

Header Text: c4591001

Visit: COHORT_SELECTION

Form: COHORT_SELECTION

Form Version: 30-Jul-2020 21:29

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1013

Site Name: (1013) Clinical Neuroscience Solutions Inc.

Subject No: 10131386

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	24 JUL 2020
2.	Select appropriate response - What cohort does the subject belong to?	STAGE 3 COHORTS

Header Text: c4591001

Visit: COHORT_SELECTION

Form: MAIN INFORMED CONSENT

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1013

Site Name: (1013) Clinical Neuroscience Solutions Inc.

Subject No: 10131386

Subject Initials: ---

Generated By: pfe.levissc

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

[eCRF Audit Trail History](#)

Informed Consent

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

Visit: COHORT_SELECTION

Form: DEMOGRAPHY

Form Version: 06-Jul-2020 21:55

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1013

Site Name: (1013) Clinical Neuroscience Solutions Inc.

Subject No: 10131386

Subject Initials: ---

Generated By: pfe.levissc

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

[eCRF Audit Trail History](#)

Demography

1.	Subject ID	[10131386]
2.	Birth Date:	(b) (6) 1960
3.	Sex:	MALE
4.	Ethnicity:	NOT HISPANIC OR LATINO(A) OR OF SPANISH ORIGIN
5.	Race: (Check X all that apply):	WHITE
6.	Racial Designation:	

090177e196ae2f60\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: 10131386

Generated By: pfe.levisse

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	Sep/1/2020
2.	Erroneous Visit	

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 30-Jul-2020 21:29

Site No: 1013

Subject No: 10131386

Generated By: pfe.levisse

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

Exclusion Criteria Met

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

090177e196ae2f60\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: 10131386

Generated By: pfe.levissc

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	Sep/1/2020
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: 10131386

Generated By: pfe.levissc

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

[eCRF Audit Trail History](#)

Medical History Details

1.a	Line/MH Number:	[1]
	Disease/Syndrome /Surgery/Non-Drug Allergies/Drug Allergies:	[RIGHT KNEE ACL REPAIR]
	Start Date:	UNK/UNK/1980
	Ongoing:	NO End Date: UNK/UNK/1980
1.b	Line/MH Number:	[2]
	Disease/Syndrome /Surgery/Non-Drug Allergies/Drug Allergies:	[ACL TEAR RIGHT KNEE]
	Start Date:	UNK/UNK/1978
	Ongoing:	NO End Date: UNK/UNK/1980

090177e196ae2f60\Final\Final On: 01-Apr-2021 03:41 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 21-Aug-2020 02:51

Site No: 1013

Subject No: 10131386

Generated By: pfe.levissc

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:	Sep/1/2020
2.	Weight:	[96.8]
3.	Unit:	kg
4.	Height:	[187.9]
5.	Unit:	cm
6.	Body Mass Index:	[27.4]

Vital Signs Details

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

090177e196ae2f60\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: 10131386

Generated By: pfe.levissc

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 :	Sep/1/2020
2.	Randomization Number:	[248165]
3.	Randomization Group:	[]

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1013

Site Name: (1013) Clinical Neuroscience Solutions Inc.

Subject No: 10131386

Subject Initials: ---

Generated By: pfe.levisse

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: Sep/1/2020
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	[BPC3NM]
5.b	Sample ID	[BPC3NN]
5.c	Sample ID	[BPC3NP]
5.d	Sample ID	[BMN519]
5.e	Sample ID	[BMN51B]

090177e196ae2f60\Final\Final On: 01-Apr-2021 03:41 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1013

Site Name: (1013) Clinical Neuroscience Solutions Inc.

Subject No: 10131386

Subject Initials: ---

Generated By: pfe.levisse

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: Sep/1/2020
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	[BN6241]
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090177e196ae2f60\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: 10131386

Generated By: pfe.levissc

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:	Sep/1/2020 10:50
5.	Anatomical Location:	DELTOID MUSCLE
6.	Body Side:	RIGHT
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

090177e196ae2f60\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: 10131386

Generated By: pfe.lewissc

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: DATE OF VISIT

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1013

Site Name: (1013) Clinical Neuroscience Solutions Inc.

Subject No: 10131386

Subject Initials: ---

Generated By: pfe.levisse

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

[eCRF Audit Trail History](#)

Date of Visit

1.	Date of Visit	Sep/22/2020
2.	Erroneous Visit	

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 15-Sep-2020 21:54

Site No: 1013

Subject No: 10131386

Generated By: pfe.levissc

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:	Sep/22/2020
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Vital Signs Details

2.a	Record Identifier:	1
	Temperature:	[36.7]
	Unit:	C
	Temperature Location:	ORAL CAVITY

090177e196ae2f60\Final\Final On: 01-Apr-2021 03:41 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1013

Site Name: (1013) Clinical Neuroscience Solutions Inc.

Subject No: 10131386

Subject Initials: ---

Generated By: pfe.levissc

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: Sep/22/2020
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	[BPC33S]
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090177e196ae2f60\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: 10131386

Generated By: pfe.levissc

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:	Sep/22/2020 09:55
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

090177e196ae2f60\Final\Final On: 01-Apr-2021 03:41 (GMT)

Header Text: c4591001

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

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

Site No: 1013 **Site Name:** (1013) Clinical Neuroscience Solutions Inc.

Subject No: 10131386 **Subject Initials:** ---

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

[eCRF Audit Trail History](#)

Date of Visit

1.	Date of Visit	Oct/20/2020
2.	Erroneous Visit	

Header Text: c4591001

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

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

Site No: 1013 **Site Name:** (1013) Clinical Neuroscience Solutions Inc.

Subject No: 10131386 **Subject Initials:** ---

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

Aliquot

Please enter barcode for each aliquot.

5.a	Sample ID	[BRC8FV]
5.b	Sample ID	[BRC8FW]
5.c	Sample ID	[BRC8FX]
5.d	Sample ID	[BMN5HW]
5.e	Sample ID	[BMN5HX]

090177e196ae2f60\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: 10131386

Generated By: pfe.levisse

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: 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: 10131386

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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090177e196ae2f60\Final\Final On: 01-Apr-2021 03:41 (GMT)

Header Text: c4591001

Visit: V5_MONTH12_L

Form Version: 22-Apr-2020 21:02

Site No: 1013

Subject No: 10131386

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: 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: 10131386

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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090177e196ae2f60\Final\Final On: 01-Apr-2021 03:41 (GMT)

Header Text: c4591001

Visit: V6_MONTH24_L

Form Version: 22-Apr-2020 21:02

Site No: 1013

Subject No: 10131386

Generated By: pfe.lewissc

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: 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: 10131386

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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090177e196ae2f60\Final\Final On: 01-Apr-2021 03:41 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL - New
Unscheduled Visit

Form: DATE OF VISIT - ILLNESS ONSET

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1013

Site Name: (1013) Clinical Neuroscience Solutions Inc.

Subject No: 10131386

Subject Initials: ---

Generated By: pfe.lewissc

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_ILL - New
Unscheduled Visit

Form Version: 20-Feb-2021 02:17

Site No: 1013

Subject No: 10131386

Generated By: pfe.levisse

Form: SIGNS AND SYMPTOMS OF POTENTIAL
COVID-19

Form Status: Not Started

Site Name: (1013) Clinical Neuroscience Solutions Inc.

Subject Initials: ---

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

090177e196ae2f60\Final\Final On: 01-Apr-2021 03:41 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL - New
Unscheduled Visit

Form Version: 22-Apr-2020 21:03

Site No: 1013

Subject No: 10131386

Generated By: pfe.levissc

Form: ELECTRONIC SAMPLE TRACKING - NASAL
SWAB SELF

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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090177e196ae2f60\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: 10131386

Subject Initials: ---

Generated By: pfe.lewissc

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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090177e196ae2f60\Final\Final On: 01-Apr-2021 03:41 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL - New
Unscheduled Visit

Form: HEALTH CARE UTILIZATION

Form Version: 20-Feb-2021 02:19

Form Status: Not Started

Site No: 1013

Site Name: (1013) Clinical Neuroscience Solutions Inc.

Subject No: 10131386

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?	
----	--	--

090177e196ae2f60\Final\Final On: 01-Apr-2021 03:41 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL - New
Unscheduled Visit

Form: ILLNESS DETAILS

Form Version: 06-Jul-2020 21:52

Form Status: Not Started

Site No: 1013

Site Name: (1013) Clinical Neuroscience Solutions Inc.

Subject No: 10131386

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: 10131386

Subject Initials: ---

Generated By: pfe.lewissc

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: 10131386

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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090177e196ae2f60\Final\Final On: 01-Apr-2021 03:41 (GMT)

Header Text: c4591001

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

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

Site No: 1013

Site Name: (1013) Clinical Neuroscience Solutions Inc.

Subject No: 10131386

Subject Initials: ---

Generated By: pfe.lewissc

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: 10131386 **Subject Initials:** ---

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

Unplanned Assessments

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

090177e196ae2f60\Final\Final On: 01-Apr-2021 03:41 (GMT)

Header Text: c4591001

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

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

Site No: 1013

Site Name: (1013) Clinical Neuroscience Solutions Inc.

Subject No: 10131386

Subject Initials: ---

Generated By: pfe.levisse

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

[eCRF Audit Trail History](#)

Disposition - Treatment

1.	Date of Completion/Discontinuation/Death :	Oct/20/2020
2.	Phase of Disposition:	VACCINATION
3.	Status:	COMPLETED
4.	Specify Status:	[]

Header Text: c4591001

Visit: Follow-Up - Unscheduled

Form: DISPOSITION - FOLLOW-UP

Form Version: 15-Sep-2020 21:53

Form Status: Not Started

Site No: 1013

Site Name: (1013) Clinical Neuroscience Solutions Inc.

Subject No: 10131386

Subject Initials: ---

Generated By: pfe.levisse

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

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

Site No: 1013

Site Name: (1013) Clinical Neuroscience Solutions Inc.

Subject No: 10131386

Subject Initials: ---

Generated By: pfe.lewissc

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:	
----	-----------------------	--

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: 10131386 **Subject Initials:** ---

Generated By: pfe.levisse **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	[]
----	-----------	-----

090177e196ae2f60\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: 10131386

Generated By: pfe.levissc

Form: ADVERSE EVENT REPORT

Form Status: Not Started

Site Name: (1013) Clinical Neuroscience Solutions Inc.

Subject Initials: ---

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

Adverse Event Report

1.	Category:	
2.	AE ID:	[]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[]
4.	Start Date Time:	//
5.	Is the adverse event still ongoing?	
6.	Toxicity Grade:	
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).	

090177e196ae2f60\Final\Final On: 01-Apr-2021 03:41 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT

Form Version: 22-Apr-2020 21:02

Form Status: Not Started

Site No: 1013

Site Name: (1013) Clinical Neuroscience Solutions Inc.

Subject No: 10131386

Subject Initials: ---

Generated By: pfe.lewissc

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

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.	
9.	Is this event related to study treatment:	
10.	Latest Action Taken with Study Treatment:	
11.	Was a Concomitant Medication given?	
12.	Was a Non-Drug Treatment given?	
13.	What was the outcome of this adverse event?:	
14.	Did the adverse event cause the subject to be discontinued from the study?	
15.	Serious Adverse Event Number: For Pfizer Use Only	[]

090177e196ae2f60\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: 10131386

Subject Initials: ---

Generated By: pfe.levissc

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.						Repeating Pages

Header Text: c4591001

Visit: Logs - Unscheduled

Form: MEDICATION ERROR

Form Version: 17-Jul-2020 21:54

Form Status: Not Started

Site No: 1013

Site Name: (1013) Clinical Neuroscience Solutions Inc.

Subject No: 10131386

Subject Initials: ---

Generated By: pfe.levisse

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

[Back to Form](#)

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	[]

090177e196ae2f60\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: 10131386

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.						Repeating Pages

Header Text: c4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - NON STUDY VACCINATIONS

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1013

Site Name: (1013) Clinical Neuroscience Solutions Inc.

Subject No: 10131386

Subject Initials: ---

Generated By: pfe.lewissc

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

[Back to Form](#)

Concomitant Medications

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

090177e196ae2f60\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: 10131386

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.						Repeating Pages

Header Text: c4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - PROHIBITED

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1013

Site Name: (1013) Clinical Neuroscience Solutions Inc.

Subject No: 10131386

Subject Initials: ---

Generated By: pfe.lewissc

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

[Back to Form](#)

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?	

090177e196ae2f60\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: 10131386

Subject Initials: ---

Generated By: pfe.levissc

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

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

Header Text: c4591001

Visit: Logs - Unscheduled

Form: RADIATION TREATMENT

Form Version: 22-Apr-2020 21:02

Form Status: Not Started

Site No: 1013

Site Name: (1013) Clinical Neuroscience Solutions Inc.

Subject No: 10131386

Subject Initials: ---

Generated By: pfe.levisse

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

[Back to Form](#)

Radiation Treatment

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

090177e196ae2f60\Final\Final On: 01-Apr-2021 03:41 (GMT)

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: 10131386

Subject Initials: ---

Generated By: pfe.levissc

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

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

Header Text: c4591001

Visit: Logs - Unscheduled

Form: TRANSFUSIONS

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1013

Site Name: (1013) Clinical Neuroscience Solutions Inc.

Subject No: 10131386

Subject Initials: ---

Generated By: pfe.levisse

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

[Back to Form](#)

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

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: 10131386

Subject Initials: ---

Generated By: pfe.lewissc

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: 10131386

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:	

090177e196ae2f60\Final\Final On: 01-Apr-2021 03:41 (GMT)

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: 10131386

Subject Initials: ---

Generated By: pfe.levisse

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?	

090177e196ae2f60\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: 10131386

Subject Initials: ---

Generated By: pfe.lewissc

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: 10131386

Subject Initials: ---

Generated By: pfe.lewissc

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 - **Form:** DATE OF VISIT
Unscheduled

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

Site No: 1013

Site Name: (1013) Clinical Neuroscience Solutions Inc.

Subject No: 10131386

Subject Initials: ---

Generated By: pfe.lewissc

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: 10131386

Subject Initials: ---

Generated By: pfe.levissc

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: 10131386

Subject Initials: ---

Generated By: pfe.lewissc

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

090177e196ae2f60\Final\Final On: 01-Apr-2021 03:41 (GMT)

Header Text: c4591001**Visit:** V201_SURVEIL_CONSENT -
Unscheduled**Form:** ELECTRONIC SAMPLE TRACKING - NASAL
SWAB**Form Version:** 22-Apr-2020 21:03**Form Status:** Not Started**Site No:** 1013**Site Name:** (1013) Clinical Neuroscience Solutions Inc.**Subject No:** 10131386**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: Potential ReVax Initial Contact - **Form:** DATE OF VISIT
Unscheduled

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

Site No: 1013

Site Name: (1013) Clinical Neuroscience Solutions Inc.

Subject No: 10131386

Subject Initials: ---

Generated By: pfe.lewissc

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

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

090177e196ae2f60\Final\Final On: 01-Apr-2021 03:41 (GMT)

Header Text: c4591001

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

Form Version: 10-Dec-2020 02:25 **Form Status:** Not Started

Site No: 1013

Site Name: (1013) Clinical Neuroscience Solutions Inc.

Subject No: 10131386

Subject Initials: ---

Generated By: pfe.lewissc

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

Further Vaccination Confirmation

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

Header Text: c4591001

Visit: Disposition - Unscheduled

Form: TREATMENT UNBLINDED

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1013

Site Name: (1013) Clinical Neuroscience Solutions Inc.

Subject No: 10131386

Subject Initials: ---

Generated By: pfe.levisse

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

Treatment Unblinded

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

Header Text: c4591001

Visit: Disposition - Unscheduled

Form: WITHDRAWAL OF CONSENT

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1013

Site Name: (1013) Clinical Neuroscience Solutions Inc.

Subject No: 10131386

Subject Initials: ---

Generated By: pfe.levissc

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

Withdrawal Of Consent

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

Header Text: c4591001

Visit: Disposition - Unscheduled

Form: DEATH DETAILS CODED

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1013

Site Name: (1013) Clinical Neuroscience Solutions Inc.

Subject No: 10131386

Subject Initials: ---

Generated By: pfe.levissc

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: SUBJECT STATUS

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Verified

Site No: 1013

Site Name: (1013) Clinical Neuroscience Solutions Inc.

Subject No: 10131386

Subject Initials: ---

Generated By: pfe.levisse

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

[eCRF Audit Trail History](#)

Subject Status

1.	Subject Status	FOLLOW-UP
2.	Subject Status Date	Oct/20/2020

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: 10131386

Subject Initials: ---

Generated By: pfe.lewissc

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: 10131386

Subject Initials: ---

Generated By: pfe.lewissc

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	Oct-26-2020 10:36:27 (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.

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: INCLUSION/EXCLUSION CRITERIA -
Comments

Form Version: 30-Jul-2020 21:29

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1013

Site Name: (1013) Clinical Neuroscience Solutions Inc.

Subject No: 10131386

Subject Initials: ---

Generated By: pfe.levissc

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

[Back to Form](#)

Item	Date	User	Comment
Form	Sep-01-2020 16:38:02 (UTC-05:00) Eastern Time (US & Canada)	Matthew Stephens (pfe.mstephens)	Not Applicable

Header Text: c4591001

Visit: Investigator Signature -
Unscheduled

Form: CASEBOOK SIGNATURE FORM - Signature
History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Signed, Verified

Site No: 1013

Site Name: (1013) Clinical Neuroscience Solutions Inc.

Subject No: 10131386

Subject Initials: ---

Generated By: pfe.lewissc

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

[Back to Form](#)

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	Oct-26-2020 10:36:27 (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.

Matthew Stephens	N/A	Oct-20-2020 10:44:52 (UTC-05:00) Eastern Time (US & Canada)		Edit - All signatures invalidated
------------------	-----	--	--	-----------------------------------

Affidavit:

N/A

Michael Dever	Approved	Oct-06-2020 07:26:21 (UTC-05:00) Eastern Time (US & Canada)	BOOK	Signed
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090177e196ae2f60\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: 10131386

Subject Initials: ---

Generated By: pfe.lewissc

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

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.

090177e196ae2f60\Final\Final On: 01-Apr-2021 03:41 (GMT)

Header Text: c4591001

Visit: COHORT_SELECTION

Form: COHORT SELECTION - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:29

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1013

Site Name: (1013) Clinical Neuroscience Solutions Inc.

Subject No: 10131386

Subject Initials: ---

Generated By: pfe.lewissc

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

[Back to Form](#)

1. Select appropriate response - Protocol version

Date	Location	User	Value	Reason
Sep-01-2020 16:37:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe.mstephens)	Data Entry: 24 JUL 2020	Initial Entry

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

Date	Location	User	Value	Reason
Sep-01-2020 16:37:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe.mstephens)	Data Entry: STAGE 3 COHOR TS	Initial Entry

Header Text: c4591001

Visit: COHORT_SELECTION

Form: MAIN INFORMED CONSENT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1013

Site Name: (1013) Clinical Neuroscience Solutions Inc.

Subject No: 10131386

Subject Initials: ---

Generated By: pfe.levissc

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

[Back to Form](#)

1. Consent Was:

Date	Location	User	Value	Reason
Sep-01-2020 16:37:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe.mstephens)	Data Entry: OBTAINED Date Written Cons ent Obtained Sep/1/2020	Initial Entry

090177e196ae2f60\Final\Final On: 01-Apr-2021 03:41 (GMT)

Header Text: c4591001

Visit: COHORT_SELECTION

Form Version: 06-Jul-2020 21:55

Site No: 1013

Subject No: 10131386

Generated By: pfe.lewissc

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

[Back to Form](#)

1. Subject ID

Date	Location	User	Value	Reason
Sep-01-2020 16:37:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 10131386	Item copied from previous form

2. Birth Date:

Date	Location	User	Value	Reason
Sep-01-2020 16:37:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: (b) (6) 1960	Enrollment Entry

3. Sex:

Date	Location	User	Value	Reason
Sep-01-2020 16:37:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe.mstephens)	Data Entry: MALE	Initial Entry

4. Ethnicity:

Date	Location	User	Value	Reason
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090177e196ae2f60\Final\Final On: 01-Apr-2021 03:41 (GMT)

Header Text: c4591001

Visit: COHORT_SELECTION

Form: DEMOGRAPHY - eCRF Audit Trail History

Form Version: 06-Jul-2020 21:55

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1013

Site Name: (1013) Clinical Neuroscience Solutions Inc.

Subject No: 10131386

Subject Initials: ---

Generated By: pfe.levissc

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

Sep-01-2020 16:37:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe.mstephens)	Data Entry: NOT HISPANIC O R LATINO(A) OR OF SPANISH ORI GIN	Initial Entry
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5. Race: (Check X all that apply):

Date	Location	User	Value	Reason
Sep-01-2020 16:37:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe.mstephens)	Data Entry: WHITE	Initial Entry

090177e196ae2f60\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: 10131386

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

[Back to Form](#)

1. Date of Visit

Date	Location	User	Value	Reason
Sep-01-2020 16:37:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe.mstephens)	Data Entry: Sep/1/2020	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1013

Subject No: 10131386

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

[Back to Form](#)

1. Date of Completion/Discontinuation/Death

Date	Location	User	Value	Reason
Sep-01-2020 16:38:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe.mstephens)	Data Entry: Sep/1/2020	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Sep-01-2020 16:38:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SCREENING	Initial Entry

3. Status:

Date	Location	User	Value	Reason
Sep-01-2020 16:38:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe.mstephens)	Data Entry: COMPLETED	Initial Entry

090177e196ae2f60\Final\Final On: 01-Apr-2021 03:41 (GMT)

Header Text: c4591001**Visit:** V1_DAY1_VAX1_L**Form:** GENERAL MEDICAL HISTORY - eCRF Audit Trail History**Form Version:** 22-Apr-2020 21:03**Form Status:** Data Complete, Locked, Frozen, Verified**Site No:** 1013**Site Name:** (1013) Clinical Neuroscience Solutions Inc.**Subject No:** 10131386**Subject Initials:** ---**Generated By:** pfe.levisse**Generated Time (GMT):** 29-Mar-2021 04:21[Back to Form](#)*1.a*

Date	Location	User	Value	Reason
Sep-01-2020 16:38:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/M 1 H Numb er: Medical RIGHT KN History EE ACL RE Term: PAIR Start Da UNK/UNK/ te: 1980 Ongoing NO : End Date: UNK/UN K/1980	Initial Entry

1.a Line/MH Number:

Date	Location	User	Value	Reason
Sep-01-2020 16:38:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 1	Initial Entry

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

Date	Location	User	Value	Reason
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Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1013

Site Name: (1013) Clinical Neuroscience Solutions Inc.

Subject No: 10131386

Subject Initials: ---

Generated By: pfe.lewissc

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

Sep-01-2020 16:38:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe.mstephens)	Data Entry: RIGHT KNEE AC L REPAIR	Initial Entry
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1.a Start Date:

Date	Location	User	Value	Reason
Sep-01-2020 16:38:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe.mstephens)	Data Entry: UNK/UNK/1980	Initial Entry

1.a Ongoing:

Date	Location	User	Value	Reason
Sep-01-2020 16:38:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe.mstephens)	Data Entry: NO End Date: UNK/UNK/1980	Initial Entry

1.b

Date	Location	User	Value	Reason
Sep-01-2020 16:38:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH 2 Number:	Initial Entry

090177e196ae2f60\Final\Final On: 01-Apr-2021 03:41 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1013

Site Name: (1013) Clinical Neuroscience Solutions Inc.

Subject No: 10131386

Subject Initials: ---

Generated By: pfe.levissc

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

			Medical History Term: ACL TEAR Start Date: RIGHT KN Ongoing: EE End Date: UNK/UNK/ 1978 UNK/U NK/1980
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090177e196ae2f60\Final\Final On: 01-Apr-2021 03:41 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1013

Site Name: (1013) Clinical Neuroscience Solutions Inc.

Subject No: 10131386

Subject Initials: ---

Generated By: pfe.lewissc

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

1.b Line/MH Number:

Date	Location	User	Value	Reason
Sep-01-2020 16:38:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 2	Initial Entry

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

Date	Location	User	Value	Reason
Sep-01-2020 16:38:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe.mstephens)	Data Entry: ACL TEAR RIGH T KNEE	Initial Entry

1.b Start Date:

Date	Location	User	Value	Reason
Sep-01-2020 16:38:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe.mstephens)	Data Entry: UNK/UNK/1978	Initial Entry

1.b Ongoing:

Date	Location	User	Value	Reason
Sep-01-2020 16:38:49	ACV0PFEINFP6000	Matthew Stephens	Data Entry: NO	Initial Entry

090177e196ae2f60\Final\Final On: 01-Apr-2021 03:41 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1013

Site Name: (1013) Clinical Neuroscience Solutions Inc.

Subject No: 10131386

Subject Initials: ---

Generated By: pfe.levissc

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

(UTC-05:00) Eastern Time (US & Canada)		(pfe.mstephens)	End Date: UNK/UNK/1980	
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Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: VITAL SIGNS - BASELINE - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1013

Site Name: (1013) Clinical Neuroscience Solutions Inc.

Subject No: 10131386

Subject Initials: ---

Generated By: pfe.lewissc

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

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1. Date:

Date	Location	User	Value	Reason
Sep-01-2020 16:39:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe.mstephens)	Data Entry: Sep/1/2020	Initial Entry

2. Weight:

Date	Location	User	Value	Reason
Sep-01-2020 16:39:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe.mstephens)	Data Entry: 96.8	Initial Entry

3. Unit:

Date	Location	User	Value	Reason
Sep-01-2020 16:39:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe.mstephens)	Data Entry: kg	Initial Entry

4. Height:

Date	Location	User	Value	Reason
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090177e196ae2f60\Final\Final On: 01-Apr-2021 03:41 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: VITAL SIGNS - BASELINE - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1013

Site Name: (1013) Clinical Neuroscience Solutions Inc.

Subject No: 10131386

Subject Initials: ---

Generated By: pfe.levisse

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

Sep-01-2020 16:39:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe.mstephens)	Data Entry: 187.9	Initial Entry
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5. Unit:

Date	Location	User	Value	Reason
Sep-01-2020 16:39:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe.mstephens)	Data Entry: cm	Initial Entry

6. Body Mass Index:

Date	Location	User	Value	Reason
Sep-01-2020 16:39:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 27.4	Initial Entry

7.a

Date	Location	User	Value	Reason
Sep-01-2020 16:39:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe.mstephens)	Data Entry: Record Id 1 entifier:: Temperat 36.8 ure:	Initial Entry

090177e196ae2f60\Final\Final On: 01-Apr-2021 03:41 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: VITAL SIGNS - BASELINE - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1013

Site Name: (1013) Clinical Neuroscience Solutions Inc.

Subject No: 10131386

Subject Initials: ---

Generated By: pfe.lewissc

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

			Temperat C ure Unit: Temperat ORAL ure Locati CAVIT on:: Y	
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7.a Record Identifier:

Date	Location	User	Value	Reason
Sep-01-2020 16:39:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe.mstephens)	Data Entry: 1	Initial Entry

7.a Temperature:

Date	Location	User	Value	Reason
Sep-01-2020 16:39:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe.mstephens)	Data Entry: 36.8	Initial Entry

7.a Unit:

Date	Location	User	Value	Reason
Sep-01-2020 16:39:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe.mstephens)	Data Entry: C	Initial Entry

090177e196ae2f60\Final\Final On: 01-Apr-2021 03:41 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: VITAL SIGNS - BASELINE - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1013

Site Name: (1013) Clinical Neuroscience Solutions Inc.

Subject No: 10131386

Subject Initials: ---

Generated By: pfe.levissc

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

7.a Temperature Location:

Date	Location	User	Value	Reason
Sep-01-2020 16:39:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe.mstephens)	Data Entry: ORAL CAVITY	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1013

Subject No: 10131386

Generated By: pfe.levissc

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
Sep-01-2020 16:39:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe.mstephens)	Data Entry: Sep/1/2020	Initial Entry

2. Randomization Number:

Date	Location	User	Value	Reason
Sep-01-2020 16:39:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe.mstephens)	Data Entry: 248165	Initial Entry

090177e196ae2f60\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: 10131386

Generated By: pfe.levisse

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - 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. Data Origin

Date	Location	User	Value	Reason
Sep-01-2020 16:39:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Sep-01-2020 16:39:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SERUM	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Sep-01-2020 17:13:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Sep-01-2020 16:39:28 (UTC-05:00)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidat e	'Sample Collected?' is Yes, however

090177e196ae2f60\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: 10131386

Subject Initials: ---

Generated By: pfe.lewissc

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

Eastern Time (US & Canada)				no barcodes are entered. Please review and correct as appropriate.
Sep-01-2020 16:39:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe.mstephens)	Data Entry: YES Date of Collection: Sep/1/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Sep-01-2020 17:13:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe.mstephens)	Data Entry: Sample I BPC3N D: M	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Sep-01-2020 17:13:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe.mstephens)	Data Entry: BPC3NM	Initial Entry

5.b

090177e196ae2f60\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: 10131386

Subject Initials: ---

Generated By: pfe.lewissc

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

Date	Location	User	Value	Reason
Sep-01-2020 17:13:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe.mstephens)	Data Entry: Sample I BPC3N D: N	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Sep-01-2020 17:13:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe.mstephens)	Data Entry: BPC3NN	Initial Entry

5.c

Date	Location	User	Value	Reason
Sep-01-2020 17:13:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe.mstephens)	Data Entry: Sample I BPC3N D: P	Initial Entry

090177e196ae2f60\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: 10131386

Subject Initials: ---

Generated By: pfe.lewissc

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

5.c Sample ID

Date	Location	User	Value	Reason
Sep-01-2020 17:13:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe.mstephens)	Data Entry: BPC3NP	Initial Entry

5.d

Date	Location	User	Value	Reason
Sep-01-2020 17:14:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe.mstephens)	Data Entry: Sample I BMN51 D: 9	Initial Entry

5.d Sample ID

Date	Location	User	Value	Reason
Sep-01-2020 17:14:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe.mstephens)	Data Entry: BMN519	Initial Entry

5.e

Date	Location	User	Value	Reason
Sep-01-2020 17:14:09	ACV0PFEINFP6000	Matthew Stephens	Data Entry: Sample I BMN51	Initial Entry

090177e196ae2f60\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: 10131386

Subject Initials: ---

Generated By: pfe.lewissc

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

(UTC-05:00) Eastern Time (US & Canada)		(pfe.mstephens)	D: B	
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5.e Sample ID

Date	Location	User	Value	Reason
Sep-01-2020 17:14:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe.mstephens)	Data Entry: BMN51B	Initial Entry

090177e196ae2f60\Final\Final On: 01-Apr-2021 03:41 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1013

Site Name: (1013) Clinical Neuroscience Solutions Inc.

Subject No: 10131386

Subject Initials: ---

Generated By: pfe.levisse

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

[Back to Form](#)

1. Data Origin

Date	Location	User	Value	Reason
Sep-01-2020 16:39:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Sep-01-2020 16:39:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: NASAL_SWAB	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Sep-01-2020 17:14:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Sep-01-2020 16:39:34 (UTC-05:00)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidat e	'Sample Collected?' is Yes, however

090177e196ae2f60\Final\Final On: 01-Apr-2021 03:41 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1013

Site Name: (1013) Clinical Neuroscience Solutions Inc.

Subject No: 10131386

Subject Initials: ---

Generated By: pfe.lewissc

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

Eastern Time (US & Canada)				no barcodes are entered. Please review and correct as appropriate.
Sep-01-2020 16:39:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe.mstephens)	Data Entry: YES Date of Collection: Sep/1/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Sep-01-2020 17:14:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe.mstephens)	Data Entry: Sample I BN624 D: 1	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Sep-01-2020 17:14:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe.mstephens)	Data Entry: BN6241	Initial Entry

090177e196ae2f60\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: 10131386

Generated By: pfe.lewissc

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
Sep-01-2020 16:39:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe.mstephens)	Data Entry: NO	Initial Entry

2. Treatment Name

Date	Location	User	Value	Reason
Sep-01-2020 16:39:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: BLINDED THERAPY	Initial Entry

3. Formulation:

Date	Location	User	Value	Reason
Sep-01-2020 16:39:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INJECTION	Initial Entry

4. Dose Date Time:

Date	Location	User	Value	Reason
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090177e196ae2f60\Final\Final On: 01-Apr-2021 03:41 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: VACCINATION - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1013

Site Name: (1013) Clinical Neuroscience Solutions Inc.

Subject No: 10131386

Subject Initials: ---

Generated By: pfe.levissc

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

Sep-01-2020 16:39:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe.mstephens)	Data Entry: Sep/1/2020 10:50	Initial Entry
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5. Anatomical Location:

Date	Location	User	Value	Reason
Sep-01-2020 16:39:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: DELTOID MUSCLE	Initial Entry

6. Body Side:

Date	Location	User	Value	Reason
Sep-01-2020 16:39:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe.mstephens)	Data Entry: RIGHT	Initial Entry

7. Route:

Date	Location	User	Value	Reason
Sep-01-2020 16:39:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INTRAMUSCULAR	Initial Entry

090177e196ae2f60\Final\Final On: 01-Apr-2021 03:41 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: VACCINATION - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1013

Site Name: (1013) Clinical Neuroscience Solutions Inc.

Subject No: 10131386

Subject Initials: ---

Generated By: pfe.lewissc

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

10. Timeframe Subject Was Observed

Date	Location	User	Value	Reason
Sep-01-2020 16:39:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: THE PROTOCOL SPE CIFIED OBSERVATIO N PERIOD	Initial Entry

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

Date	Location	User	Value	Reason
Sep-01-2020 16:39:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe.mstephens)	Data Entry: YES	Initial Entry

090177e196ae2f60\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: 10131386

Generated By: pfe.levissc

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
Sep-01-2020 16:39:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe.mstephens)	Data Entry: NO - REACTOGE NICITY E-DIARY NOT COLLECTED FOR THIS SUBJE CT	Initial Entry

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 1013

Subject No: 10131386

Generated By: pfe.lewissc

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
Sep-22-2020 12:13:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe.mstephens)	Data Entry: Sep/22/2020	Initial Entry

090177e196ae2f60\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: 10131386

Generated By: pfe.lewissc

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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1. Date:

Date	Location	User	Value	Reason
Sep-22-2020 12:13:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe.mstephens)	Data Entry: Sep/22/2020	Initial Entry

2.a

Date	Location	User	Value	Reason
Sep-22-2020 12:13:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe.mstephens)	Data Entry: Record Id 1 entifier:: Temperat 36.7 ure: Temperat C ure Unit: Temperat ORAL ure Locati CAVIT on:: Y	Initial Entry

2.a Record Identifier:

Date	Location	User	Value	Reason
Sep-22-2020 12:13:23 (UTC-05:00) Eastern Time (US	ACV0PFEINFP6000	Matthew Stephens (pfe.mstephens)	Data Entry: 1	Initial Entry

090177e196ae2f60\Final\Final On: 01-Apr-2021 03:41 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form: VITAL SIGNS - TEMP - eCRF Audit Trail History

Form Version: 15-Sep-2020 21:54

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1013

Site Name: (1013) Clinical Neuroscience Solutions Inc.

Subject No: 10131386

Subject Initials: ---

Generated By: pfe.lewissc

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

& Canada)

2.a Temperature:

Date	Location	User	Value	Reason
Sep-22-2020 12:13:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe.mstephens)	Data Entry: 36.7	Initial Entry

2.a Unit:

Date	Location	User	Value	Reason
Sep-22-2020 12:13:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe.mstephens)	Data Entry: C	Initial Entry

2.a Temperature Location:

Date	Location	User	Value	Reason
Sep-22-2020 12:13:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe.mstephens)	Data Entry: ORAL CAVITY	Initial Entry

090177e196ae2f60\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: 10131386

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
Sep-22-2020 12:13:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Sep-22-2020 12:13:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: NASAL_SWAB	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Sep-22-2020 15:53:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Sep-22-2020 12:13:30 (UTC-05:00)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however

090177e196ae2f60\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: 10131386

Subject Initials: ---

Generated By: pfe.lewissc

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

Eastern Time (US & Canada)				no barcodes are entered. Please review and correct as appropriate.
Sep-22-2020 12:13:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe.mstephens)	Data Entry: YES Date of Collection: Sep/22/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Sep-22-2020 15:53:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe.mstephens)	Data Entry: Sample I BPC33 D: S	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Sep-22-2020 15:53:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe.mstephens)	Data Entry: BPC33S	Initial Entry

090177e196ae2f60\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: 10131386

Generated By: pfe.lewissc

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
Sep-22-2020 12:13:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe.mstephens)	Data Entry: NO	Initial Entry

2. Treatment Name

Date	Location	User	Value	Reason
Sep-22-2020 12:13:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: BLINDED THERAPY	Initial Entry

3. Formulation:

Date	Location	User	Value	Reason
Sep-22-2020 12:13:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INJECTION	Initial Entry

4. Dose Date Time:

Date	Location	User	Value	Reason
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090177e196ae2f60\Final\Final On: 01-Apr-2021 03:41 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form: VACCINATION - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1013

Site Name: (1013) Clinical Neuroscience Solutions Inc.

Subject No: 10131386

Subject Initials: ---

Generated By: pfe.levissc

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

Sep-22-2020 12:13:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe.mstephens)	Data Entry: Sep/22/2020 09:55	Initial Entry
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5. Anatomical Location:

Date	Location	User	Value	Reason
Sep-22-2020 12:13:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: DELTOID MUSCLE	Initial Entry

6. Body Side:

Date	Location	User	Value	Reason
Sep-22-2020 12:13:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe.mstephens)	Data Entry: LEFT	Initial Entry

7. Route:

Date	Location	User	Value	Reason
Sep-22-2020 12:13:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INTRAMUSCULAR	Initial Entry

090177e196ae2f60\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: 10131386

Generated By: pfe.lewissc

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

10. Timeframe Subject Was Observed

Date	Location	User	Value	Reason
Sep-22-2020 12:13:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: THE PROTOCOL SPE CIFIED OBSERVATIO N PERIOD	Initial Entry

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

Date	Location	User	Value	Reason
Sep-22-2020 12:13:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe.mstephens)	Data Entry: YES	Initial Entry

090177e196ae2f60\Final\Final On: 01-Apr-2021 03:41 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form: DATE OF VISIT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1013

Site Name: (1013) Clinical Neuroscience Solutions Inc.

Subject No: 10131386

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
Nov-10-2020 01:30:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Nancy Vedamuthu (pfe.vedamn)	Query 1: Closed	Response satisfies query
Nov-09-2020 13:39:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe.mstephens)	Query 1: Answer ed	CRC WILL UPDATE WITH DCF.
Nov-09-2020 13:12:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Pamela Benne prod (pfe.bennep07)	Query 1: Reissue d:Opened	Ill ediary: Thanks for the response, however he Data in the Ediary is YES for 03NOV2020. Please enter a COVID Illness Visit or consider raising DCF to correct eDiary data.
Nov-09-2020 09:02:55 (UTC-05:00)	ACV0PFEINFP6000	Matthew Stephens (pfe.mstephens)	Query 1: Answer ed	CRC HAS LEFT MESSAGES

090177e196ae2f60\Final\Final On: 01-Apr-2021 03:41 (GMT)

Header Text: c4591001

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

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

Site No: 1013 **Site Name:** (1013) Clinical Neuroscience Solutions Inc.

Subject No: 10131386 **Subject Initials:** ---

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

Eastern Time (US & Canada)				FOR SUBJECT TO CONFIRM SYMPTOMS.
Nov-08-2020 04:28:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Sharat Nair (pfe.nairs51)	Query 1: Opened	Illness eduary: As per Illness eduary records, subject reported "Yes" for the question "Have you experienced any of the following?" for the COVID-19 symptoms or diagnosis on 03NOV2020. But corresponding COVID Illness visit not reported. Please clarify.
Oct-20-2020 10:44:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe.mstephens)	Data Entry: Oct/20/2020	Initial Entry

090177e196ae2f60\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: 10131386 **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-20-2020 10:44:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Oct-20-2020 10:44:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SERUM	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Oct-21-2020 00:33:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Ankita Thakur (pfe.thakua20)	Query 1: Closed	Response satisfies query.
Oct-20-2020 11:06:34 (UTC-05:00)	ACV0PFEINFP6000	Matthew Stephens (pfe.mstephens)	Query 1: Answered	will update today when barcodes are

090177e196ae2f60\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:** 10131386**Subject Initials:** ---**Generated By:** pfe.lewissc**Generated Time (GMT):** 29-Mar-2021 04:21

Eastern Time (US & Canada)				received from lab.
Oct-20-2020 10:49:52 (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-20-2020 10:44:59 (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-20-2020 10:44:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe.mstephens)	Data Entry: YES Date of Collection: Oct/20/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Oct-20-2020 16:44:11 (UTC-05:00) Eastern Time (US	ACV0PFEINFP6000	Matthew Stephens (pfe.mstephens)	Data Entry: Sample I BRC8F D: V	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: 10131386 **Subject Initials:** ---

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

& Canada)				
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5.a Sample ID

Date	Location	User	Value	Reason
Oct-20-2020 16:44:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe.mstephens)	Data Entry: BRC8FV	Initial Entry

5.b

Date	Location	User	Value	Reason
Oct-20-2020 16:44:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe.mstephens)	Data Entry: Sample I BRC8F D: W	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Oct-20-2020 16:44:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe.mstephens)	Data Entry: BRC8FW	Initial Entry

5.c

Date	Location	User	Value	Reason
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090177e196ae2f60\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: 10131386 **Subject Initials:** ---

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

Oct-20-2020 16:44:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe.mstephens)	Data Entry: Sample I BRC8F D: X	Initial Entry
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5.c Sample ID

Date	Location	User	Value	Reason
Oct-20-2020 16:44:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe.mstephens)	Data Entry: BRC8FX	Initial Entry

5.d

Date	Location	User	Value	Reason
Oct-20-2020 16:44:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe.mstephens)	Data Entry: Sample I BMN5H D: W	Initial Entry

5.d Sample ID

Date	Location	User	Value	Reason
Oct-20-2020 16:44:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe.mstephens)	Data Entry: BMN5HW	Initial Entry

090177e196ae2f60\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: 10131386 **Subject Initials:** ---

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

5.e

Date	Location	User	Value	Reason
Oct-20-2020 16:44:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe.mstephens)	Data Entry: Sample I BMN5H D: X	Initial Entry

5.e Sample ID

Date	Location	User	Value	Reason
Oct-20-2020 16:44:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe.mstephens)	Data Entry: BMN5HX	Initial Entry

090177e196ae2f60\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, Locked, Frozen, Verified

Site No: 1013 **Site Name:** (1013) Clinical Neuroscience Solutions Inc.

Subject No: 10131386 **Subject Initials:** ---

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

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1. Date of Completion/Discontinuation/Death :

Date	Location	User	Value	Reason
Oct-20-2020 10:45:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe.mstephens)	Data Entry: Oct/20/2020	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Oct-20-2020 10:45:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: VACCINATION	Initial Entry

3. Status:

Date	Location	User	Value	Reason
Oct-20-2020 10:45:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe.mstephens)	Data Entry: COMPLETED	Initial Entry

090177e196ae2f60\Final\Final On: 01-Apr-2021 03:41 (GMT)

Header Text: c4591001

Visit: Subject Status - Unscheduled

Form: SUBJECT STATUS - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Verified

Site No: 1013

Site Name: (1013) Clinical Neuroscience Solutions Inc.

Subject No: 10131386

Subject Initials: ---

Generated By: pfe.lewissc

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

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1. Subject Status

Date	Location	User	Value	Reason
Oct-20-2020 10:45:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: FOLLOW-UP	Initial Entry
Sep-01-2020 16:39:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: ENROLLED/RANDOMIZED	Initial Entry
Sep-01-2020 16:38:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SCREENED	Initial Entry

2. Subject Status Date

Date	Location	User	Value	Reason
Oct-20-2020 10:45:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Oct/20/2020	Initial Entry
Sep-01-2020 16:39:21	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sep/1/2020	Initial Entry

090177e196ae2f60\Final\Final On: 01-Apr-2021 03:41 (GMT)

Header Text: c4591001

Visit: Subject Status - Unscheduled

Form: SUBJECT STATUS - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Verified

Site No: 1013

Site Name: (1013) Clinical Neuroscience Solutions Inc.

Subject No: 10131386

Subject Initials: ---

Generated By: pfe.levisse

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

(UTC-05:00) Eastern Time (US & Canada)				
Sep-01-2020 16:38:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sep/1/2020	Initial Entry

090177e196ae2f60\Final\Final On: 01-Apr-2021 03:41 (GMT)

Header Text: c4591001

Visit: Investigator Signature -
Unscheduled

Form Version: 22-Apr-2020 21:04

Site No: 1013

Subject No: 10131386

Generated By: pfe.lewissc

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