

**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:** 1013

**Site Name:** (1013) Clinical Neuroscience Solutions Inc.

**Subject No:** 10131658

**Subject Initials:** ---

**Generated By:** pfe.levisse

**Generated Time (GMT):** 29-Mar-2021 04:21

[eCRF Audit Trail History](#)

**Cohort Selection**

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

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

<b>Header Text:</b> c4591001	
<b>Visit:</b> COHORT_SELECTION	<b>Form:</b> MAIN INFORMED CONSENT
<b>Form Version:</b> 22-Apr-2020 21:02	<b>Form Status:</b> Data Complete, Locked, Frozen, Verified
<b>Site No:</b> 1013	<b>Site Name:</b> (1013) Clinical Neuroscience Solutions Inc.
<b>Subject No:</b> 10131658	<b>Subject Initials:</b> ---
<b>Generated By:</b> pfe.lewissc	<b>Generated Time (GMT):</b> 29-Mar-2021 04:21

[eCRF Audit Trail History](#)

Informed Consent		
1.	Consent Was:	OBTAINED Date Written Consent Obtained Oct/7/2020

**Header Text:** c4591001

**Visit:** COHORT\_SELECTION

**Form Version:** 15-Sep-2020 21:54

**Site No:** 1013

**Subject No:** 10131658

**Generated By:** pfe.lewissc

**Form:** DEMOGRAPHY

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site Name:** (1013) Clinical Neuroscience Solutions Inc.

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:21

[eCRF Audit Trail History](#)

**Demography**

1.	Subject ID	[10131658]
2.	Birth Date:	(b) (6)/1978
3.	Sex:	MALE
4.	Ethnicity:	NOT HISPANIC OR LATINO(A) OR OF SPANISH ORIGIN
5.	Race: (Check X all that apply):	BLACK OR AFRICAN AMERICAN
6.	Racial Designation:	

**Header Text:** c4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form Version:** 22-Apr-2020 21:02

**Site No:** 1013

**Subject No:** 10131658

**Generated By:** pfe.levissc

**Form:** DATE OF VISIT

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site Name:** (1013) Clinical Neuroscience Solutions Inc.

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:21

**eCRF Audit Trail History**

**Date of Visit**

1.	Date of Visit	Oct/7/2020
2.	Erroneous Visit	

**Header Text:** c4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form Version:** 15-Sep-2020 21:53

**Site No:** 1013

**Subject No:** 10131658

**Generated By:** pfe.levisc

**Form:** INCLUSION/EXCLUSION CRITERIA

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site Name:** (1013) Clinical Neuroscience Solutions Inc.

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:21

**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:** 1013

**Subject No:** 10131658

**Generated By:** pfe.levisse

**Form:** DISPOSITION - SCREENING

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site Name:** (1013) Clinical Neuroscience Solutions Inc.

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:21

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

**Disposition - Screening**

1.	Date of Completion/Discontinuation/Death	Oct/7/2020
2.	Phase of Disposition:	SCREENING
3.	Status:	COMPLETED
4.	Specify Status:	[ ]

**Header Text:** c4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1013

**Subject No:** 10131658

**Generated By:** pfe.levisse

**Form:** GENERAL MEDICAL HISTORY

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site Name:** (1013) Clinical Neuroscience Solutions Inc.

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:21

**Form Comments**

**Medical History Details**

1.	Line/MH Number:	Not Applicable _____ [ ]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	Not Applicable _____ [ ]
	Start Date:	Not Applicable _____ //
	Ongoing:	Not Applicable _____ _____

090177e196ae2f5e\Final\Final On: 01-Apr-2021 03:41 (GMT)

**Header Text:** c4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form Version:** 15-Sep-2020 21:57

**Site No:** 1013

**Subject No:** 10131658

**Generated By:** pfe.levisse

**Form:** HIV STATUS

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site Name:** (1013) Clinical Neuroscience Solutions Inc.

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:21

[eCRF Audit Trail History](#)

**HIV Status**

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



**Header Text:** c4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form Version:** 15-Sep-2020 21:56

**Site No:** 1013

**Subject No:** 10131658

**Generated By:** pfe.levisse

**Form:** VITAL SIGNS - BASELINE

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site Name:** (1013) Clinical Neuroscience Solutions Inc.

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:21

[eCRF Audit Trail History](#)

**Vital Signs**

1.	Date:	Oct/7/2020
2.	Weight:	[76.0]
3.	Unit:	kg
4.	Height:	[177.5]
5.	Unit:	cm
6.	Body Mass Index:	[24.1]

**Vital Signs Details**

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

090177e196ae2f5e\Final\Final On: 01-Apr-2021 03:41 (GMT)

**Header Text:** c4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1013

**Subject No:** 10131658

**Generated By:** pfe.lewissc

**Form:** RANDOMIZATION

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site Name:** (1013) Clinical Neuroscience Solutions Inc.

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:21

[eCRF Audit Trail History](#)

**Disposition**

1.	Randomization Date :	Oct/7/2020
2.	Randomization Number:	[104653]
3.	Randomization Group:	[ ]

**Header Text:** c4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1013

**Subject No:** 10131658

**Generated By:** pfe.levissc

**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site Name:** (1013) Clinical Neuroscience Solutions Inc.

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:21

**eCRF Audit Trail History**

**Electronic Sample Tracking**

1.	Data Origin	SITE
2.	Sample Type	SERUM
3.	Sample Collected?	YES Date of Collection: Oct/7/2020
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	[BPC2K3]
5.b	Sample ID	[BPC2K4]
5.c	Sample ID	[BPC2K5]
5.d	Sample ID	[BS6ZCY]
5.e	Sample ID	[BS6ZCZ]

090177e196ae2f5e\Final\Final On: 01-Apr-2021 03:41 (GMT)

**Header Text:** c4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1013

**Subject No:** 10131658

**Generated By:** pfe.lewissc

**Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site Name:** (1013) Clinical Neuroscience Solutions Inc.

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:21

**eCRF Audit Trail History**

**Electronic Sample Tracking**

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Oct/7/2020
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	[BRG2TM]
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090177e196ae2f5e\Final\Final On: 01-Apr-2021 03:41 (GMT)

**Header Text:** c4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form Version:** 22-Apr-2020 21:04

**Site No:** 1013

**Subject No:** 10131658

**Generated By:** pfe.levisse

**Form:** VACCINATION

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site Name:** (1013) Clinical Neuroscience Solutions Inc.

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:21

**eCRF Audit Trail History**

**Vaccination**

1.	Was there a temporary delay of vaccination?	NO
2.	Treatment Name	[BLINDED THERAPY]
3.	Formulation:	INJECTION
4.	Dose Date Time:	Oct/7/2020 11:30
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

090177e196ae2f5e\Final\Final On: 01-Apr-2021 03:41 (GMT)

**Header Text:** c4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form Version:** 06-Jul-2020 21:53

**Site No:** 1013

**Subject No:** 10131658

**Generated By:** pfe.levisse

**Form:** REACTOGENICITY DIARY

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site Name:** (1013) Clinical Neuroscience Solutions Inc.

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:21

[eCRF Audit Trail History](#)

**Reactogenicity Diary**

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

**Visit:** V2\_VAX2\_L

**Form Version:** 22-Apr-2020 21:02

**Site No:** 1013

**Subject No:** 10131658

**Generated By:** pfe.levissc

**Form:** DATE OF VISIT

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site Name:** (1013) Clinical Neuroscience Solutions Inc.

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:21

[Form Comments](#)

[eCRF Audit Trail History](#)

**Date of Visit**

1.	Date of Visit	Oct/27/2020
2.	Erroneous Visit	

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

**Form Version:** 15-Sep-2020 21:54

**Site No:** 1013

**Subject No:** 10131658

**Generated By:** pfe.lewissc

**Form:** VITAL SIGNS - TEMP

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site Name:** (1013) Clinical Neuroscience Solutions Inc.

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:21

[eCRF Audit Trail History](#)

**Vital Signs**

1.	Date:	Oct/27/2020
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**Vital Signs Details**

2.a	Record Identifier:	1
	Temperature:	[36.8]
	Unit:	C
	Temperature Location:	ORAL CAVITY



**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1013

**Subject No:** 10131658

**Generated By:** pfe.lewissc

**Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site Name:** (1013) Clinical Neuroscience Solutions Inc.

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:21

**eCRF Audit Trail History**

**Electronic Sample Tracking**

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Oct/27/2020
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	[BR9TJL]
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090177e196ae2f5e\Final\Final On: 01-Apr-2021 03:41 (GMT)

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

**Form Version:** 22-Apr-2020 21:04

**Site No:** 1013

**Subject No:** 10131658

**Generated By:** pfe.levisc

**Form:** VACCINATION

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site Name:** (1013) Clinical Neuroscience Solutions Inc.

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:21

**eCRF Audit Trail History**

**Vaccination**

1.	Was there a temporary delay of vaccination?	NO
2.	Treatment Name	[BLINDED THERAPY]
3.	Formulation:	INJECTION
4.	Dose Date Time:	Oct/27/2020 13:52
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

090177e196ae2f5e\Final\Final On: 01-Apr-2021 03:41 (GMT)

**Header Text:** c4591001

**Visit:** V3\_MONTH1\_POSTVAX2\_L

**Form Version:** 22-Apr-2020 21:02

**Site No:** 1013

**Subject No:** 10131658

**Generated By:** pfe.levissc

**Form:** DATE OF VISIT

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site Name:** (1013) Clinical Neuroscience Solutions Inc.

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:21

**eCRF Audit Trail History**

**Date of Visit**

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

090177e196ae2f5e\Final\Final On: 01-Apr-2021 03:41 (GMT)

**Header Text:** c4591001

**Visit:** V3\_MONTH1\_POSTVAX2\_L

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1013

**Subject No:** 10131658

**Generated By:** pfe.levisc

**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site Name:** (1013) Clinical Neuroscience Solutions Inc.

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:21

**eCRF Audit Trail History**

**Electronic Sample Tracking**

1.	Data Origin	SITE
2.	Sample Type	SERUM
3.	Sample Collected?	YES Date of Collection: Nov/24/2020
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[ ]

**Aliquot**

Please enter barcode for each aliquot.

5.a	Sample ID	[BRHW2M]
5.b	Sample ID	[BRHW2N]
5.c	Sample ID	[BRHW2P]
5.d	Sample ID	[BS0JH2]
5.e	Sample ID	[BS0JH3]

090177e196ae2f5e\Final\Final On: 01-Apr-2021 03:41 (GMT)

**Header Text:** c4591001

**Visit:** V4\_MONTH6\_L

**Form Version:** 22-Apr-2020 21:02

**Site No:** 1013

**Subject No:** 10131658

**Generated By:** pfe.levissc

**Form:** DATE OF VISIT

**Form Status:** Not Started

**Site Name:** (1013) Clinical Neuroscience Solutions Inc.

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:21

**Date of Visit**

1.	Date of Visit	//
2.	Erroneous Visit	

**Header Text:** c4591001

**Visit:** V4\_MONTH6\_L

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1013

**Subject No:** 10131658

**Generated By:** pfe.levisse

**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

**Form Status:** Not Started

**Site Name:** (1013) Clinical Neuroscience Solutions Inc.

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:21

**Electronic Sample Tracking**

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

**Aliquot**

Please enter barcode for each aliquot.

5.	Sample ID	[ ]
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**Header Text:** c4591001

**Visit:** V5\_MONTH12\_L

**Form Version:** 22-Apr-2020 21:02

**Site No:** 1013

**Subject No:** 10131658

**Generated By:** pfe.levissc

**Form:** DATE OF VISIT

**Form Status:** Not Started

**Site Name:** (1013) Clinical Neuroscience Solutions Inc.

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:21

**Date of Visit**

1.	Date of Visit	//
2.	Erroneous Visit	

**Header Text:** c4591001

**Visit:** V5\_MONTH12\_L

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1013

**Subject No:** 10131658

**Generated By:** pfe.lewissc

**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

**Form Status:** Not Started

**Site Name:** (1013) Clinical Neuroscience Solutions Inc.

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:21

**Electronic Sample Tracking**

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

**Aliquot**

Please enter barcode for each aliquot.

5.	Sample ID	[ ]
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**Header Text:** c4591001

**Visit:** V6\_MONTH24\_L

**Form Version:** 22-Apr-2020 21:02

**Site No:** 1013

**Subject No:** 10131658

**Generated By:** pfe.levissc

**Form:** DATE OF VISIT

**Form Status:** Not Started

**Site Name:** (1013) Clinical Neuroscience Solutions Inc.

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:21

**Date of Visit**

1.	Date of Visit	//
2.	Erroneous Visit	

**Header Text:** c4591001

**Visit:** V6\_MONTH24\_L

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1013

**Subject No:** 10131658

**Generated By:** pfe.levisse

**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

**Form Status:** Not Started

**Site Name:** (1013) Clinical Neuroscience Solutions Inc.

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:21

**Electronic Sample Tracking**

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

**Aliquot**

Please enter barcode for each aliquot.

5.	Sample ID	[ ]
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**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL - New Unscheduled Visit

**Form:** DATE OF VISIT - ILLNESS ONSET

**Form Version:** 22-Apr-2020 21:03

**Form Status:** Not Started

**Site No:** 1013

**Site Name:** (1013) Clinical Neuroscience Solutions Inc.

**Subject No:** 10131658

**Subject Initials:** ---

**Generated By:** pfe.levissc

**Generated Time (GMT):** 29-Mar-2021 04:21

**Date of Visit**

1.	Date of Visit	//
2.	Erroneous Visit	

**COVID-19 Illness Visit**

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

090177e196ae2f5e\Final\Final On: 01-Apr-2021 03:41 (GMT)

**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:** 1013

**Site Name:** (1013) Clinical Neuroscience Solutions Inc.

**Subject No:** 10131658

**Subject Initials:** ---

**Generated By:** pfe.levissc

**Generated Time (GMT):** 29-Mar-2021 04:21

**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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**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:** 1013

**Site Name:** (1013) Clinical Neuroscience Solutions Inc.

**Subject No:** 10131658

**Subject Initials:** ---

**Generated By:** pfe.levissc

**Generated Time (GMT):** 29-Mar-2021 04:21

**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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090177e196ae2f5e\Final\Final On: 01-Apr-2021 03:41 (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:** 1013

**Site Name:** (1013) Clinical Neuroscience Solutions Inc.

**Subject No:** 10131658

**Subject Initials:** ---

**Generated By:** pfe.levissc

**Generated Time (GMT):** 29-Mar-2021 04:21

**Electronic Sample Tracking**

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

**Aliquot**

Please enter barcode for each aliquot.

5.	Sample ID	[ ]
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**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL - New Unscheduled Visit

**Form:** HEALTH CARE UTILIZATION

**Form Version:** 20-Feb-2021 02:19

**Form Status:** Not Started

**Site No:** 1013

**Site Name:** (1013) Clinical Neuroscience Solutions Inc.

**Subject No:** 10131658

**Subject Initials:** ---

**Generated By:** pfe.levisse

**Generated Time (GMT):** 29-Mar-2021 04:21

**Health Care Utilization**

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

**Health Care Utilization Other**

2.	Other Type of Practitioner Specify:	[ ]
----	-------------------------------------	-----

**Health Care Utilization**

3.	Has the subject been hospitalized due to potential COVID-19 illness?	
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**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:** 1013      **Site Name:** (1013) Clinical Neuroscience Solutions Inc.

**Subject No:** 10131658      **Subject Initials:** ---

**Generated By:** pfe.levissc      **Generated Time (GMT):** 29-Mar-2021 04:21

**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:** 1013

**Site Name:** (1013) Clinical Neuroscience Solutions Inc.

**Subject No:** 10131658

**Subject Initials:** ---

**Generated By:** pfe.levissc

**Generated Time (GMT):** 29-Mar-2021 04:21

**Date of Visit**

1.	Date of Visit	//
2.	Erroneous Visit	

**COVID-19 Illness Visit**

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

**Header Text:** c4591001

**Visit:** POT\_COVID\_CONVA - New  
Unscheduled Visit

**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

**Form Version:** 22-Apr-2020 21:03

**Form Status:** Not Started

**Site No:** 1013

**Site Name:** (1013) Clinical Neuroscience Solutions Inc.

**Subject No:** 10131658

**Subject Initials:** ---

**Generated By:** pfe.levissc

**Generated Time (GMT):** 29-Mar-2021 04:21

**Electronic Sample Tracking**

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

**Aliquot**

Please enter barcode for each aliquot.

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

**Header Text:** c4591001

**Visit:** 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:** 1013

**Site Name:** (1013) Clinical Neuroscience Solutions Inc.

**Subject No:** 10131658

**Subject Initials:** ---

**Generated By:** pfe.levisse

**Generated Time (GMT):** 29-Mar-2021 04:21

**Date of Visit**

1.	Date of Visit	//
2.	Erroneous Visit	

**COVID-19 Repeat Swab**

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

090177e196ae2f5e\Final\Final On: 01-Apr-2021 03:41 (GMT)

**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:** 1013

**Site Name:** (1013) Clinical Neuroscience Solutions Inc.

**Subject No:** 10131658

**Subject Initials:** ---

**Generated By:** pfe.levissc

**Generated Time (GMT):** 29-Mar-2021 04:21

**Electronic Sample Tracking**

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

**Aliquot**

Please enter barcode for each aliquot.

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

**Header Text:** c4591001

**Visit:** Unplanned - New Unscheduled Visit

**Form:** DATE OF VISIT

**Form Version:** 22-Apr-2020 21:02

**Form Status:** Not Started

**Site No:** 1013

**Site Name:** (1013) Clinical Neuroscience Solutions Inc.

**Subject No:** 10131658

**Subject Initials:** ---

**Generated By:** pfe.levissc

**Generated Time (GMT):** 29-Mar-2021 04:21

**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:** 1013

**Site Name:** (1013) Clinical Neuroscience Solutions Inc.

**Subject No:** 10131658

**Subject Initials:** ---

**Generated By:** pfe.levisse

**Generated Time (GMT):** 29-Mar-2021 04:21

**Unplanned Assessments**

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

**Header Text:** c4591001

**Visit:** Logs

**Form:** ADVERSE EVENT REPORT

**Form Version:** 22-Apr-2020 21:02

**Site No:** 1013

**Site Name:** (1013) Clinical Neuroscience Solutions Inc.

**Subject No:** 10131658

**Subject Initials:** ---

**Generated By:** pfe.levissc

**Generated Time (GMT):** 29-Mar-2021 04:21

#	Category	AE Identifier	Adverse Event	Start Date	Is the Adverse Event Still Ongoing	Form Instance
1.	ADVERSE EVENT	1	LYMPH NODE SWELLING LEFT AUXILLARY	Oct/28/2020 18:00	NO End Date Time: Oct/30/2020 08:00	<a href="#">Repeating Pages</a>

090177e196ae2f5e\Final\Final On: 01-Apr-2021 03:41 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

**Form Version:** 22-Apr-2020 21:02

**Site No:** 1013

**Subject No:** 10131658

**Generated By:** pfe.levisse

**Form:** ADVERSE EVENT REPORT

**Form Status:** Data Complete, Frozen

**Site Name:** (1013) Clinical Neuroscience Solutions Inc.

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:21

[Back to Form](#)  
[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)	[LYMPH NODE SWELLING LEFT AUXILLARY]
4.	Start Date Time:	Oct/28/2020 18:00
5.	Is the adverse event still ongoing?	NO End Date Time: Oct/30/2020 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
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

090177e196ae2f5e\Final\Final On: 01-Apr-2021 03:41 (GMT)



**Header Text:** c4591001

**Visit:** Logs - Unscheduled

**Form Version:** 22-Apr-2020 21:02

**Site No:** 1013

**Subject No:** 10131658

**Generated By:** pfe.levisse

**Form:** ADVERSE EVENT REPORT

**Form Status:** Data Complete, Frozen

**Site Name:** (1013) Clinical Neuroscience Solutions Inc.

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:21

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	[ ]

090177e196ae2f5e\Final\Final On: 01-Apr-2021 03:41 (GMT)

**Header Text:** c4591001

**Visit:** Logs

**Form:** MEDICATION ERROR

**Form Version:** 17-Jul-2020 21:54

**Site No:** 1013

**Site Name:** (1013) Clinical Neuroscience Solutions Inc.

**Subject No:** 10131658

**Subject Initials:** ---

**Generated By:** pfe.lewissc

**Generated Time (GMT):** 29-Mar-2021 04:21

#	Category	Medication Error	Start Date	Is the medication error Still Ongoing	Study Medication Errors Action	Form Instance
1.						<a href="#">Repeating Pages</a>

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

**Form Version:** 17-Jul-2020 21:54

**Site No:** 1013

**Subject No:** 10131658

**Generated By:** pfe.levisse

**Form:** MEDICATION ERROR

**Form Status:** Not Started

**Site Name:** (1013) Clinical Neuroscience Solutions Inc.

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:21

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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	[ ]

090177e196ae2f5e\Final\Final On: 01-Apr-2021 03:41 (GMT)

**Header Text:** c4591001

**Visit:** Logs

**Form:** CONCOMITANT MEDICATIONS - NON STUDY  
VACCINATIONS

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1013

**Site Name:** (1013) Clinical Neuroscience Solutions Inc.

**Subject No:** 10131658

**Subject Initials:** ---

**Generated By:** pfe.lewissc

**Generated Time (GMT):** 29-Mar-2021 04:21

#	Sponsor-Defined Identifier	Category for Medication	Concomitant Medications Pre-specified	Name of Medication	Start Date	Form Instance
1.						<a href="#">Repeating Pages</a>

**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:** 1013

**Site Name:** (1013) Clinical Neuroscience Solutions Inc.

**Subject No:** 10131658

**Subject Initials:** ---

**Generated By:** pfe.levisse

**Generated Time (GMT):** 29-Mar-2021 04:21

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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:	//

090177e196ae2f5e\Final\Final On: 01-Apr-2021 03:41 (GMT)

**Header Text:** c4591001

**Visit:** Logs

**Form:** CONCOMITANT MEDICATIONS - PROHIBITED

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1013

**Site Name:** (1013) Clinical Neuroscience Solutions Inc.

**Subject No:** 10131658

**Subject Initials:** ---

**Generated By:** pfe.lewissc

**Generated Time (GMT):** 29-Mar-2021 04:21

#	Sponsor-Defined Identifier	Category for Medication	Concomitant Medications Pre-specified	Name of Medication	Dose Description	Form Instance
1.						<a href="#">Repeating Pages</a>

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1013

**Subject No:** 10131658

**Generated By:** pfe.levisse

**Form:** CONCOMITANT MEDICATIONS - PROHIBITED

**Form Status:** Not Started

**Site Name:** (1013) Clinical Neuroscience Solutions Inc.

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:21

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**Concomitant Medications**

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

090177e196ae2f5e\Final\Final On: 01-Apr-2021 03:41 (GMT)

**Header Text:** c4591001

**Visit:** Logs

**Form:** RADIATION TREATMENT

**Form Version:** 22-Apr-2020 21:02

**Site No:** 1013

**Site Name:** (1013) Clinical Neuroscience Solutions Inc.

**Subject No:** 10131658

**Subject Initials:** ---

**Generated By:** pfe.lewissc

**Generated Time (GMT):** 29-Mar-2021 04:21

#	Category	Treatment Identifier	Con Non-Drug Treatments Pre-specified	Treatment	Start Date	Form Instance
1.						<a href="#">Repeating Pages</a>



**Header Text:** c4591001

**Visit:** Logs - Unscheduled

**Form Version:** 22-Apr-2020 21:02

**Site No:** 1013

**Subject No:** 10131658

**Generated By:** pfe.levisse

**Form:** RADIATION TREATMENT

**Form Status:** Not Started

**Site Name:** (1013) Clinical Neuroscience Solutions Inc.

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:21

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**Radiation Treatment**

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

**Header Text:** c4591001

**Visit:** Logs

**Form:** TRANSFUSIONS

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1013

**Site Name:** (1013) Clinical Neuroscience Solutions Inc.

**Subject No:** 10131658

**Subject Initials:** ---

**Generated By:** pfe.levisse

**Generated Time (GMT):** 29-Mar-2021 04:21

#	Transfusion Type	Date of Transfusion	Form Instance
1.			<a href="#">Repeating Pages</a>

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1013

**Subject No:** 10131658

**Generated By:** pfe.levisse

**Form:** TRANSFUSIONS

**Form Status:** Not Started

**Site Name:** (1013) Clinical Neuroscience Solutions Inc.

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:21

[Back to Form](#)

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

**Header Text:** c4591001

**Visit:** End of Treatment - Unscheduled

**Form Version:** 15-Sep-2020 21:55

**Site No:** 1013

**Subject No:** 10131658

**Generated By:** pfe.levissc

**Form:** DISPOSITION - TREATMENT

**Form Status:** Data Complete, Frozen, Verified

**Site Name:** (1013) Clinical Neuroscience Solutions Inc.

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:21

**eCRF Audit Trail History**

**Disposition - Treatment**

1.	Date of Completion/Discontinuation/Death :	Nov/24/2020
2.	Phase of Disposition:	VACCINATION
3.	Status:	COMPLETED
4.	Specify Status:	[ ]

**Header Text:** c4591001

**Visit:** Unplanned Vaccination - Unscheduled

**Form:** DATE OF VISIT

**Form Version:** 22-Apr-2020 21:02

**Form Status:** Not Started

**Site No:** 1013

**Site Name:** (1013) Clinical Neuroscience Solutions Inc.

**Subject No:** 10131658

**Subject Initials:** ---

**Generated By:** pfe.levisse

**Generated Time (GMT):** 29-Mar-2021 04:21

**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:** 1013

**Site Name:** (1013) Clinical Neuroscience Solutions Inc.

**Subject No:** 10131658

**Subject Initials:** ---

**Generated By:** pfe.levisse

**Generated Time (GMT):** 29-Mar-2021 04:21

**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:** 1013

**Site Name:** (1013) Clinical Neuroscience Solutions Inc.

**Subject No:** 10131658

**Subject Initials:** ---

**Generated By:** pfe.levisc

**Generated Time (GMT):** 29-Mar-2021 04:21

**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?	

090177e196ae2f5e\Final\Final On: 01-Apr-2021 03:41 (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:** 1013

**Site Name:** (1013) Clinical Neuroscience Solutions Inc.

**Subject No:** 10131658

**Subject Initials:** ---

**Generated By:** pfe.levisse

**Generated Time (GMT):** 29-Mar-2021 04:21

**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:** 1013

**Site Name:** (1013) Clinical Neuroscience Solutions Inc.

**Subject No:** 10131658

**Subject Initials:** ---

**Generated By:** pfe.levisse

**Generated Time (GMT):** 29-Mar-2021 04:21

**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:** 1013

**Site Name:** (1013) Clinical Neuroscience Solutions Inc.

**Subject No:** 10131658

**Subject Initials:** ---

**Generated By:** pfe.levisse

**Generated Time (GMT):** 29-Mar-2021 04:21

**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:** 1013

**Site Name:** (1013) Clinical Neuroscience Solutions Inc.

**Subject No:** 10131658

**Subject Initials:** ---

**Generated By:** pfe.levisse

**Generated Time (GMT):** 29-Mar-2021 04:21

**Informed Consent - Asymptomatic Surveillance**

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

**Header Text:** c4591001

**Visit:** V201\_SURVEIL\_CONSENT -  
Unscheduled

**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

**Form Version:** 22-Apr-2020 21:03

**Form Status:** Not Started

**Site No:** 1013

**Site Name:** (1013) Clinical Neuroscience Solutions Inc.

**Subject No:** 10131658

**Subject Initials:** ---

**Generated By:** pfe.levissc

**Generated Time (GMT):** 29-Mar-2021 04:21

**Electronic Sample Tracking**

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

**Aliquot**

Please enter barcode for each aliquot.

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

**Header Text:** c4591001

**Visit:** V201\_SURVEIL\_CONSENT -  
Unscheduled

**Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB

**Form Version:** 22-Apr-2020 21:03

**Form Status:** Not Started

**Site No:** 1013

**Site Name:** (1013) Clinical Neuroscience Solutions Inc.

**Subject No:** 10131658

**Subject Initials:** ---

**Generated By:** pfe.levissc

**Generated Time (GMT):** 29-Mar-2021 04:21

**Electronic Sample Tracking**

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

**Aliquot**

Please enter barcode for each aliquot.

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

**Header Text:** c4591001

**Visit:** Follow-Up - Unscheduled

**Form Version:** 15-Sep-2020 21:53

**Site No:** 1013

**Subject No:** 10131658

**Generated By:** pfe.levissc

**Form:** DISPOSITION - FOLLOW-UP

**Form Status:** Not Started

**Site Name:** (1013) Clinical Neuroscience Solutions Inc.

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:21

**Disposition - Follow-Up**

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

**Header Text:** c4591001

**Visit:** Potential ReVax Initial Contact -  
Unscheduled

**Form:** DATE OF VISIT

**Form Version:** 22-Apr-2020 21:02

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1013

**Site Name:** (1013) Clinical Neuroscience Solutions Inc.

**Subject No:** 10131658

**Subject Initials:** ---

**Generated By:** pfe.levissc

**Generated Time (GMT):** 29-Mar-2021 04:21

[eCRF Audit Trail History](#)

**Date of Visit**

1.	Date of Visit	Feb/9/2021
2.	Erroneous Visit	

**Header Text:** c4591001

**Visit:** Potential ReVax Initial Contact -  
Unscheduled

**Form:** FURTHER VACCINATION CONFIRMATION

**Form Version:** 10-Dec-2020 02:25

**Form Status:** Data Complete, Frozen

**Site No:** 1013

**Site Name:** (1013) Clinical Neuroscience Solutions Inc.

**Subject No:** 10131658

**Subject Initials:** ---

**Generated By:** pfe.levissc

**Generated Time (GMT):** 29-Mar-2021 04:21

[eCRF Audit Trail History](#)

**Further Vaccination Confirmation**

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



**Header Text:** c4591001

**Visit:** Disposition - Unscheduled

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1013

**Subject No:** 10131658

**Generated By:** pfe.levissc

**Form:** TREATMENT UNBLINDED

**Form Status:** Data Complete, Frozen, Verified

**Site Name:** (1013) Clinical Neuroscience Solutions Inc.

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:21

**eCRF Audit Trail History**

**Treatment Unblinded**

1.	Date Treatment Unblinded :	Feb/9/2021
2.	Primary Reason for Unblinding:	ASSESS ELIGIBILITY FOR ADDITIONAL VACCINATION

090177e196ae2f5e\Final\Final On: 01-Apr-2021 03:41 (GMT)

**Header Text:** c4591001

**Visit:** Disposition - Unscheduled

**Form:** WITHDRAWAL OF CONSENT

**Form Version:** 22-Apr-2020 21:03

**Form Status:** Not Started

**Site No:** 1013

**Site Name:** (1013) Clinical Neuroscience Solutions Inc.

**Subject No:** 10131658

**Subject Initials:** ---

**Generated By:** pfe.levisse

**Generated Time (GMT):** 29-Mar-2021 04:21

**Withdrawal Of Consent**

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

**Header Text:** c4591001

**Visit:** Disposition - Unscheduled

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1013

**Subject No:** 10131658

**Generated By:** pfe.levisse

**Form:** DEATH DETAILS CODED

**Form Status:** Not Started

**Site Name:** (1013) Clinical Neuroscience Solutions Inc.

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:21

**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 Version:** 22-Apr-2020 21:03

**Site No:** 1013

**Subject No:** 10131658

**Generated By:** pfe.levissc

**Form:** SUBJECT STATUS

**Form Status:** Data Complete, Verified

**Site Name:** (1013) Clinical Neuroscience Solutions Inc.

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:21

**eCRF Audit Trail History**

**Subject Status**

1.	Subject Status	FOLLOW-UP
2.	Subject Status Date	Nov/24/2020

**Header Text:** c4591001

**Visit:** Investigator Signature - Unscheduled

**Form Version:** 22-Apr-2020 21:04

**Site No:** 1013

**Subject No:** 10131658

**Generated By:** pfe.levisc

**Form:** CASEBOOK SIGNATURE FORM

**Form Status:** Data Complete, Signed, Verified

**Site Name:** (1013) Clinical Neuroscience Solutions Inc.

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:21

[eCRF Audit Trail History](#)

**Casebook Signature Form**

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

**Header Text:** c4591001

**Visit:** Investigator Signature - Unscheduled

**Form:** CASEBOOK SIGNATURE FORM

**Form Version:** 22-Apr-2020 21:04

**Form Status:** Data Complete, Signed, Verified

**Site No:** 1013

**Site Name:** (1013) Clinical Neuroscience Solutions Inc.

**Subject No:** 10131658

**Subject Initials:** ---

**Generated By:** pfe.levissc

**Generated Time (GMT):** 29-Mar-2021 04:21

[Audit Trail](#)

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

- CRF\_Sign

Name	Signature Meaning	Date	Type	Action
Patricia Brown	Approved	Feb-25-2021 14:40:01 (UTC-05:00) Eastern Time (US & Canada)	BOOK	Signed

**Affidavit:**

By my dated signature below, I, PatriciaBrown, 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.

090177e196ae2f5e\Final\Final On: 01-Apr-2021 03:41 (GMT)

**Header Text:** c4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form Version:** 15-Sep-2020 21:53

**Site No:** 1013

**Subject No:** 10131658

**Generated By:** pfe.levisse

**Form:** INCLUSION/EXCLUSION CRITERIA - Comments

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site Name:** (1013) Clinical Neuroscience Solutions Inc.

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:21

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Item	Date	User	Comment
Form	Oct-07-2020 15:44:00 (UTC-05:00) Eastern Time (US & Canada)	Scott Salmon (pfe.ssalmon)	Not Applicable

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**Header Text:** c4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1013

**Subject No:** 10131658

**Generated By:** pfe.levisse

**Form:** GENERAL MEDICAL HISTORY - Comments

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site Name:** (1013) Clinical Neuroscience Solutions Inc.

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:21

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Item	Date	User	Comment
Form	Oct-07-2020 15:46:13 (UTC-05:00) Eastern Time (US & Canada)	Scott Salmon (pfe.ssalmon)	NO KNOWN MEDICAL HISTORY ----- Not Applicable
Form	Oct-07-2020 15:45:47 (UTC-05:00) Eastern Time (US & Canada)	Scott Salmon (pfe.ssalmon)	NO KNOWN MEDICAL HISTORY



**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

**Form Version:** 22-Apr-2020 21:02

**Site No:** 1013

**Subject No:** 10131658

**Generated By:** pfe.levisse

**Form:** DATE OF VISIT - Comments

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site Name:** (1013) Clinical Neuroscience Solutions Inc.

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:21

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Item	Date	User	Comment
Form	Oct-08-2020 08:25:50 (UTC-05:00) Eastern Time (US & Canada)	Matthew Stephens (pfe mstephens)	VISIT ENTERED IN ERROR

090177e196ae2f5e\Final\Final On: 01-Apr-2021 03:41 (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, Signed, Verified

**Site No:** 1013

**Site Name:** (1013) Clinical Neuroscience Solutions Inc.

**Subject No:** 10131658

**Subject Initials:** ---

**Generated By:** pfe.levisse

**Generated Time (GMT):** 29-Mar-2021 04:21

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

- CRF\_Sign

Name	Signature Meaning	Date	Type	Action
Patricia Brown	Approved	Feb-25-2021 14:40:01 (UTC-05:00) Eastern Time (US & Canada)	BOOK	Signed

**Affidavit:**

By my dated signature below, I, PatriciaBrown, 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.

Monica Cooper	N/A	Feb-12-2021 11:55:33 (UTC-05:00) Eastern Time (US & Canada)		Edit - All signatures invalidated
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**Affidavit:**

N/A

Michael Dever	Approved	Jan-21-2021 07:07:06 (UTC-05:00) Eastern Time (US & Canada)	BOOK	Signed
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**Affidavit:**

By my dated signature below, I, MichaelDever, 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.

Scott Salmon	N/A	Nov-24-2020 15:42:29 (UTC-05:00) Eastern Time (US & Canada)		Edit - All signatures invalidated
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**Affidavit:**

N/A

090177e196ae2f5e\Final\Final On: 01-Apr-2021 03:41 (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, Signed, Verified

**Site No:** 1013

**Site Name:** (1013) Clinical Neuroscience Solutions Inc.

**Subject No:** 10131658

**Subject Initials:** ---

**Generated By:** pfe.levisse

**Generated Time (GMT):** 29-Mar-2021 04:21

Michael Dever	Approved	Nov-10-2020 08:29:57 (UTC-05:00) Eastern Time (US & Canada)	BOOK	Signed
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**Affidavit:**

By my dated signature below, I, MichaelDever, 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.

090177e196ae2f5e\Final\Final On: 01-Apr-2021 03:41 (GMT)

**Header Text:** c4591001

**Visit:** COHORT\_SELECTION

**Form Version:** 15-Sep-2020 21:55

**Site No:** 1013

**Subject No:** 10131658

**Generated By:** pfe.lewissc

**Form:** COHORT SELECTION - eCRF Audit Trail History

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site Name:** (1013) Clinical Neuroscience Solutions Inc.

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:21

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*1. Select appropriate response - Protocol version*

Date	Location	User	Value	Reason
Oct-07-2020 15:42:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Scott Salmon (pfe.ssalmon)	<b>Data Entry:</b> 08 SEP 2020	Initial Entry

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

Date	Location	User	Value	Reason
Oct-07-2020 15:42:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Scott Salmon (pfe.ssalmon)	<b>Data Entry:</b> STAGE 3 COHORTS	Initial Entry

**Header Text:** c4591001

**Visit:** COHORT\_SELECTION

**Form Version:** 22-Apr-2020 21:02

**Site No:** 1013

**Subject No:** 10131658

**Generated By:** pfe.levisse

**Form:** MAIN INFORMED CONSENT - eCRF Audit Trail History

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site Name:** (1013) Clinical Neuroscience Solutions Inc.

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:21

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*I. Consent Was:*

Date	Location	User	Value	Reason
Oct-07-2020 15:43:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Scott Salmon (pfe.ssalmson)	<b>Data Entry:</b> OBTAINED Date Written Consent Obtained  Oct/7/2020	Initial Entry

090177e196ae2f5e\Final\Final On: 01-Apr-2021 03:41 (GMT)

Header Text: c4591001

Visit: COHORT\_SELECTION

Form Version: 15-Sep-2020 21:54

Site No: 1013

Subject No: 10131658

Generated By: pfe.levisse

Form: DEMOGRAPHY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1013) Clinical Neuroscience Solutions Inc.

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:21

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**1. Subject ID**

Date	Location	User	Value	Reason
Oct-07-2020 15:42:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 10131658	Item copied from previous form

**2. Birth Date:**

Date	Location	User	Value	Reason
Oct-07-2020 15:42:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> (b) (6)/1978	Enrollment Entry

**3. Sex:**

Date	Location	User	Value	Reason
Oct-07-2020 15:43:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Scott Salmon (pfe.ssalmon)	<b>Data Entry:</b> MALE	Initial Entry

**4. Ethnicity:**

Date	Location	User	Value	Reason
Oct-07-2020 15:43:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Scott Salmon (pfe.ssalmon)	<b>Data Entry:</b> NOT HISPANIC OR LATINO(A ) OR OF SPANISH ORIGIN	Initial Entry

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

Date	Location	User	Value	Reason
Oct-07-2020 15:43:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Scott Salmon (pfe.ssalmon)	<b>Data Entry:</b> BLACK OR AFRICAN AMERI CAN	Initial Entry

090177e196ae2f5e\Final\Final On: 01-Apr-2021 03:41 (GMT)

**Header Text:** c4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form Version:** 22-Apr-2020 21:02

**Site No:** 1013

**Subject No:** 10131658

**Generated By:** pfe.levisse

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

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site Name:** (1013) Clinical Neuroscience Solutions Inc.

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:21

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*1. Date of Visit*

Date	Location	User	Value	Reason
Oct-07-2020 15:43:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Scott Salmon (pfe.ssalmon)	<b>Data Entry:</b> Oct/7/2020	Initial Entry

090177e196ae2f5e\Final\Final On: 01-Apr-2021 03:41 (GMT)

**Header Text:** c4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form Version:** 15-Sep-2020 21:52

**Site No:** 1013

**Subject No:** 10131658

**Generated By:** pfe.levisse

**Form:** DISPOSITION - SCREENING - eCRF Audit Trail History

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site Name:** (1013) Clinical Neuroscience Solutions Inc.

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:21

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**1. Date of Completion/Discontinuation/Death**

Date	Location	User	Value	Reason
Oct-07-2020 15:44:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Scott Salmon (pfe.ssalmon)	<b>Data Entry:</b> Oct/7/2020	Initial Entry

**2. Phase of Disposition:**

Date	Location	User	Value	Reason
Oct-07-2020 15:44:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SCREENING	Initial Entry

**3. Status:**

Date	Location	User	Value	Reason
Oct-07-2020 15:44:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Scott Salmon (pfe.ssalmon)	<b>Data Entry:</b> COMPLETED	Initial Entry

090177e196ae2f5e\Final\Final On: 01-Apr-2021 03:41 (GMT)



**Header Text:** c4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form Version:** 15-Sep-2020 21:57

**Site No:** 1013

**Subject No:** 10131658

**Generated By:** pfe.levisse

**Form:** HIV STATUS - eCRF Audit Trail History

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site Name:** (1013) Clinical Neuroscience Solutions Inc.

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:21

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

Date	Location	User	Value	Reason
Oct-07-2020 15:46:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Scott Salmon (pfe.ssalmson)	<b>Data Entry:</b> The subject is NOT known to be HIV POSITIVE	Initial Entry

**Header Text:** c4591001**Visit:** V1\_DAY1\_VAX1\_L**Form Version:** 15-Sep-2020 21:56**Site No:** 1013**Subject No:** 10131658**Generated By:** pfe.levisse**Form:** VITAL SIGNS - BASELINE - eCRF Audit Trail History**Form Status:** Data Complete, Locked, Frozen, Verified**Site Name:** (1013) Clinical Neuroscience Solutions Inc.**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 04:21[Back to Form](#)**1. Date:**

Date	Location	User	Value	Reason
Oct-08-2020 15:56:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (pfe.DMW_QUERY)	Query 1: Closed	Auto closed by Validation Check: VC_VS001_02
Oct-08-2020 08:27:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe.mstephens)	Query 1: Answered	Changed data per query
Oct-08-2020 04:53:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (pfe.DMW_QUERY)	Query 1: Opened	DMW4914711;The Vitals 'Date Time' at Visit V1_DAY1_VAX1_L is the same as the other Vitals Date Time at Visit V2_VAX2_L Please review for duplication and update as appropriate.
Oct-07-2020 15:47:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Scott Salmon (pfe.ssalmon)	<b>Data Entry:</b> Oct/7/ 2020	Initial Entry

**2. Weight:**

Date	Location	User	Value	Reason
Oct-07-2020 15:47:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Scott Salmon (pfe.ssalmon)	<b>Data Entry:</b> 76.0	Initial Entry

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 15-Sep-2020 21:56

Site No: 1013

Subject No: 10131658

Generated By: pfe.levisse

Form: VITAL SIGNS - BASELINE - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1013) Clinical Neuroscience Solutions Inc.

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:21

3. Unit:

Date	Location	User	Value	Reason
Oct-07-2020 15:47:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Scott Salmon (pfe.ssalmon)	<b>Data Entry:</b> kg	Initial Entry

4. Height:

Date	Location	User	Value	Reason
Oct-07-2020 15:47:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Scott Salmon (pfe.ssalmon)	<b>Data Entry:</b> 177.5	Initial Entry

5. Unit:

Date	Location	User	Value	Reason
Oct-07-2020 15:47:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Scott Salmon (pfe.ssalmon)	<b>Data Entry:</b> cm	Initial Entry

6. Body Mass Index:

Date	Location	User	Value	Reason
Oct-07-2020 15:47:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 24.1	Initial Entry

7.a

Date	Location	User	Value	Reason
Oct-07-2020 15:47:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Scott Salmon (pfe.ssalmon)	<b>Data Entry:</b> <b>Record Identifier:</b> 1 : <b>Temperature:</b> 36.2 <b>Temperature Unit</b> C : <b>Temperature Loc</b> ORAL CAV <b>ation::</b> ITY	Initial Entry

7.a Record Identifier:

090177e196ae2f5e\Final\Final On: 01-Apr-2021 03:41 (GMT)

**Header Text:** c4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form Version:** 15-Sep-2020 21:56

**Site No:** 1013

**Subject No:** 10131658

**Generated By:** pfe.levisse

**Form:** VITAL SIGNS - BASELINE - eCRF Audit Trail History

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site Name:** (1013) Clinical Neuroscience Solutions Inc.

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:21

Date	Location	User	Value	Reason
Oct-07-2020 15:47:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Scott Salmon (pfe.ssalmon)	<b>Data Entry:</b> 1	Initial Entry

**7.a Temperature:**

Date	Location	User	Value	Reason
Oct-07-2020 15:47:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Scott Salmon (pfe.ssalmon)	<b>Data Entry:</b> 36.2	Initial Entry

**7.a Unit:**

Date	Location	User	Value	Reason
Oct-07-2020 15:47:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Scott Salmon (pfe.ssalmon)	<b>Data Entry:</b> C	Initial Entry

**7.a Temperature Location:**

Date	Location	User	Value	Reason
Oct-07-2020 15:47:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Scott Salmon (pfe.ssalmon)	<b>Data Entry:</b> ORAL CAVITY	Initial Entry

090177e196ae2f5e\Final\Final On: 01-Apr-2021 03:41 (GMT)

**Header Text:** c4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1013

**Subject No:** 10131658

**Generated By:** pfe.levisse

**Form:** RANDOMIZATION - eCRF Audit Trail History

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site Name:** (1013) Clinical Neuroscience Solutions Inc.

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:21

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**1. Randomization Date :**

Date	Location	User	Value	Reason
Oct-07-2020 15:47:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Scott Salmon (pfe.ssalmon)	<b>Data Entry:</b> Oct/7/2020	Initial Entry

**2. Randomization Number:**

Date	Location	User	Value	Reason
Oct-07-2020 15:47:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Scott Salmon (pfe.ssalmon)	<b>Data Entry:</b> 104653	Initial Entry

090177e196ae2f5e\Final\Final On: 01-Apr-2021 03:41 (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: 1013

Site Name: (1013) Clinical Neuroscience Solutions Inc.

Subject No: 10131658

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:21

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**1. Data Origin**

Date	Location	User	Value	Reason
Oct-07-2020 15:47:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SITE	Initial Entry

**2. Sample Type**

Date	Location	User	Value	Reason
Oct-07-2020 15:47:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SERUM	Initial Entry

**3. Sample Collected?**

Date	Location	User	Value	Reason
Oct-07-2020 15:56:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Oct-07-2020 15:47:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Oct-07-2020 15:47:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Scott Salmon (pfe.ssalmon)	<b>Data Entry:</b> YES Date of Collection:  Oct/7/2020	Initial Entry

**5.a**

Date	Location	User	Value	Reason
Oct-07-2020 15:56:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe.mstephens)	<b>Data Entry:</b> Sample ID: BPC2K3	Initial Entry

090177e196ae2f5e\Final\Final On: 01-Apr-2021 03:41 (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: 1013

Site Name: (1013) Clinical Neuroscience Solutions Inc.

Subject No: 10131658

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:21

5.a Sample ID

Date	Location	User	Value	Reason
Oct-07-2020 15:56:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe.mstephens)	<b>Data Entry:</b> BPC2K3	Initial Entry

5.b

Date	Location	User	Value	Reason
Oct-07-2020 15:57:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe.mstephens)	<b>Data Entry:</b> <b>Sample ID:</b> BPC2K4	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Oct-07-2020 15:57:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe.mstephens)	<b>Data Entry:</b> BPC2K4	Initial Entry

5.c

Date	Location	User	Value	Reason
Oct-07-2020 15:57:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe.mstephens)	<b>Data Entry:</b> <b>Sample ID:</b> BPC2K5	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Oct-07-2020 15:57:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe.mstephens)	<b>Data Entry:</b> BPC2K5	Initial Entry

5.d

Date	Location	User	Value	Reason
Oct-07-2020 15:57:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe.mstephens)	<b>Data Entry:</b> <b>Sample ID:</b> BS6ZCY	Initial Entry

090177e196ae2f5e\Final\Final On: 01-Apr-2021 03:41 (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:** 1013

**Site Name:** (1013) Clinical Neuroscience Solutions Inc.

**Subject No:** 10131658

**Subject Initials:** ---

**Generated By:** pfe.levisse

**Generated Time (GMT):** 29-Mar-2021 04:21

**5.d Sample ID**

Date	Location	User	Value	Reason
Oct-07-2020 15:57:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe.mstephens)	<b>Data Entry:</b> BS6ZCY	Initial Entry

**5.e**

Date	Location	User	Value	Reason
Oct-07-2020 15:57:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe.mstephens)	<b>Data Entry:</b> <b>Sample ID:</b> BS6ZCZ	Initial Entry

**5.e Sample ID**

Date	Location	User	Value	Reason
Oct-07-2020 15:57:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe.mstephens)	<b>Data Entry:</b> BS6ZCZ	Initial Entry

090177e196ae2f5e\Final\Final On: 01-Apr-2021 03:41 (GMT)



**Header Text:** c4591001**Visit:** V1\_DAY1\_VAX1\_L**Form Version:** 22-Apr-2020 21:03**Site No:** 1013**Subject No:** 10131658**Generated By:** pfe.levisse**Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB - eCRF  
Audit Trail History**Form Status:** Data Complete, Locked, Frozen, Verified**Site Name:** (1013) Clinical Neuroscience Solutions Inc.**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 04:21[Back to Form](#)**1. Data Origin**

Date	Location	User	Value	Reason
Oct-07-2020 15:48:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SITE	Initial Entry

**2. Sample Type**

Date	Location	User	Value	Reason
Oct-07-2020 15:48:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> NASAL_SWAB	Initial Entry

**3. Sample Collected?**

Date	Location	User	Value	Reason
Oct-07-2020 15:57:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Oct-07-2020 15:48:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Oct-07-2020 15:48:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Scott Salmon (pfe.ssalmon)	<b>Data Entry:</b> YES Date of Collection:  Oct/7/2020	Initial Entry

**5.a**

Date	Location	User	Value	Reason
Oct-07-2020 15:57:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe.mstephens)	<b>Data Entry:</b> <b>Sample ID:</b> BRG2TM	Initial Entry

**Header Text:** c4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1013

**Subject No:** 10131658

**Generated By:** pfe.levisse

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

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site Name:** (1013) Clinical Neuroscience Solutions Inc.

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:21

**5.a Sample ID**

Date	Location	User	Value	Reason
Oct-07-2020 15:57:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe.mstephens)	<b>Data Entry:</b> BRG2TM	Initial Entry

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 22-Apr-2020 21:04

Site No: 1013

Subject No: 10131658

Generated By: pfe.levisse

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1013) Clinical Neuroscience Solutions Inc.

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:21

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**1. Was there a temporary delay of vaccination?**

Date	Location	User	Value	Reason
Oct-07-2020 15:49:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Scott Salmon (pfe.ssalmon)	<b>Data Entry:</b> NO	Initial Entry

**2. Treatment Name**

Date	Location	User	Value	Reason
Oct-07-2020 15:49:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> BLINDED THERAPY	Initial Entry

**3. Formulation:**

Date	Location	User	Value	Reason
Oct-07-2020 15:49:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> INJECTION	Initial Entry

**4. Dose Date Time:**

Date	Location	User	Value	Reason
Oct-07-2020 15:49:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Scott Salmon (pfe.ssalmon)	<b>Data Entry:</b> Oct/7/2020 11:30	Initial Entry

**5. Anatomical Location:**

Date	Location	User	Value	Reason
Oct-07-2020 15:49:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> DELTOID MUSCLE	Initial Entry

**6. Body Side:**

Date	Location	User	Value	Reason
Oct-07-2020 15:49:36 (UTC-05:00) Eastern	ACV0PFEINFP6000	Scott Salmon (pfe.ssalmon)	<b>Data Entry:</b> LEFT	Initial Entry

090177e196ae2f5e\Final\Final On: 01-Apr-2021 03:41 (GMT)

**Header Text:** c4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form Version:** 22-Apr-2020 21:04

**Site No:** 1013

**Subject No:** 10131658

**Generated By:** pfe.levisse

**Form:** VACCINATION - eCRF Audit Trail History

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site Name:** (1013) Clinical Neuroscience Solutions Inc.

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:21

Time (US & Canada)

**7. Route:**

Date	Location	User	Value	Reason
Oct-07-2020 15:49:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> INTRAMUSCULAR	Initial Entry

**10. Timeframe Subject Was Observed**

Date	Location	User	Value	Reason
Oct-07-2020 15:49:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> THE PROTOCOL SPECIFIED O BSERVATION PERIOD	Initial Entry

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

Date	Location	User	Value	Reason
Oct-07-2020 15:49:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Scott Salmon (pfe.ssalmon)	<b>Data Entry:</b> YES	Initial Entry

090177e196ae2f5e\Final\Final On: 01-Apr-2021 03:41 (GMT)

**Header Text:** c4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form Version:** 06-Jul-2020 21:53

**Site No:** 1013

**Subject No:** 10131658

**Generated By:** pfe.lewissc

**Form:** REACTOGENICITY DIARY - eCRF Audit Trail History

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site Name:** (1013) Clinical Neuroscience Solutions Inc.

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:21

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*1. Select appropriate response - Reactogenicity diary collection*

Date	Location	User	Value	Reason
Oct-07-2020 15:49:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Scott Salmon (pfe.ssalmson)	<b>Data Entry:</b> NO - REACTOGENICITY E-DI ARY NOT COLLECTED FOR T HIS SUBJECT	Initial Entry

Header Text: c4591001

Visit: V2\_VAX2\_L

Form Version: 22-Apr-2020 21:02

Site No: 1013

Subject No: 10131658

Generated By: pfe.levissc

Form: DATE OF VISIT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1013) Clinical Neuroscience Solutions Inc.

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:21

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*I. Date of Visit*

Date	Location	User	Value	Reason
Oct-29-2020 09:46:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 3: Clo sed	Close Auto Query
Oct-29-2020 09:45:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Sandip Namdeorao Suryawanshi (pfe.suryas18)	Query 3: Op ened	Erroneous Visit is marked, but date of visit is entered. Please check whether other assessments are performed at this visit.
Oct-28-2020 07:51:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 3: Ca ndidat e	Erroneous Visit is marked, but date of visit is entered. Please check whether other assessments are performed at this visit.
Oct-28-2020 07:51:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe.mstephens)	<b>Data Entry</b> : Oct/2 7/202 0	Transcription Error
Oct-13-2020 02:04:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Swapna Varikuti (pfe.variks)	Query 2: Clo sed	As per site confirmation - updated PD tracker
Oct-12-2020 12:44:46	ACV0PFEINFP6000	Matthew Stephens (pfe.mstephens)	Query 2: An	Original value is correct

090177e196ae2f5e\Final\Final On: 01-Apr-2021 03:41 (GMT)

**Header Text:** c4591001**Visit:** V2\_VAX2\_L**Form Version:** 22-Apr-2020 21:02**Site No:** 1013**Subject No:** 10131658**Generated By:** pfe.levisse**Form:** DATE OF VISIT - eCRF Audit Trail History**Form Status:** Data Complete, Locked, Frozen, Verified**Site Name:** (1013) Clinical Neuroscience Solutions Inc.**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 04:21

(UTC-05:00) Eastern Time (US & Canada)			swere d	
Oct-12-2020 12:11:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	PFE SDQ PROD (pfe.PFESDQ_PROD)	Query 2: Op ened	PDQ: Date of visit at V2_VAX2_L is out of window for -19 days from V1_DAY1_VAX1_L Dose Date. Please verify and update. Else, confirm in query response appropriately. "[cefall01 SDQ=16139]"
Oct-10-2020 06:10:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Roshni Nair (pfe.nairr29)	Query 1: Del eted	No other assessments are performed at this visit.
Oct-08-2020 08:25:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Ca ndidat e	Erroneous Visit is marked, but date of visit is entered. Please check whether other assessments are performed at this visit.
Oct-07-2020 16:01:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Scott Salmon (pfe.ssalmon)	<b>Data Entry</b> : Oct/7/ 2020	Initial Entry

**2. Erroneous Visit**

Date	Location	User	Value	Reason
Oct-29-2020 09:46:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe.mstephens)	<b>Data Entry:</b>	Transcription Error

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

**Form Version:** 22-Apr-2020 21:02

**Site No:** 1013

**Subject No:** 10131658

**Generated By:** pfe.levisse

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

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site Name:** (1013) Clinical Neuroscience Solutions Inc.

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:21

Oct-08-2020 08:25:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe mstephens)	<b>Data Entry:</b> ERRONEOUS VISIT	Initial Entry
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Header Text: c4591001

Visit: V2\_VAX2\_L

Form Version: 15-Sep-2020 21:54

Site No: 1013

Subject No: 10131658

Generated By: pfe.levisse

Form: VITAL SIGNS - TEMP - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1013) Clinical Neuroscience Solutions Inc.

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:21

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**I. Date:**

Date	Location	User	Value	Reason
Oct-27-2020 16:02:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Scott Salmon (pfe.ssalmon)	<b>Data Entry</b> : Oct/27/2020	Initial Entry
Oct-08-2020 15:56:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (pfe.DMW_QUERY)	Query 1: Closed	Auto closed by Validation Check: VC_VS001_02
Oct-08-2020 08:26:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Transcription Error
Oct-08-2020 08:26:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe.mstephens)	<b>Data Entry</b> :	Transcription Error
Oct-08-2020 04:53:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (pfe.DMW_QUERY)	Query 1: Opened	DMW4914714;The Vitals 'Date Time' at Visit V2_VAX2_L is the same as the other Vitals Date Time at Visit V1_DAY1_VAX1_L. Please review for duplication and update as appropriate.
Oct-07-2020 16:01:57	ACV0PFEINFP6000	Scott Salmon (pfe.ssalmon)	<b>Data Entry</b>	Initial Entry

090177e196ae2f5e\Final\Final On: 01-Apr-2021 03:41 (GMT)

Header Text: c4591001

Visit: V2\_VAX2\_L

Form Version: 15-Sep-2020 21:54

Site No: 1013

Subject No: 10131658

Generated By: pfe.levisse

Form: VITAL SIGNS - TEMP - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1013) Clinical Neuroscience Solutions Inc.

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:21

(UTC-05:00) Eastern Time (US & Canada)			:	
			Oct/7/ 2020	

2.a

Date	Location	User	Value	Reason
Oct-27-2020 16:02:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Scott Salmon (pfe.ssalmon)	<b>Data Entry:</b> <b>Record Identifier:</b> 1 <b>Temperature:</b> 36.8 <b>Temperature Unit:</b> C <b>Temperature Location:</b> ORAL CAVITY	Initial Entry
Oct-08-2020 08:26:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe.mstephens)	<b>Data Entry:</b> <b>Record Identifier:</b> 1 <b>Temperature:</b> <b>Temperature Unit:</b> <b>Temperature Location:</b>	Transcription Error
Oct-08-2020 08:26:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe.mstephens)	<b>Data Entry:</b> <b>Record Identifier:</b> 1 <b>Temperature:</b> <b>Temperature Unit:</b> <b>Temperature Location:</b> ORAL CAVITY	Transcription Error
Oct-08-2020 08:26:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe.mstephens)	<b>Data Entry:</b> <b>Record Identifier:</b> 1 <b>Temperature:</b> <b>Temperature Unit:</b> <b>Temperature Location:</b> ORAL CAVITY	Transcription Error
Oct-07-2020 16:01:57 (UTC-05:00) Eastern	ACV0PFEINFP6000	Scott Salmon (pfe.ssalmon)	<b>Data Entry:</b> <b>Record Identifier:</b> 1	Initial Entry

090177e196ae2f5e\Final\Final On: 01-Apr-2021 03:41 (GMT)

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

**Form Version:** 15-Sep-2020 21:54

**Site No:** 1013

**Subject No:** 10131658

**Generated By:** pfe.levisse

**Form:** VITAL SIGNS - TEMP - eCRF Audit Trail History

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site Name:** (1013) Clinical Neuroscience Solutions Inc.

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:21

Time (US & Canada)			<b>r::</b> <b>Temperature:</b> 36.8 <b>Temperature Unit:</b> C <b>Temperature Location:</b> ORAL CAVITY
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**2.a Record Identifier:**

Date	Location	User	Value	Reason
Oct-07-2020 16:01:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Scott Salmon (pfe.ssalmon)	<b>Data Entry:</b> 1	Initial Entry

**2.a Temperature:**

Date	Location	User	Value	Reason
Oct-27-2020 16:02:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Scott Salmon (pfe.ssalmon)	<b>Data Entry:</b> 36.8	Initial Entry
Oct-08-2020 08:26:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe.mstephens)	<b>Data Entry:</b>	Transcription Error
Oct-07-2020 16:01:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Scott Salmon (pfe.ssalmon)	<b>Data Entry:</b> 36.8	Initial Entry

**2.a Unit:**

Date	Location	User	Value	Reason
Oct-27-2020 16:02:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Scott Salmon (pfe.ssalmon)	<b>Data Entry:</b> C	Initial Entry
Oct-08-2020 08:26:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe.mstephens)	<b>Data Entry:</b>	Transcription Error
Oct-07-2020 16:01:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Scott Salmon (pfe.ssalmon)	<b>Data Entry:</b> C	Initial Entry

090177e196ae2f5e\Final\Final On: 01-Apr-2021 03:41 (GMT)

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

**Form Version:** 15-Sep-2020 21:54

**Site No:** 1013

**Subject No:** 10131658

**Generated By:** pfe.levisse

**Form:** VITAL SIGNS - TEMP - eCRF Audit Trail History

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site Name:** (1013) Clinical Neuroscience Solutions Inc.

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:21

**2.a Temperature Location:**

<b>Date</b>	<b>Location</b>	<b>User</b>	<b>Value</b>	<b>Reason</b>
Oct-27-2020 16:02:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Scott Salmon (pfe.ssalmon)	<b>Data Entry:</b> ORAL CAVITY	Initial Entry
Oct-08-2020 08:26:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe.mstephens)	<b>Data Entry:</b>	Transcription Error
Oct-07-2020 16:01:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Scott Salmon (pfe.ssalmon)	<b>Data Entry:</b> ORAL CAVITY	Initial Entry

Header Text: c4591001

Visit: V2\_VAX2\_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1013

Site Name: (1013) Clinical Neuroscience Solutions Inc.

Subject No: 10131658

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:21

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**1. Data Origin**

Date	Location	User	Value	Reason
Oct-27-2020 16:02:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SITE	Initial Entry
Oct-08-2020 08:26:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b>	Transcription Error
Oct-07-2020 16:02:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SITE	Initial Entry

**2. Sample Type**

Date	Location	User	Value	Reason
Oct-27-2020 16:02:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> NASAL_SWAB	Initial Entry
Oct-08-2020 08:26:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b>	Transcription Error
Oct-07-2020 16:02:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> NASAL_SWAB	Initial Entry

**3. Sample Collected?**

Date	Location	User	Value	Reason
Oct-29-2020 09:44:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Sandip Namdeorao Suryawanshi (pfe.suryas18)	Query 2: Closed	Response satisfies query
Oct-28-2020 07:51:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Answered	Answer Auto Query

090177e196ae2f5e\Final\Final On: 01-Apr-2021 03:41 (GMT)

**Header Text:** c4591001**Visit:** V2\_VAX2\_L**Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB - eCRF  
Audit Trail History**Form Version:** 22-Apr-2020 21:03**Form Status:** Data Complete, Locked, Frozen, Verified**Site No:** 1013**Site Name:** (1013) Clinical Neuroscience Solutions Inc.**Subject No:** 10131658**Subject Initials:** ---**Generated By:** pfe.levisse**Generated Time (GMT):** 29-Mar-2021 04:21

Oct-28-2020 01:12:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Gajanan Deshmukh (pfe.deshmg08)	Query 2: Reissued:Opened	DM : DOV form is not frozen at this visit. Date of Collection 27/Oct/2020 is greater than Date of Visit 07/Oct/2020. Please review and update as appropriate, else clarify.
Oct-27-2020 17:13:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 3: Deleted	Close Auto Query
Oct-27-2020 16:18:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe.mstephens)	Query 2: Answered	PLEASE UNLOCK DOV CRF PAGE, SO DATA CAN BE UPDATED
Oct-27-2020 16:02:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 3: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Oct-27-2020 16:02:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Opened	Date of Collection 27/Oct/2020 is greater than Date of Visit 07/Oct/2020. Please review and update as appropriate, else clarify.
Oct-27-2020 16:02:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Scott Salmon (pfe.ssalmon)	<b>Data Entry:</b> YES Date of Collection:  Oct/27/2020	Initial Entry
Oct-08-2020 08:26:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe.mstephens)	<b>Data Entry:</b>	Transcription Error

**Header Text:** c4591001**Visit:** V2\_VAX2\_L**Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB - eCRF  
Audit Trail History**Form Version:** 22-Apr-2020 21:03**Form Status:** Data Complete, Locked, Frozen, Verified**Site No:** 1013**Site Name:** (1013) Clinical Neuroscience Solutions Inc.**Subject No:** 10131658**Subject Initials:** ---**Generated By:** pfe.levisse**Generated Time (GMT):** 29-Mar-2021 04:21

Oct-08-2020 08:17:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Oct-08-2020 03:05:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Roshni Nair (pfe nairr29)	Query 1: Opened	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Oct-07-2020 16:02:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Oct-07-2020 16:02:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Scott Salmon (pfe.ssalmon)	<b>Data Entry:</b> YES Date of Collection:  Oct/7/2020	Initial Entry

**5.a**

Date	Location	User	Value	Reason
Oct-27-2020 17:13:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Scott Salmon (pfe.ssalmon)	<b>Data Entry:</b> <b>Sample ID:</b> BR9TJL	Initial Entry
Oct-08-2020 08:26:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe mstephens)	<b>Data Entry:</b> <b>Sample ID:</b>	Transcription Error
Oct-08-2020 08:17:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe mstephens)	<b>Data Entry:</b> <b>Sample ID:</b> BRG2TM	Initial Entry

**5.a Sample ID**

Date	Location	User	Value	Reason
Oct-27-2020 17:13:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Scott Salmon (pfe.ssalmon)	<b>Data Entry:</b> BR9TJL	Initial Entry

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

**Form Version:** 22-Apr-2020 21:03

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site No:** 1013

**Site Name:** (1013) Clinical Neuroscience Solutions Inc.

**Subject No:** 10131658

**Subject Initials:** ---

**Generated By:** pfe.levisse

**Generated Time (GMT):** 29-Mar-2021 04:21

Oct-08-2020 08:26:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe mstephens)	<b>Data Entry:</b>	Transcription Error
Oct-08-2020 08:17:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe mstephens)	<b>Data Entry:</b> BRG2TM	Initial Entry



Header Text: c4591001

Visit: V2\_VAX2\_L

Form Version: 22-Apr-2020 21:04

Site No: 1013

Subject No: 10131658

Generated By: pfe.levisse

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1013) Clinical Neuroscience Solutions Inc.

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:21

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**1. Was there a temporary delay of vaccination?**

Date	Location	User	Value	Reason
Oct-27-2020 16:03:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Scott Salmon (pfe.ssalmson)	<b>Data Entry:</b> NO	Initial Entry
Oct-08-2020 08:27:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe.mstephens)	<b>Data Entry:</b>	Transcription Error
Oct-07-2020 16:03:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Scott Salmon (pfe.ssalmson)	<b>Data Entry:</b> NO	Initial Entry

**2. Treatment Name**

Date	Location	User	Value	Reason
Oct-27-2020 16:03:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> BLINDED THERAPY	Initial Entry
Oct-08-2020 08:27:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b>	Transcription Error
Oct-07-2020 16:03:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> BLINDED THERAPY	Initial Entry

**3. Formulation:**

Date	Location	User	Value	Reason
Oct-27-2020 16:03:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> INJECTION	Initial Entry
Oct-08-2020 08:27:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b>	Transcription Error
Oct-07-2020 16:03:19 (UTC-05:00) Eastern	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> INJECTION	Initial Entry

090177e196ae2f5e\Final\Final On: 01-Apr-2021 03:41 (GMT)

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

**Form Version:** 22-Apr-2020 21:04

**Site No:** 1013

**Subject No:** 10131658

**Generated By:** pfe.levisse

**Form:** VACCINATION - eCRF Audit Trail History

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site Name:** (1013) Clinical Neuroscience Solutions Inc.

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:21

Time (US & Canada)

**4. Dose Date Time:**

Date	Location	User	Value	Reason
Oct-29-2020 09:44:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Sandip Namdeorao Suryawanshi (pfe.suryas18)	Query 1: Closed	Response satisfies query
Oct-28-2020 07:51:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Answer Auto Query
Oct-28-2020 05:31:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Swetha Thangellapally (pfe.thangs22)	Query 1: Reissued:Opened	DM1: Per response DOV CRF is unfreeze. Kindly amend data as appropriate. Thanks.
Oct-27-2020 16:18:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe.mstephens)	Query 1: Answered	PLEASE UNLOCK DOV CRF PAGE SO DATA CAN BE UPDATED
Oct-27-2020 16:03:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	Dose Date is not equal to Date of Visit 07/Oct/2020 of the corresponding Visit. Please review and update as appropriate.
Oct-27-2020 16:03:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Scott Salmon (pfe.ssalmon)	<b>Data Entry:</b> Oct/27/2020 13:52	Initial Entry
Oct-08-2020 08:27:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe.mstephens)	<b>Data Entry:</b>	Transcription Error
Oct-07-2020 16:03:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Scott Salmon (pfe.ssalmon)	<b>Data Entry:</b> Oct/7/2020 14:35	Initial Entry

090177e196ae2f5e\Final\Final On: 01-Apr-2021 03:41 (GMT)

Header Text: c4591001

Visit: V2\_VAX2\_L

Form Version: 22-Apr-2020 21:04

Site No: 1013

Subject No: 10131658

Generated By: pfe.levisse

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1013) Clinical Neuroscience Solutions Inc.

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:21

5. Anatomical Location:

Date	Location	User	Value	Reason
Oct-27-2020 16:03:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> DELTOID MUSCLE	Initial Entry
Oct-08-2020 08:27:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b>	Transcription Error
Oct-07-2020 16:03:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> DELTOID MUSCLE	Initial Entry

6. Body Side:

Date	Location	User	Value	Reason
Oct-27-2020 16:03:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Scott Salmon (pfe.ssalmon)	<b>Data Entry:</b> LEFT	Initial Entry
Oct-08-2020 08:27:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe.mstephens)	<b>Data Entry:</b>	Transcription Error
Oct-07-2020 16:03:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Scott Salmon (pfe.ssalmon)	<b>Data Entry:</b> LEFT	Initial Entry

7. Route:

Date	Location	User	Value	Reason
Oct-27-2020 16:03:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> INTRAMUSCULAR	Initial Entry
Oct-08-2020 08:27:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b>	Transcription Error
Oct-07-2020 16:03:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> INTRAMUSCULAR	Initial Entry

10. Timeframe Subject Was Observed

090177e196ae2f5e\Final\Final On: 01-Apr-2021 03:41 (GMT)

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

**Form Version:** 22-Apr-2020 21:04

**Site No:** 1013

**Subject No:** 10131658

**Generated By:** pfe.levisse

**Form:** VACCINATION - eCRF Audit Trail History

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site Name:** (1013) Clinical Neuroscience Solutions Inc.

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:21

Date	Location	User	Value	Reason
Oct-27-2020 16:03:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> THE PROTOCOL SPECIFIED O BSERVATION PERIOD	Initial Entry
Oct-08-2020 08:27:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b>	Transcription Error
Oct-07-2020 16:03:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> THE PROTOCOL SPECIFIED O BSERVATION PERIOD	Initial Entry

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

Date	Location	User	Value	Reason
Oct-27-2020 16:03:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Scott Salmon (pfe.ssalmon)	<b>Data Entry:</b> YES	Initial Entry
Oct-08-2020 08:27:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe.mstephens)	<b>Data Entry:</b>	Transcription Error
Oct-07-2020 16:03:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Scott Salmon (pfe.ssalmon)	<b>Data Entry:</b> YES	Initial Entry

090177e196ae2f5e\Final\Final On: 01-Apr-2021 03:41 (GMT)

**Header Text:** c4591001

**Visit:** V3\_MONTH1\_POSTVAX2\_L

**Form Version:** 22-Apr-2020 21:02

**Site No:** 1013

**Subject No:** 10131658

**Generated By:** pfe.levissc

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

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site Name:** (1013) Clinical Neuroscience Solutions Inc.

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:21

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*1. Date of Visit*

Date	Location	User	Value	Reason
Nov-24-2020 15:42:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Scott Salmon (pfe.ssalmon)	<b>Data Entry:</b> Nov/24/2020	Initial Entry

**Header Text:** c4591001

**Visit:** V3\_MONTH1\_POSTVAX2\_L

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

**Form Version:** 22-Apr-2020 21:03

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site No:** 1013

**Site Name:** (1013) Clinical Neuroscience Solutions Inc.

**Subject No:** 10131658

**Subject Initials:** ---

**Generated By:** pfe.levisse

**Generated Time (GMT):** 29-Mar-2021 04:21

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**1. Data Origin**

Date	Location	User	Value	Reason
Nov-24-2020 15:42:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SITE	Initial Entry

**2. Sample Type**

Date	Location	User	Value	Reason
Nov-24-2020 15:42:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SERUM	Initial Entry

**3. Sample Collected?**

Date	Location	User	Value	Reason
Nov-24-2020 17:39:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Nov-24-2020 15:42:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Nov-24-2020 15:42:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Scott Salmon (pfe.ssalmon)	<b>Data Entry:</b> YES Date of Collection:  Nov/24/2020	Initial Entry

**5.a**

Date	Location	User	Value	Reason
Nov-24-2020 17:39:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Scott Salmon (pfe.ssalmon)	<b>Data Entry:</b> Sample ID: BRHW2M	Initial Entry

090177e196ae2f5e\Final\Final On: 01-Apr-2021 03:41 (GMT)

Header Text: c4591001

Visit: V3\_MONTH1\_POSTVAX2\_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1013

Site Name: (1013) Clinical Neuroscience Solutions Inc.

Subject No: 10131658

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:21

5.a Sample ID

Date	Location	User	Value	Reason
Nov-24-2020 17:39:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Scott Salmon (pfe.ssalmon)	<b>Data Entry:</b> BRHW2M	Initial Entry

5.b

Date	Location	User	Value	Reason
Nov-24-2020 17:39:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Scott Salmon (pfe.ssalmon)	<b>Data Entry:</b> <b>Sample ID:</b> BRHW2N	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Nov-24-2020 17:39:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Scott Salmon (pfe.ssalmon)	<b>Data Entry:</b> BRHW2N	Initial Entry

5.c

Date	Location	User	Value	Reason
Nov-24-2020 17:39:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Scott Salmon (pfe.ssalmon)	<b>Data Entry:</b> <b>Sample ID:</b> BRHW2P	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Nov-24-2020 17:39:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Scott Salmon (pfe.ssalmon)	<b>Data Entry:</b> BRHW2P	Initial Entry

5.d

Date	Location	User	Value	Reason
Nov-24-2020 17:40:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Scott Salmon (pfe.ssalmon)	<b>Data Entry:</b> <b>Sample ID:</b> BS0JH2	Initial Entry

090177e196ae2f5e\Final\Final On: 01-Apr-2021 03:41 (GMT)

**Header Text:** c4591001

**Visit:** V3\_MONTH1\_POSTVAX2\_L

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

**Form Version:** 22-Apr-2020 21:03

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site No:** 1013

**Site Name:** (1013) Clinical Neuroscience Solutions Inc.

**Subject No:** 10131658

**Subject Initials:** ---

**Generated By:** pfe.levisse

**Generated Time (GMT):** 29-Mar-2021 04:21

**5.d Sample ID**

Date	Location	User	Value	Reason
Nov-24-2020 17:40:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Scott Salmon (pfe.ssalmon)	<b>Data Entry:</b> BS0JH2	Initial Entry

**5.e**

Date	Location	User	Value	Reason
Nov-24-2020 17:40:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Scott Salmon (pfe.ssalmon)	<b>Data Entry:</b> <b>Sample ID:</b> BS0JH3	Initial Entry

**5.e Sample ID**

Date	Location	User	Value	Reason
Nov-24-2020 17:40:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Scott Salmon (pfe.ssalmon)	<b>Data Entry:</b> BS0JH3	Initial Entry



**Header Text:** c4591001

**Visit:** Logs - Unscheduled

**Form Version:** 22-Apr-2020 21:02

**Site No:** 1013

**Subject No:** 10131658

**Generated By:** pfe.levissc

**Form:** ADVERSE EVENT REPORT - Audit Trail

**Form Status:**

**Site Name:** (1013) Clinical Neuroscience Solutions Inc.

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:21

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Date	Location	User	Value	Reason
Nov-24-2020 15:45:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Scott Salmon (pfe.ssalmon)	Form Created	

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1013

Subject No: 10131658

Generated By: pfe.levisse

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Frozen

Site Name: (1013) Clinical Neuroscience Solutions Inc.

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:21

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**1. Category:**

Date	Location	User	Value	Reason
Nov-24-2020 15:45:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> ADVERSE EVENT	Initial Entry

**2. AE ID:**

Date	Location	User	Value	Reason
Nov-24-2020 15:45:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 1	Initial Entry

**3. Adverse Event:**

*(If possible specify diagnosis, not individual symptoms)*

Date	Location	User	Value	Reason
Nov-24-2020 15:45:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Scott Salmon (pfe.ssalmon)	<b>Data Entry:</b> LYMPH NODE SWELLING LE FT AUXILLARY	Initial Entry

**4. Start Date Time:**

Date	Location	User	Value	Reason
Nov-24-2020 15:45:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Scott Salmon (pfe.ssalmon)	<b>Data Entry:</b> Oct/28/2020 18:00	Initial Entry

**5. Is the adverse event still ongoing?**

Date	Location	User	Value	Reason
Nov-24-2020 15:45:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Scott Salmon (pfe.ssalmon)	<b>Data Entry:</b> NO End Date Time:  Oct/30/2020 08:00	Initial Entry

**6. Toxicity Grade:**

Date	Location	User	Value	Reason
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090177e196ae2f5e\Final\Final On: 01-Apr-2021 03:41 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1013

Subject No: 10131658

Generated By: pfe.levisse

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Frozen

Site Name: (1013) Clinical Neuroscience Solutions Inc.

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:21

Nov-24-2020 15:45:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Scott Salmon (pfe.ssalmon)	<b>Data Entry:</b> 1	Initial Entry
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**7. Is the adverse event serious?**

**If Yes, NOTIFY PFIZER IMMEDIATELY.**

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

Date	Location	User	Value	Reason
Nov-24-2020 15:45:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Scott Salmon (pfe.ssalmon)	<b>Data Entry:</b> 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-24-2020 15:45:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Scott Salmon (pfe.ssalmon)	<b>Data Entry:</b> NO	Initial Entry

**9. Is this event related to study treatment:**

Date	Location	User	Value	Reason
Nov-24-2020 15:45:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Scott Salmon (pfe.ssalmon)	<b>Data Entry:</b> RELATED	Initial Entry

**10. Latest Action Taken with Study Treatment:**

Date	Location	User	Value	Reason
Nov-24-2020 15:45:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Scott Salmon (pfe.ssalmon)	<b>Data Entry:</b> NOT APPLICABLE	Initial Entry

**11. Was a Concomitant Medication given?**

Date	Location	User	Value	Reason
Nov-24-2020 15:45:38	ACV0PFEINFP6000	Scott Salmon	<b>Data Entry:</b>	Initial Entry

090177e196ae2f5e\Final\Final On: 01-Apr-2021 03:41 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

**Form Version:** 22-Apr-2020 21:02

**Site No:** 1013

**Subject No:** 10131658

**Generated By:** pfe.levisse

**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History

**Form Status:** Data Complete, Frozen

**Site Name:** (1013) Clinical Neuroscience Solutions Inc.

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:21

(UTC-05:00) Eastern  
Time (US & Canada)

(pfe.ssalmon) NO

**12. Was a Non-Drug Treatment given?**

Date	Location	User	Value	Reason
Nov-24-2020 15:45:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Scott Salmon (pfe.ssalmon)	<b>Data Entry:</b> NO	Initial Entry

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

Date	Location	User	Value	Reason
Nov-24-2020 15:45:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Scott Salmon (pfe.ssalmon)	<b>Data Entry:</b> RECOVERED/RESOLVED	Initial Entry

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

Date	Location	User	Value	Reason
Nov-24-2020 15:45:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Scott Salmon (pfe.ssalmon)	<b>Data Entry:</b> NO	Initial Entry

090177e196ae2f5e\Final\Final On: 01-Apr-2021 03:41 (GMT)

**Header Text:** c4591001

**Visit:** End of Treatment - Unscheduled

**Form:** DISPOSITION - TREATMENT - eCRF Audit Trail History

**Form Version:** 15-Sep-2020 21:55

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1013

**Site Name:** (1013) Clinical Neuroscience Solutions Inc.

**Subject No:** 10131658

**Subject Initials:** ---

**Generated By:** pfe.levissc

**Generated Time (GMT):** 29-Mar-2021 04:21

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**1. Date of Completion/Discontinuation/Death :**

Date	Location	User	Value	Reason
Nov-24-2020 15:43:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Scott Salmon (pfe.ssalmon)	<b>Data Entry:</b> Nov/24/2020	Initial Entry

**2. Phase of Disposition:**

Date	Location	User	Value	Reason
Nov-24-2020 15:43:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> VACCINATION	Initial Entry

**3. Status:**

Date	Location	User	Value	Reason
Nov-24-2020 15:43:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Scott Salmon (pfe.ssalmon)	<b>Data Entry:</b> COMPLETED	Initial Entry

090177e196ae2f5e\Final\Final On: 01-Apr-2021 03:41 (GMT)

**Header Text:** c4591001

**Visit:** Potential ReVax Initial Contact -  
Unscheduled

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

**Form Version:** 22-Apr-2020 21:02

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1013

**Site Name:** (1013) Clinical Neuroscience Solutions Inc.

**Subject No:** 10131658

**Subject Initials:** ---

**Generated By:** pfe.lewissc

**Generated Time (GMT):** 29-Mar-2021 04:21

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*1. Date of Visit*

Date	Location	User	Value	Reason
Feb-12-2021 11:55:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Monica Cooper (pfe.mcooper)	<b>Data Entry:</b> Feb/9/2021	Initial Entry

**Header Text:** c4591001

**Visit:** Potential ReVax Initial Contact -  
Unscheduled

**Form Version:** 10-Dec-2020 02:25

**Site No:** 1013

**Subject No:** 10131658

**Generated By:** pfe.levisse

**Form:** FURTHER VACCINATION CONFIRMATION - eCRF Audit  
Trail History

**Form Status:** Data Complete, Frozen

**Site Name:** (1013) Clinical Neuroscience Solutions Inc.

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:21

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

Date	Location	User	Value	Reason
Feb-12-2021 11:56:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Feb-12-2021 11:55:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	The response indicates participant was unblinded, however the TREATMENT UNBLINDED date is missing in the DISP visit. Please complete this date.
Feb-12-2021 11:55:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Monica Cooper (pfe.mcooper)	<b>Data Entry:</b> Participant is willing to return f or Vaccination 3 Participant is:  eligible and NOT confirmed to have received only placeb o at Vaccination 1/2	Initial Entry

090177e196ae2f5e\Final\Final On: 01-Apr-2021 03:41 (GMT)

**Header Text:** c4591001

**Visit:** Disposition - Unscheduled

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1013

**Subject No:** 10131658

**Generated By:** pfe.levissc

**Form:** TREATMENT UNBLINDED - eCRF Audit Trail History

**Form Status:** Data Complete, Frozen, Verified

**Site Name:** (1013) Clinical Neuroscience Solutions Inc.

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:21

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**1. Date Treatment Unblinded :**

Date	Location	User	Value	Reason
Feb-12-2021 11:56:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Monica Cooper (pfe.mcooper)	<b>Data Entry:</b> Feb/9/2021	Initial Entry

**2. Primary Reason for Unblinding:**

Date	Location	User	Value	Reason
Feb-12-2021 11:56:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Monica Cooper (pfe.mcooper)	<b>Data Entry:</b> ASSESS ELIGIBILITY FOR A DDITIONAL VACCINATION	Initial Entry

090177e196ae2f5e\Final\Final On: 01-Apr-2021 03:41 (GMT)



**Header Text:** c4591001

**Visit:** Subject Status - Unscheduled

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1013

**Subject No:** 10131658

**Generated By:** pfe.levissc

**Form:** SUBJECT STATUS - eCRF Audit Trail History

**Form Status:** Data Complete, Verified

**Site Name:** (1013) Clinical Neuroscience Solutions Inc.

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:21

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**1. Subject Status**

Date	Location	User	Value	Reason
Nov-24-2020 15:43:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> FOLLOW-UP	Initial Entry
Oct-07-2020 15:47:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> ENROLLED/RANDOMIZED	Initial Entry
Oct-07-2020 15:44:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SCREENED	Initial Entry

**2. Subject Status Date**

Date	Location	User	Value	Reason
Nov-24-2020 15:43:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> Nov/24/2020	Initial Entry
Oct-07-2020 15:47:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> Oct/7/2020	Initial Entry
Oct-07-2020 15:44:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> Oct/7/2020	Initial Entry

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**Visit:** Investigator Signature - Unscheduled

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**Form Version:** 22-Apr-2020 21:04

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**Site No:** 1013

**Site Name:** (1013) Clinical Neuroscience Solutions Inc.

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Date	Location	User	Value	Reason
Oct-07-2020 15:53:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe.mstephens)	<b>Data Entry:</b> Click Here to Enable	Initial Entry