: 11491239

Subject Initials: ---

Generated By: (b) (4)

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

Informed Consent - Asymptomatic Surveillance

1.	Consent Was:	
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Header Text: c4591001

Visit: V201_SURVEIL_CONSENT -
Unscheduled

Form: ELECTRONIC SAMPLE TRACKING -
IMMUNOGENICITY

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1149

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

Subject No: 11491239

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	[]
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090177e196ae30c7\Final\Final On: 01-Apr-2021 04:16 (GMT)

Header Text: c4591001

Visit: V201_SURVEIL_CONSENT -
Unscheduled

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1149

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

Subject No: 11491239

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	[]
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090177e196ae30c7\Final\Final On: 01-Apr-2021 04:16 (GMT)

Header Text: c4591001

Visit: Follow-Up - Unscheduled

Form: DISPOSITION - FOLLOW-UP

Form Version: 15-Sep-2020 21:53

Form Status: Not Started

Site No: 1149

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

Subject No: 11491239

Subject Initials: ---

Generated By: (b) (4)

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: Not Started

Site No: 1149

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

Subject No: 11491239

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: Potential ReVax Initial Contact -
Unscheduled

Form: FURTHER VACCINATION CONFIRMATION

Form Version: 10-Dec-2020 02:25

Form Status: Not Started

Site No: 1149

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

Subject No: 11491239

Subject Initials: ---

Generated By: (b) (4)

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

Further Vaccination Confirmation

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

Header Text: c4591001

Visit: Disposition - Unscheduled

Form: TREATMENT UNBLINDED

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1149

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

Subject No: 11491239

Subject Initials: ---

Generated By: (b) (4)

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

Treatment Unblinded

1.	Date Treatment Unblinded :	//
2.	Primary Reason for Unblinding:	

Header Text: c4591001

Visit: Disposition - Unscheduled

Form: WITHDRAWAL OF CONSENT

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1149

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

Subject No: 11491239

Subject Initials: ---

Generated By: (b) (4)

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

Withdrawal Of Consent

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

Visit: Disposition - Unscheduled

Form: DEATH DETAILS CODED

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1149

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

Subject No: 11491239

Subject Initials: ---

Generated By: (b) (4)

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:	[]

Header Text: c4591001

Visit: Subject Status - Unscheduled

Form: SUBJECT STATUS

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Verified

Site No: 1149

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

Subject No: 11491239

Subject Initials: ---

Generated By: (b) (4)

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

[eCRF Audit Trail History](#)

Subject Status

1.	Subject Status	ENROLLED/RANDOMIZED
2.	Subject Status Date	Sep/15/2020

Header Text: c4591001

Visit: Investigator Signature -
Unscheduled

Form: CASEBOOK SIGNATURE FORM

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Verified

Site No: 1149

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

Subject No: 11491239

Subject Initials: ---

Generated By: (b) (4)

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: 11491239

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: 11491239

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

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Item	Date	User	Comment
Form	Sep-16-2020 14:28:43 (UTC-08:00) Pacific Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 1149

Subject No: 11491239

Generated By: (b) (4)

Form: DATE OF VISIT - 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
Form	Nov-15-2020 12:48:26 (UTC-08:00) Pacific Time (US & Canada)	(b) (4), (b) (6)	Patient unable to return to site until January 2021 but still willing to continue with study. Per monitor, pt can perform Visit 4 when he returns.
Form	Nov-15-2020 12:44:20 (UTC-08:00) Pacific Time (US & Canada)	(b) (4), (b) (6)	Patient unable to return to site until January 2021 but still willing to continue with study. Per monitor, pt can continue with Visit 4 when he returns. <hr/> Not Done

090177e196ae30c7\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: 11491239

Generated By: (b) (4)

Form: DATE OF VISIT - Comments

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](#)

Item	Date	User	Comment
1	Nov-15-2020 12:44:20 (UTC-08:00) Pacific Time (US & Canada)	(b) (4), (b) (6)	Patient unable to return to site until January 2021 but still willing to continue with study. Per monitor, pt can continue with Visit 4 when he returns. <hr/> Not Done

090177e196ae30c7\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: 11491239

Generated By: (b) (4)

Form: DATE OF VISIT - 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
2	Nov-15-2020 12:44:20 (UTC-08:00) Pacific Time (US & Canada)	(b) (4), (b) (6)	Patient unable to return to site until January 2021 but still willing to continue with study. Per monitor, pt can continue with Visit 4 when he returns. <hr/> Not Done

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 1149

Subject No: 11491239

Generated By: (b) (4)

Form: DATE OF VISIT - 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
Form	Nov-15-2020 12:48:38 (UTC-08:00) Pacific Time (US & Canada)	(b) (4), (b) (6)	Patient unable to return to site until January 2021 but still willing to continue with study. Per monitor, pt can perform Visit 4 when he returns. <hr/> Not Done

090177e196ae30c7\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: 11491239

Generated By: (b) (4)

Form: DATE OF VISIT - Comments

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](#)

Item	Date	User	Comment
1	Nov-15-2020 12:48:38 (UTC-08:00) Pacific Time (US & Canada)	(b) (4), (b) (6)	Patient unable to return to site until January 2021 but still willing to continue with study. Per monitor, pt can perform Visit 4 when he returns. <hr/> Not Done

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 1149

Subject No: 11491239

Generated By: (b) (4)

Form: DATE OF VISIT - Comments

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](#)

Item	Date	User	Comment
2	Nov-15-2020 12:48:38 (UTC-08:00) Pacific Time (US & Canada)	(b) (4), (b) (6)	Patient unable to return to site until January 2021 but still willing to continue with study. Per monitor, pt can perform Visit 4 when he returns. <hr/> Not Done

090177e196ae30c7\Final\Final On: 01-Apr-2021 04:16 (GMT)

Header Text: c4591001

Visit: Investigator Signature -
Unscheduled

Form: CASEBOOK SIGNATURE FORM - Signature History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Verified

Site No: 1149

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

Subject No: 11491239

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-30-2020 11:38:40 (UTC-08:00) Pacific Time (US & Canada)		Edit - All signatures invalidated

Affidavit:
N/A

Steven Reynolds	Approved	Nov-17-2020 17:17:46 (UTC-08:00) Pacific Time (US & Canada)	BOOK	Signed
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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.

(b) (6)	N/A	Nov-17-2020 14:30:07 (UTC-08:00) Pacific Time (US & Canada)		Edit - All signatures invalidated
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Affidavit:
N/A

Steven Reynolds	Approved	Nov-17-2020 12:36:55 (UTC-08:00) Pacific Time (US & Canada)	BOOK	Signed
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090177e196ae30c7\Final\Final On: 01-Apr-2021 04:16 (GMT)

Header Text: c4591001

Visit: Investigator Signature -
Unscheduled

Form: CASEBOOK SIGNATURE FORM - Signature History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Verified

Site No: 1149

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

Subject No: 11491239

Subject Initials: ---

Generated By: (b) (4)

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

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.

(b) (6)	N/A	Nov-16-2020 16:07:27 (UTC-08:00) Pacific Time (US & Canada)		Edit - All signatures invalidated
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Affidavit:

N/A

Steven Reynolds	Approved	Nov-16-2020 12:54:12 (UTC-08:00) Pacific Time (US & Canada)	BOOK	Signed
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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.

(b) (6)	N/A	Nov-15-2020 12:44:20 (UTC-08:00) Pacific Time (US & Canada)		Edit - All signatures invalidated
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Affidavit:

N/A

Steven Reynolds	Approved	Nov-09-2020 17:52:59 (UTC-08:00) Pacific Time (US & Canada)	BOOK	Signed
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090177e196ae30c7\Final\Final On: 01-Apr-2021 04:16 (GMT)

Header Text: c4591001

Visit: Investigator Signature -
Unscheduled

Form: CASEBOOK SIGNATURE FORM - Signature History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Verified

Site No: 1149

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

Subject No: 11491239

Subject Initials: ---

Generated By: (b) (4)

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

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.

Header Text: c4591001

Visit: COHORT_SELECTION

Form: COHORT SELECTION - eCRF Audit Trail History

Form Version: 15-Sep-2020 21:55

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1149

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

Subject No: 11491239

Subject Initials: ---

Generated By: (b) (4)

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

[Back to Form](#)

1. Select appropriate response - Protocol version

Date	Location	User	Value	Reason
Sep-16-2020 14:27:16 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 24 JUL 2020	Initial Entry

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

Date	Location	User	Value	Reason
Sep-16-2020 14:27:16 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: STAGE 3 COHORTS	Initial Entry

090177e196ae30c7\Final\Final On: 01-Apr-2021 04:16 (GMT)

Header Text: c4591001

Visit: COHORT_SELECTION

Form: MAIN INFORMED CONSENT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1149

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

Subject No: 11491239

Subject Initials: ---

Generated By: (b) (4)

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

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I. Consent Was:

Date	Location	User	Value	Reason
Sep-16-2020 14:27:27 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: OBTAINED Date Written Consent Obtained Sep/15/2020	Initial Entry

Header Text: c4591001

Visit: COHORT_SELECTION

Form: DEMOGRAPHY - eCRF Audit Trail History

Form Version: 15-Sep-2020 21:54

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1149

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

Subject No: 11491239

Subject Initials: ---

Generated By: (b) (4)

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

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1. Subject ID

Date	Location	User	Value	Reason
Sep-16-2020 14:24:21 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 11491239	Item copied from previous form

2. Birth Date:

Date	Location	User	Value	Reason
Sep-16-2020 14:24:17 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: (b) (6)/1953	Enrollment Entry

3. Sex:

Date	Location	User	Value	Reason
Sep-16-2020 14:27:41 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: MALE	Initial Entry

4. Ethnicity:

Date	Location	User	Value	Reason
Sep-16-2020 14:27:41 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NOT HISPANIC OR LATINO(A) OR OF SPANISH ORIGIN	Initial Entry

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

090177e196ae30c7\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: 11491239

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-16-2020 14:27:41 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: WHITE	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: DATE OF VISIT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1149

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

Subject No: 11491239

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
Nov-07-2020 11:22:21 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Nov-07-2020 09:38:07 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Subject will continue in study. Coordinator scheduling follow up visit.
Nov-05-2020 10:04:21 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Balaji Prabu R (b) (4)	Query 1: Opened	If subject is lost to follow up, please complete disposition-treatment and disposition follow up CRFs to indicate that. Thank you.
Sep-16-2020 14:28:01 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sep/15/2020	Initial Entry

090177e196ae30c7\Final\Final On: 01-Apr-2021 04:16 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: DISPOSITION - SCREENING - eCRF Audit Trail History

Form Version: 15-Sep-2020 21:52

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1149

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

Subject No: 11491239

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
Sep-16-2020 14:29:37 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sep/15/2020	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Sep-16-2020 14:29:37 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SCREENING	Initial Entry

3. Status:

Date	Location	User	Value	Reason
Sep-16-2020 14:29:37 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: COMPLETED	Initial Entry

090177e196ae30c7\Final\Final On: 01-Apr-2021 04:16 (GMT)

Header Text: c4591001**Visit:** V1_DAY1_VAX1_L**Form:** GENERAL MEDICAL HISTORY - eCRF Audit Trail History**Form Version:** 22-Apr-2020 21:03**Form Status:** Data Complete, Frozen, Verified**Site No:** 1149**Site Name:** (1149) Collaborative Neuroscience Network, LLC.**Subject No:** 11491239**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 11:56[Back to Form](#)*I.a*

Date	Location	User	Value	Reason
Sep-16-2020 14:31:43 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Nu 1 mber: Medical Histo High blood ry Term: pressure Start Date: UNK/UNK/ 2018 Ongoing: YES	Initial Entry

I.a Line/MH Number:

Date	Location	User	Value	Reason
Sep-16-2020 14:31:43 (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-16-2020 14:31:43 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: High blood pressure	Initial Entry

I.a Start Date:

Date	Location	User	Value	Reason
Sep-16-2020 14:31:43	ACV0PFEINFP6000	(b) (6)	Data Entry: UNK/UNK/2018	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1149

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

Subject No: 11491239

Subject Initials: ---

Generated By: (b) (4)

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

(UTC-08:00) Pacific Time (US & Canada)		(b) (4)		
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1.a Ongoing:

Date	Location	User	Value	Reason
Sep-16-2020 14:31:43 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

1.b

Date	Location	User	Value	Reason
Sep-16-2020 14:38:42 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Line/M H Number: 2 Medical History Term: Lumbar fusion surgery (L1) Start Date: UNK/UNK/2018 Ongoing: NO : End Date: UNK/UNK/2018	Transcription Error
Sep-16-2020 14:33:59 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 2 Medical History Term: Lumbar surgery (L1)	Initial Entry

090177e196ae30c7\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: 11491239

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - 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

			Start Date UNK/UN : K/2018 Ongoing: NO End Date : UNK/U NK/2018	
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Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1149

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

Subject No: 11491239

Subject Initials: ---

Generated By: (b) (4)

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

1.b Line/MH Number:

Date	Location	User	Value	Reason
Sep-16-2020 14:33:59 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 2	Initial Entry

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

Date	Location	User	Value	Reason
Sep-16-2020 14:38:42 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Lumbar fusion surgery (L1)	Transcription Error
Sep-16-2020 14:33:59 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Lumbar surgery (L1)	Initial Entry

1.b Start Date:

Date	Location	User	Value	Reason
Sep-16-2020 14:33:59 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNK/UNK/2018	Initial Entry

1.b Ongoing:

Date	Location	User	Value	Reason
Sep-16-2020 14:33:59 (UTC-08:00) Pacific	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO End Date:	Initial Entry

090177e196ae30c7\Final\Final On: 01-Apr-2021 04:16 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1149

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

Subject No: 11491239

Subject Initials: ---

Generated By: (b) (4)

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

Time (US & Canada)			UNK/UNK/2018	
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090177e196ae30c7\Final\Final On: 01-Apr-2021 04:16 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: VITAL SIGNS - BASELINE - eCRF Audit Trail History

Form Version: 15-Sep-2020 21:56

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1149

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

Subject No: 11491239

Subject Initials: ---

Generated By: (b) (4)

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

[Back to Form](#)

1. Date:

Date	Location	User	Value	Reason
Sep-16-2020 14:40:11 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sep/15/2020	Initial Entry

2. Weight:

Date	Location	User	Value	Reason
Sep-16-2020 14:40:11 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 96.7	Initial Entry

3. Unit:

Date	Location	User	Value	Reason
Sep-16-2020 14:40:11 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: kg	Initial Entry

4. Height:

Date	Location	User	Value	Reason
Sep-16-2020 14:40:11 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 182.0	Initial Entry

090177e196ae30c7\Final\Final On: 01-Apr-2021 04:16 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 15-Sep-2020 21:56

Site No: 1149

Subject No: 11491239

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

5. Unit:

Date	Location	User	Value	Reason
Sep-16-2020 14:40:11 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: cm	Initial Entry

6. Body Mass Index:

Date	Location	User	Value	Reason
Sep-16-2020 14:40:11 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 29.2	Initial Entry

7.a

Date	Location	User	Value	Reason
Sep-16-2020 14:40:11 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Record Identifier: Temperature: 36.5 Temperature C Unit: Temperature FOREH Location: EAD	Initial Entry

7.a Record Identifier:

Date	Location	User	Value	Reason
Sep-16-2020 14:40:11 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 1	Initial Entry

090177e196ae30c7\Final\Final On: 01-Apr-2021 04:16 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: VITAL SIGNS - BASELINE - eCRF Audit Trail History

Form Version: 15-Sep-2020 21:56

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1149

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

Subject No: 11491239

Subject Initials: ---

Generated By: (b) (4)

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

7.a Temperature:

Date	Location	User	Value	Reason
Sep-16-2020 14:40:11 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 36.5	Initial Entry

7.a Unit:

Date	Location	User	Value	Reason
Sep-16-2020 14:40:11 (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-16-2020 14:40:11 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: FOREHEAD	Initial Entry

090177e196ae30c7\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: 11491239

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-16-2020 14:40:41 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sep/15/2020	Initial Entry

2. Randomization Number:

Date	Location	User	Value	Reason
Sep-16-2020 14:40:41 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 259243	Initial Entry

090177e196ae30c7\Final\Final On: 01-Apr-2021 04:16 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1149

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

Subject No: 11491239

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
Sep-16-2020 14:41:29 (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-16-2020 14:41:29 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SERUM	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Sep-17-2020 07:50:44 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Sep-17-2020 01:31:02 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Query 1: Opened	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Sep-16-2020 14:41:29 (UTC-08:00)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no

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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: 11491239

Subject Initials: ---

Generated By: (b) (4)

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

Pacific Time (US & Canada)				barcodes are entered. Please review and correct as appropriate.
Sep-16-2020 14:41:29 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Collection: Sep/15/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Sep-17-2020 07:50:44 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Data Entry: Sample ID: BPV0ZG	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Sep-17-2020 07:50:44 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Data Entry: BPV0ZG	Initial Entry

5.b

Date	Location	User	Value	Reason
Sep-17-2020 07:50:52 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Data Entry: Sample ID: BPV0ZH	Initial Entry

090177e196ae30c7\Final\Final On: 01-Apr-2021 04:16 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1149

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

Subject No: 11491239

Subject Initials: ---

Generated By: (b) (4)

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

5.b Sample ID

Date	Location	User	Value	Reason
Sep-17-2020 07:50:52 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	<u>Data Entry:</u> BPVOZH	Initial Entry

5.c

Date	Location	User	Value	Reason
Sep-17-2020 07:51:07 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	<u>Data Entry:</u> Sample ID: BRVJSX	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Sep-17-2020 07:51:07 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	<u>Data Entry:</u> BRVJSX	Initial Entry

5.d

Date	Location	User	Value	Reason
Sep-17-2020 07:51:16 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	<u>Data Entry:</u> Sample ID: BRVJSY	Initial Entry

090177e196ae30c7\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: 11491239

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

5.d Sample ID

Date	Location	User	Value	Reason
Sep-17-2020 07:51:16 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	<u>Data Entry:</u> BRVJSY	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1149

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

Subject No: 11491239

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
Sep-16-2020 14:41:40 (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-16-2020 14:41:40 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: NASAL_SWAB	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Sep-17-2020 07:47:08 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Sep-17-2020 01:31:02 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Query 1: Opened	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Sep-16-2020 14:41:40 (UTC-08:00)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no

090177e196ae30c7\Final\Final On: 01-Apr-2021 04:16 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1149

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

Subject No: 11491239

Subject Initials: ---

Generated By: (b) (4)

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

Pacific Time (US & Canada)				barcodes are entered. Please review and correct as appropriate.
Sep-16-2020 14:41:40 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Collection: Sep/15/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Sep-17-2020 07:47:08 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Data Entry: Sample ID: BPV0ZJ	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Sep-17-2020 07:47:08 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Data Entry: BPV0ZJ	Initial Entry

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Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: VACCINATION - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1149

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

Subject No: 11491239

Subject Initials: ---

Generated By: (b) (4)

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-16-2020 14:42:13 (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-16-2020 14:42:13 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: BLINDED THERAPY	Initial Entry

3. Formulation:

Date	Location	User	Value	Reason
Sep-16-2020 14:42:13 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INJECTION	Initial Entry

4. Dose Date Time:

Date	Location	User	Value	Reason
Sep-16-2020 14:42:13 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sep/15/2020 12:25	Initial Entry

5. Anatomical Location:

Date	Location	User	Value	Reason
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090177e196ae30c7\Final\Final On: 01-Apr-2021 04:16 (GMT)

Header Text: c4591001
Visit: V1_DAY1_VAX1_L **Form:** VACCINATION - eCRF Audit Trail History
Form Version: 22-Apr-2020 21:04 **Form Status:** Data Complete, Locked, Frozen, Verified
Site No: 1149 **Site Name:** (1149) Collaborative Neuroscience Network, LLC.
Subject No: 11491239 **Subject Initials:** ---
Generated By: (b) (4) **Generated Time (GMT):** 29-Mar-2021 11:56

Sep-16-2020 14:42:13 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: DELTOID MUSCLE	Initial Entry
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6. Body Side:

Date	Location	User	Value	Reason
Sep-16-2020 14:42:13 (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-16-2020 14:42:13 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INTRAMUSCULAR	Initial Entry

10. Timeframe Subject Was Observed

Date	Location	User	Value	Reason
Sep-16-2020 14:42:13 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: THE PROTOCOL SPECIFI ED OBSERVATION PERIO D	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-16-2020 14:42:13 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

090177e196ae30c7\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: 11491239

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-16-2020 14:42:28 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO - REACTOGENICI TY E-DIARY NOT CO LLECTED FOR THIS S UBJECT	Initial Entry

Header Text: c4591001

Visit: V2_VAX2_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: 11491239

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
Jan-07-2021 22:21:25 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Deleted	Query placed on subject status.
Nov-20-2020 03:32:46 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Candidate	To be followed up till jan2021
Nov-15-2020 12:44:20 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

2. Erroneous Visit

Date	Location	User	Value	Reason
Nov-15-2020 12:44:20 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Data Entry: Not Done	Initial Entry

090177e196ae30c7\Final\Final On: 01-Apr-2021 04:16 (GMT)

Header Text: c4591001
Visit: V3_MONTH1_POSTVAX2_L **Form:** DATE OF VISIT - eCRF Audit Trail History
Form Version: 22-Apr-2020 21:02 **Form Status:** Data Complete, Frozen, Verified
Site No: 1149 **Site Name:** (1149) Collaborative Neuroscience Network, LLC.
Subject No: 11491239 **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
Nov-15-2020 12:48:38 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

2. Erroneous Visit

Date	Location	User	Value	Reason
Nov-15-2020 12:48:38 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

090177e196ae30c7\Final\Final On: 01-Apr-2021 04:16 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - Audit Trail

Form Version: 22-Apr-2020 21:02

Form Status:

Site No: 1149

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

Subject No: 11491239

Subject Initials: ---

Generated By: (b) (4)

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Date	Location	User	Value	Reason
Nov-16-2020 16:08:53 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Form Created	

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1149

Subject No: 11491239

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-16-2020 16:10:25 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

Header Text: c4591001

Visit: Logs - Unscheduled

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Site No: 1149

Subject No: 11491239

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
Feb-18-2021 09:16:42 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

090177e196ae30c7\Final\Final On: 01-Apr-2021 04:16 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Queries, Frozen

Site No: 1149

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

Subject No: 11491239

Subject Initials: ---

Generated By: (b) (4)

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1. Category:

Date	Location	User	Value	Reason
Nov-16-2020 16:08:53 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: ADVERSE EVENT	Initial Entry

2. AE ID:

Date	Location	User	Value	Reason
Nov-16-2020 16:08:53 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 1	Initial Entry

3. Adverse Event:

(If possible specify diagnosis, not individual symptoms)

Date	Location	User	Value	Reason
Mar-10-2021 01:41:30 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Opened	SAE RECON:AER#202103769,in Safety database Drug dependence was recorded as separate entry. Please consider to record Opioid dependence as separate entry for reconciliation with SDB data.
Mar-04-2021 17:50:33 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Opioid dependence withdrawal	New Information

090177e196ae30c7\Final\Final On: 01-Apr-2021 04:16 (GMT)

Header Text: c4591001**Visit:** Logs - Unscheduled**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History**Form Version:** 22-Apr-2020 21:02**Form Status:** Data Complete, Queries, Frozen**Site No:** 1149**Site Name:** (1149) Collaborative Neuroscience Network, LLC.**Subject No:** 11491239**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 11:56

Feb-19-2021 08:28:56 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Giselle Castillo (b) (4)	Query 1: Closed	Response satisfies query
Feb-16-2021 12:23:06 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Seriousness has been updated.
Feb-15-2021 07:35:04 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Giselle Castillo (b) (4)	Query 1: Reissued:Opened	This event has been report has serious (resulted in hospitalization). Please review and update seriousness accordingly. Thanks
Feb-12-2021 16:39:11 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Transcription Error
Feb-12-2021 16:39:11 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Heart Attack	Transcription Error
Feb-02-2021 16:34:36 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Giselle Castillo (b) (4)	Query 1: Reissued:Opened	thanks for confirming. However, AER#2021037695 has already been submitted to safety. Pls clarify.
Jan-27-2021 21:23:41 (UTC-08:00) Pacific Time (US	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	The information is pending

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Queries, Frozen

Site No: 1149

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

Subject No: 11491239

Subject Initials: ---

Generated By: (b) (4)

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

& Canada)				
Jan-27-2021 06:54:25 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Giselle Castillo (b) (4)	Query 1: Opened	An SAE of "Heart attack" has been reported to safety. Please review and update AE log accordingly. Thanks.
Nov-16-2020 16:08:53 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Right arm pain with motion	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason
Mar-09-2021 01:47:33 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	SDB updated
Mar-07-2021 23:29:43 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued: Candidate	Pending SDB update
Mar-04-2021 17:45:59 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Transcription Error
Mar-04-2021 17:45:59 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Jan/21/2021 UNK: UNK	Transcription Error

090177e196ae30c7\Final\Final On: 01-Apr-2021 04:16 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

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Form Status: Data Complete, Queries, Frozen

Site No: 1149

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

Subject No: 11491239

Subject Initials: ---

Generated By: (b) (4)

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

Feb-23-2021 22:48:59 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	SAE RECON: AER#2021037695,onset date was blank in Safety database however, recorded as 22Sep2020 on AE CRF. Please confirm correct Onset Date. If safety update is required, please submit a follow-up SAE form.
Nov-16-2020 16:08:53 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sep/22/2020 18:00	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Mar-04-2021 17:46:38 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Mar-04-2021 17:46:38 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO End Date Time: Jan/26/2021 UNK:UNK	Transcription Error
Mar-04-2021 17:45:59 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	For Heart Attack End Date & Time 25/Sep/2020 20:00 is before the Start Date &

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Header Text: c4591001

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Form Status: Data Complete, Queries, Frozen

Site No: 1149

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

Subject No: 11491239

Subject Initials: ---

Generated By: (b) (4)

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				Time 21/Jan/2021 UNK:UNK.
Nov-16-2020 16:08:53 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO End Date Time: Sep/25/2020 20:00	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
Feb-17-2021 19:30:37 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Quan Jason Gong (b) (4)	Query 1: Closed	Response satisfies query
Feb-16-2021 12:22:48 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Transcription Error
Feb-16-2021 12:22:48 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 4	Transcription Error
Feb-15-2021 12:05:24 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Quan Jason Gong (b) (4)	Query 1: Opened	GPDClin: As this was a SAE, please re-evaluate the grade.
Nov-16-2020 16:08:53 (UTC-08:00) Pacific	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 1	Initial Entry

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Header Text: c4591001

Visit: Logs - Unscheduled

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Site No: 1149

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Subject No: 11491239

Subject Initials: ---

Generated By: (b) (4)

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

Time (US & Canada)				
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7. Is the adverse event serious?

If Yes, NOTIFY PFIZER IMMEDIATELY.

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

Date	Location	User	Value	Reason
Feb-16-2021 22:48:16 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Feb-16-2021 12:22:34 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	For AE Heart Attack: Response to "Is the adverse event serious?" is 'Yes' but "Serious Adverse Event Number" is blank.
Feb-16-2021 12:22:34 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [Redacted]	Data Entry: YES Is this serious event as associated with congenital anomaly or birth defect? NO Did this serious event result in death?	Transcription Error

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Header Text: c4591001

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			<p>NO</p> <p>Did this serious event require or prolong hospitalization?</p> <p>YES</p> <p>Did this serious event result in persistent or significant disability/in capacity?</p> <p>NO</p> <p>Is this serious event life threatening?</p> <p>YES</p> <p>Other medically important serious event</p> <p>NO</p>	
Nov-16-2020 16:08:53 (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
Nov-16-2020 16:08:53 (UTC-08:00) Pacific	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

Header Text: c4591001
Visit: Logs - Unscheduled **Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History
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Site No: 1149 **Site Name:** (1149) Collaborative Neuroscience Network, LLC.
Subject No: 11491239 **Subject Initials:** ---
Generated By: (b) (4) **Generated Time (GMT):** 29-Mar-2021 11:56

Time (US & Canada)				
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9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Feb-17-2021 19:25:26 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Quan Jason Gong (b) (4)	Query 1: Closed	Response satisfies query
Feb-16-2021 12:21:13 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Transcription Error
Feb-16-2021 12:21:13 (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 <i>If Other, specify:</i> medical	Transcription Error
Feb-15-2021 12:04:31 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Quan Jason Gong (b) (4)	Query 1: Opened	GPDClin: Per SAE report 2021037695, the SAE was not study drug related. If that is correct, please revise the answer and

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				provide the suspected cause for this SAE.
Nov-16-2020 16:08:53 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: RELATED	Initial Entry

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Nov-16-2020 16:08:53 (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
Nov-16-2020 16:08:53 (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-16-2020 16:08:53 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

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Generated By: (b) (4)

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

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

Date	Location	User	Value	Reason
Mar-09-2021 01:47:45 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	SDB updated
Mar-07-2021 23:29:43 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued: Candidate	Pending SDB update
Mar-04-2021 17:51:06 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	recovered and had been reconciled
Feb-23-2021 22:49:49 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	SAE RECON:AER#2021037695,outcome was reported as UNKNOWN to Safety DB however, recorded as RECOVERED/RESOLVED on AE CRF. Please confirm correct outcome. If safety update is required, please submit a follow-up form.
Nov-16-2020 16:08:53 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: RECOVERED/RESOLVED	Initial Entry

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Subject Initials: ---

Generated By: (b) (4)

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

Date	Location	User	Value	Reason
Nov-16-2020 16:08:53 (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
Feb-16-2021 22:48:16 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 2021037695	Initial Entry

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Subject No: 11491239

Subject Initials: ---

Generated By: (b) (4)

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

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1. Category:

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

2. AE ID:

Date	Location	User	Value	Reason
Nov-16-2020 16:10:25 (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
Nov-17-2020 16:28:09 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	PFETMS Oracle (b) (4)	Query 1: Closed	Discrepancy has been closed.
Nov-17-2020 14:30:07 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Transcription Error
Nov-17-2020	ACV0PFEINFP6000	(b) (6)	Data	Transcription

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Header Text: c4591001**Visit:** Logs - Unscheduled**Form Version:** 22-Apr-2020 21:02**Site No:** 1149**Subject No:** 11491239**Generated By:** (b) (4)**Form:** ADVERSE EVENT REPORT - 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

14:30:07 (UTC-08:00) Pacific Time (US & Canada)		(b) (4), (b) (6)	Entry : swollen lymph node in right axilla	Error
Nov-17-2020 12:53:03 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	PFETMS Oracle (b) (4)	Query 1: Opened	Multiple concepts in the term LUMBAR SURGERY FOR BACK PAIN. Split the term into LUMBAR SURGERY and BACK PAIN and report as separate entries. Thank you.
Nov-17-2020 09:54:08 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry : lumbar surgery for back pain	Transcription Error
Nov-16-2020 16:10:25 (UTC-08:00) Pacific Time (US &	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry : Swollen ly	Initial Entry

Header Text: c4591001

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Subject Initials: ---

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Canada)			mph n ode in right axilla	
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4. Start Date Time:

Date	Location	User	Value	Reason
Nov-16-2020 16:10:25 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Oct/5/2020 08:00	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Nov-16-2020 16:10:25 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO End Date Time: Oct/12/2020 08:00	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
Nov-16-2020 16:10:25 (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

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significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).

Date	Location	User	Value	Reason
Nov-16-2020 16:10:25 (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
Nov-16-2020 16:10:25 (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
Nov-16-2020 16:10:25 (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 <i>If Other, specify:</i> adenopathy	Initial Entry

10. Latest Action Taken with Study Treatment:

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Generated By: (b) (4)

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Date	Location	User	Value	Reason
Nov-16-2020 16:10:25 (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
Nov-16-2020 16:10:25 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Nov-16-2020 16:10:25 (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
Nov-16-2020 16:10:25 (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?

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

Subject No: 11491239

Subject Initials: ---

Generated By: (b) (4)

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Date	Location	User	Value	Reason
Nov-16-2020 16:10:25 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

Header Text: c4591001

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Generated By: (b) (4)

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1. Category:

Date	Location	User	Value	Reason
Feb-18-2021 09:16:42 (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
Feb-18-2021 09:16:42 (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-18-2021 09:16:42 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Right arm pain with motion	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason
Feb-18-2021 09:16:42 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sep/22/2020 18:00	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
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Header Text: c4591001

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Site No: 1149

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Feb-18-2021 09:16:42 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO End Date Time: Sep/25/2020 20:00	Initial Entry
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6. Toxicity Grade:

Date	Location	User	Value	Reason
Feb-18-2021 09:16:42 (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
Feb-18-2021 09:16:42 (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
Feb-18-2021 09:16:42 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

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9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Feb-18-2021 09:16:42 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry: RELATED	Initial Entry

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Feb-18-2021 09:16:42 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry: NOT APPLICABLE	Initial Entry

11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
Feb-18-2021 09:16:42 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry: NO	Initial Entry

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Feb-18-2021 09:16:42 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry: NO	Initial Entry

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

Date	Location	User	Value	Reason
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Feb-18-2021 09:16:42 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: RECOVERED/RESOLVED	Initial Entry
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14. Did the adverse event cause the subject to be discontinued from the study?

Date	Location	User	Value	Reason
Feb-18-2021 09:16:42 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

090177e196ae30c7\Final\Final On: 01-Apr-2021 04:16 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - PROHIBITED -
Audit Trail

Form Version: 22-Apr-2020 21:03

Form Status:

Site No: 1149

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

Subject No: 11491239

Subject Initials: ---

Generated By: (b) (4)

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

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

[Back to Form](#)

Date	Location	User	Value	Reason
Nov-30-2020 11:39:51 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Deleted	Deleted per query stating meds not taken more than 14 days. Not prohibited.
Nov-16-2020 16:07:27 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

090177e196ae30c7\Final\Final On: 01-Apr-2021 04:16 (GMT)

Header Text: c4591001**Visit:** Logs - Unscheduled**Form:** CONCOMITANT MEDICATIONS - PROHIBITED - eCRF Audit Trail History**Form Version:** 22-Apr-2020 21:03**Form Status:** Incomplete, Data Complete, Deleted, Frozen, Verified**Site No:** 1149**Site Name:** (1149) Collaborative Neuroscience Network, LLC.**Subject No:** 11491239**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 11:56

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

[Back to Form](#)**1. What is the medication identifier?**

Date	Location	User	Value	Reason
Nov-30-2020 11:38:40 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry:	Prednisone removed per query.
Nov-16-2020 16:07:27 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 1	Initial Entry

2. Category:

Date	Location	User	Value	Reason
Nov-16-2020 16:07:27 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: CORTICOSTEROIDS	Initial Entry

3. Concomitant Medications Pre-specified:

Date	Location	User	Value	Reason
Nov-30-2020 11:38:40 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry:	Prednisone removed per query.
Nov-16-2020 16:07:27 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: NO	Initial Entry

4. Medication:

Provide the complete generic drug name (including salt form, where applicable). Where generic name is unknown, enter the full trade or proprietary name. Include clarifying information in the Medication text (e.g., Ingredient(s), route, use, formulation).

Date	Location	User	Value	Reason
Dec-01-2020 18:04:47 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Nov-30-2020 11:38:40 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Prednisone removed per query.
Nov-30-2020 11:38:40 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Prednisone removed per query.
Nov-26-2020 16:56:12 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued:Opened	ClinQuery: Please be informed that the MH page is unfrozen. please update accordingly. Thanks! Please be noticed that Prednisone is used from Oct 1 to Oct 6, which is less than 14 days. So this does not qualify as prohibited and should be removed.
Nov-25-2020 12:31:02 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Please unfreeze medical history in Visit 1 to update.

Nov-22-2020 23:01:49 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	ClinQuery: [Prednisone] This does not qualify as prohibited per the protocol i.e., =20 mg/day for =14 days (section 6.5.1). Please review and action appropriately. Please consider listing condition that required treatment on medical history.
Nov-22-2020 16:32:28 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Candidate	ClinQuery: [Prednisone] This does not qualify as prohibited per the protocol i.e., =20 mg/day for =14 days (section 6.5.1). Please review and action appropriately. Please consider listing condition that required treatment on medical history.
Nov-16-2020 16:07:27 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Prednisone	Initial Entry
5. Dose:				
Date	Location	User	Value	Reason
Nov-16-2020 16:07:27 (UTC-08:00) Pacific	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 25	Initial Entry

Time (US & Canada)				
6. Dose Unit:				
Date	Location	User	Value	Reason
Nov-16-2020 16:07:27 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: mg	Initial Entry
7. Dose Frequency:				
Date	Location	User	Value	Reason
Nov-16-2020 16:07:27 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: QD	Initial Entry
8. Route:				
Date	Location	User	Value	Reason
Nov-16-2020 16:07:27 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: ORAL	Initial Entry
9. Start Date:				
Date	Location	User	Value	Reason
Nov-16-2020 16:07:27 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Oct/1/2020	Initial Entry
10. Ongoing?				
Date	Location	User	Value	Reason
Nov-16-2020 16:07:27 (UTC-08:00) Pacific	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO End Date:	Initial Entry

Header Text: c4591001

Visit: Subject Status - Unscheduled

Form: SUBJECT STATUS - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Verified

Site No: 1149

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

Subject No: 11491239

Subject Initials: ---

Generated By: (b) (4)

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

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1. Subject Status

Date	Location	User	Value	Reason
Mar-08-2021 00:00:02 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Closed	Response satisfies query
Mar-05-2021 13:57:56 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Answered	subject still continuing in study
Mar-01-2021 03:47:42 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Reissued:Ope ned	DM: As 'visits 2 and 3 have not been conducted., please confirm if the subject is continuing in the study. Kindly review and update 'DISP TRT' form at EOT visit.
Feb-17-2021 22:33:01 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Reissued:Cand idate	It will be tracked per site response.
Feb-17-2021 14:33:40 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Answered	Subject is still out of town, and visits 2 and 3 have not been conducted.

090177e196ae30c7\Final\Final On: 01-Apr-2021 04:16 (GMT)

Header Text: c4591001

Visit: Subject Status - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1149

Subject No: 11491239

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

Feb-16-2021 21:16:29 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Reissued:Opened	DM1: Per previous response 'V2 and V3 have been delayed to an undetermined date'. Please follow-up and confirm if subject visit V2 and V3 have been done or not. Please update as appropriate or clarify.
Jan-25-2021 01:20:06 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Reissued:Canditate	DM: Please update when data is available. Thank you
Jan-22-2021 10:49:35 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Answered	Subject is currently hospitalized, thus V2 and V3 have been delayed to an undetermined date.
Jan-07-2021 22:20:56 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Opened	DM: Per previous query "Subject is still in the study, however, will be unable to return until January. Approved per study team. V2 and V3 will not be done." Kindly

090177e196ae30c7\Final\Final On: 01-Apr-2021 04:16 (GMT)

Header Text: c4591001

Visit: Subject Status - Unscheduled

Form: SUBJECT STATUS - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Verified

Site No: 1149

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

Subject No: 11491239

Subject Initials: ---

Generated By: (b) (4)

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

				review and confirm if subject visit is scheduled?.
Nov-15-2020 13:41:38 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	per site's response, will close query.
Nov-15-2020 12:43:14 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Subject is still in the study, however, will be unable to return until January. Approved per study team. V2 and V3 will not be done.
Nov-14-2020 08:21:02 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	DM: V2 is missing. Please confirm is subject is still in the study? If so, please confirm when V2 is expected to occur. If not, please complete DISP TRT and DISP FUP.
Sep-16-2020 14:40:41 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: ENROLLED/RANDOMIZED	Initial Entry
Sep-16-2020	ACV0PFEINFP6000	auto calc	Data Entry:	Initial Entry

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Header Text: c4591001

Visit: Subject Status - Unscheduled

Form: SUBJECT STATUS - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Verified

Site No: 1149

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

Subject No: 11491239

Subject Initials: ---

Generated By: (b) (4)

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

14:29:37 (UTC-08:00) Pacific Time (US & Canada)		(autocalc)	SCREENED	
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2. Subject Status Date

Date	Location	User	Value	Reason
Feb-15-2021 09:29:28 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Closed	Response satisfies query
Feb-12-2021 16:41:40 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Answer ed	AE has been updated will submit a follow up once we receive medical records
Feb-08-2021 11:57:47 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Opened	SAE RECON:AER#2021037695 heart attack 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.
Jan-25-2021 05:54:29 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	event no longer listed in SDB
Jan-21-2021 02:52:06 (UTC-08:00) Pacific Time (US	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	SAE RECON:AER#2021037695 heart attack was reported as serious in Safety database

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Header Text: c4591001

Visit: Subject Status - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1149

Subject No: 11491239

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

& Canada)				but missing in AE CRF. Please confirm and update CRF. If safety update is required, submit a follow-up SAE Form.
Sep-16-2020 14:40:41 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sep/15/2020	Initial Entry
Sep-16-2020 14:29:37 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sep/15/2020	Initial Entry

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Header Text: c4591001

Visit: Investigator Signature -
Unscheduled

Form Version: 22-Apr-2020 21:04

Site No: 1149

Subject No: 11491239

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-09-2020 14:38:42 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Click Here to Enable	Initial Entry