

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: 10131229

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

090177e196ae2f59\Final\Final On: 01-Apr-2021 03:40 (GMT)

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: 10131229

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 Aug/19/2020
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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: 10131229

Subject Initials: ---

Generated By: pfe.levissc

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

[eCRF Audit Trail History](#)

Demography

1.	Subject ID	[10131229]
2.	Birth Date:	(b) (6)/1995
3.	Sex:	FEMALE
4.	Ethnicity:	NOT HISPANIC OR LATINO(A) OR OF SPANISH ORIGIN
5.	Race: (Check X all that apply):	ASIAN
6.	Racial Designation:	

090177e196ae2f59\Final\Final On: 01-Apr-2021 03:40 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:02

Site No: 1013

Subject No: 10131229

Generated By: pfe.lewissc

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	Aug/19/2020
2.	Erroneous Visit	

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 30-Jul-2020 21:29

Site No: 1013

Subject No: 10131229

Generated By: pfe.levissc

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

090177e196ae2f59\Final\Final On: 01-Apr-2021 03:40 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1013

Subject No: 10131229

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	Aug/19/2020
2.	Phase of Disposition:	SCREENING
3.	Status:	COMPLETED
4.	Specify Status:	[]

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: GENERAL MEDICAL HISTORY

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1013

Site Name: (1013) Clinical Neuroscience Solutions Inc.

Subject No: 10131229

Subject Initials: ---

Generated By: pfe.levissc

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:	[ATTENTION DEFICIT HYPERACTIVITY DISORDER]
	Start Date:	UNK/UNK/2010
	Ongoing:	YES
1.b	Line/MH Number:	[2]
	Disease/Syndrome /Surgery/Non-Drug Allergies/Drug Allergies:	[BREAST AUGMENTATION]
	Start Date:	Jun/UNK/2020
	Ongoing:	NO End Date: Jun/UNK/2020
1.c	Line/MH Number:	[3]
	Disease/Syndrome /Surgery/Non-Drug Allergies/Drug Allergies:	[OBESITY]
	Start Date:	UNK/UNK/2016
	Ongoing:	YES

090177e196ae2f59\Final\Final On: 01-Apr-2021 03:40 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 30-Jul-2020 21:28

Site No: 1013

Subject No: 10131229

Generated By: pfe.levisc

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:	Aug/19/2020
2.	Weight:	[79.3]
3.	Unit:	kg
4.	Height:	[162.6]
5.	Unit:	cm
6.	Body Mass Index:	[30.0]

Vital Signs Details

7.a	Record Identifier:	1
	Temperature:	[37.1]
	Unit:	C
	Temperature Location:	ORAL CAVITY

090177e196ae2f59\Final\Final On: 01-Apr-2021 03:40 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 30-Jul-2020 21:27

Site No: 1013

Subject No: 10131229

Generated By: pfe.levissc

Form: LAB URINALYSIS - PREGNANCY TEST

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](#)

Lab Urinalysis

1.	Lab Panel:	URINALYSIS
2.	Lab Sub-Panel:	PREGNANCY
3.	Collection Date:	Aug/19/2020
4.	Laboratory Name and Address (Derived)	[STUDY SITE]
5.	Specimen Type:	URINE

Lab Result

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

090177e196ae2f59\Final\Final On: 01-Apr-2021 03:40 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1013

Subject No: 10131229

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 :	Aug/19/2020
2.	Randomization Number:	[55842]
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: 10131229

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: Aug/19/2020
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	[BPYX91]
5.b	Sample ID	[BPYX92]
5.c	Sample ID	[BPYX93]
5.d	Sample ID	[BNWHMD]
5.e	Sample ID	[BNWHMF]

090177e196ae2f59\Final\Final On: 01-Apr-2021 03:40 (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: 10131229

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: Aug/19/2020
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	[BM8S6Z]
-----	-----------	----------

090177e196ae2f59\Final\Final On: 01-Apr-2021 03:40 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:04

Site No: 1013

Subject No: 10131229

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:	Aug/19/2020 09:40
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

090177e196ae2f59\Final\Final On: 01-Apr-2021 03:40 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 06-Jul-2020 21:53

Site No: 1013

Subject No: 10131229

Generated By: pfe.levissc

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
----	---	---

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: 10131229

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	Sep/10/2020
2.	Erroneous Visit	

Header Text: c4591001

Visit: V2_VAX2_L

Form: VITAL SIGNS - TEMP

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: 10131229

Subject Initials: ---

Generated By: pfe.levissc

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

[eCRF Audit Trail History](#)

Vital Signs

1.	Date:	Sep/10/2020
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Vital Signs Details

2.a	Record Identifier:	1
	Temperature:	[37.1]
	Unit:	C
	Temperature Location:	ORAL CAVITY

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 30-Jul-2020 21:27

Site No: 1013

Subject No: 10131229

Generated By: pfe.levissc

Form: LAB URINALYSIS - PREGNANCY TEST

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](#)

Lab Urinalysis

1.	Lab Panel:	URINALYSIS
2.	Lab Sub-Panel:	PREGNANCY
3.	Collection Date:	Sep/10/2020
4.	Laboratory Name and Address (Derived)	[STUDY SITE]
5.	Specimen Type:	URINE

Lab Result

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

090177e196ae2f59\Final\Final On: 01-Apr-2021 03:40 (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: 10131229

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/10/2020
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[]

Aliquot

Please enter barcode for each aliquot.

5.a	Sample ID	[BPC2WL]
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090177e196ae2f59\Final\Final On: 01-Apr-2021 03:40 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1013

Subject No: 10131229

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/10/2020 14:50
5.	Anatomical Location:	DELTOID MUSCLE
6.	Body Side:	LEFT
7.	Route:	INTRAMUSCULAR
8.	Actual Dose:	[]
9.	Unit:	
10.	Timeframe Subject Was Observed	THE PROTOCOL SPECIFIED OBSERVATION PERIOD
11.	Was the subject observed for at least the protocol specified observation period after investigational product administration?	YES

090177e196ae2f59\Final\Final On: 01-Apr-2021 03:40 (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: 10131229 **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/14/2020
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: 10131229 **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/14/2020
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	[BR9TRR]
5.b	Sample ID	[BR9TRS]
5.c	Sample ID	[BR9TRT]
5.d	Sample ID	[BMN58G]
5.e	Sample ID	[BMN58H]

090177e196ae2f59\Final\Final On: 01-Apr-2021 03:40 (GMT)

Header Text: c4591001

Visit: V4_MONTH6_L

Form Version: 22-Apr-2020 21:02

Site No: 1013

Subject No: 10131229

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: 10131229

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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090177e196ae2f59\Final\Final On: 01-Apr-2021 03:40 (GMT)

Header Text: c4591001

Visit: V5_MONTH12_L

Form Version: 22-Apr-2020 21:02

Site No: 1013

Subject No: 10131229

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: 10131229

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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090177e196ae2f59\Final\Final On: 01-Apr-2021 03:40 (GMT)

Header Text: c4591001

Visit: V6_MONTH24_L

Form Version: 22-Apr-2020 21:02

Site No: 1013

Subject No: 10131229

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: 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: 10131229

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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090177e196ae2f59\Final\Final On: 01-Apr-2021 03:40 (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: 10131229

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: 10131229

Generated By: pfe.lewissc

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

090177e196ae2f59\Final\Final On: 01-Apr-2021 03:40 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL - New
Unscheduled Visit

Form: ELECTRONIC SAMPLE TRACKING - NASAL
SWAB SELF

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1013

Site Name: (1013) Clinical Neuroscience Solutions Inc.

Subject No: 10131229

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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090177e196ae2f59\Final\Final On: 01-Apr-2021 03:40 (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: 10131229

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

090177e196ae2f59\Final\Final On: 01-Apr-2021 03:40 (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: 10131229

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?	
----	--	--

090177e196ae2f59\Final\Final On: 01-Apr-2021 03:40 (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: 10131229

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: 10131229

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: 10131229

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

090177e196ae2f59\Final\Final On: 01-Apr-2021 03:40 (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: 10131229 **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: 10131229 **Subject Initials:** ---

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

Unplanned Assessments

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

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: 10131229

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/14/2020
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: 10131229

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: 10131229

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: 10131229 **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	[]
----	-----------	-----

090177e196ae2f59\Final\Final On: 01-Apr-2021 03:40 (GMT)

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: 10131229

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	Exposure During Pregnancy	Dec/10/2020 UNK:UNK	YES	Repeating Pages

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete

Site No: 1013

Site Name: (1013) Clinical Neuroscience Solutions Inc.

Subject No: 10131229

Subject Initials: ---

Generated By: pfe.levisse

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)	[Exposure During Pregnancy]	
4.	Start Date Time:	Dec/10/2020 UNK:UNK	
5.	Is the adverse event still ongoing?	YES	
6.	Toxicity Grade:	Not Applicable	Comments

090177e196ae2f59\Final\Final On: 01-Apr-2021 03:40 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete

Site No: 1013

Site Name: (1013) Clinical Neuroscience Solutions Inc.

Subject No: 10131229

Subject Initials: ---

Generated By: pfe.levisse

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

7.	Is the adverse event serious? If Yes, NOTIFY PFIZER IMMEDIATELY. Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).	NO
8.	Is this adverse event the result of a study Medication Error? If Yes, record the type of medication error on the Medication Error Log.	NO
9.	Is this event related to study treatment:	NOT RELATED If Not Related to study treatment(s), this event is due to: OTHER If Other, specify: [PREGNANCY]
10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE

090177e196ae2f59\Final\Final On: 01-Apr-2021 03:40 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete

Site No: 1013

Site Name: (1013) Clinical Neuroscience Solutions Inc.

Subject No: 10131229

Subject Initials: ---

Generated By: pfe.lewissc

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

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

090177e196ae2f59\Final\Final On: 01-Apr-2021 03:40 (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: 10131229

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: 10131229

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	[]

090177e196ae2f59\Final\Final On: 01-Apr-2021 03:40 (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: 10131229

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: 10131229

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.	Date:	//

090177e196ae2f59\Final\Final On: 01-Apr-2021 03:40 (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: 10131229

Subject Initials: ---

Generated By: pfe.levissc

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: 10131229

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?	

090177e196ae2f59\Final\Final On: 01-Apr-2021 03:40 (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: 10131229

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: 10131229

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?	

090177e196ae2f59\Final\Final On: 01-Apr-2021 03:40 (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: 10131229

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: 10131229

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: 10131229

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: 10131229

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:	

090177e196ae2f59\Final\Final On: 01-Apr-2021 03:40 (GMT)

Header Text: c4591001

Visit: Unplanned Vaccination -
Unscheduled

Form: LAB URINALYSIS - PREGNANCY TEST

Form Version: 20-Feb-2021 02:14

Form Status: Not Started

Site No: 1013

Site Name: (1013) Clinical Neuroscience Solutions Inc.

Subject No: 10131229

Subject Initials: ---

Generated By: pfe.lewissc

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

Lab Urinalysis

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

Lab Result

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

090177e196ae2f59\Final\Final On: 01-Apr-2021 03:40 (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: 10131229

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?	

090177e196ae2f59\Final\Final On: 01-Apr-2021 03:40 (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: 10131229

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: 10131229

Subject Initials: ---

Generated By: pfe.levissc

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: 10131229

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: 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: 10131229

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:** 10131229**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: 10131229

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

090177e196ae2f59\Final\Final On: 01-Apr-2021 03:40 (GMT)

Header Text: c4591001

Visit: Potential ReVax Initial Contact - **Form:** DATE OF VISIT
Unscheduled

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: 10131229 **Subject Initials:** ---

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

[eCRF Audit Trail History](#)

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

Header Text: c4591001

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

Form Version: 10-Dec-2020 02:25 **Form Status:** Data Complete, Frozen

Site No: 1013

Site Name: (1013) Clinical Neuroscience Solutions Inc.

Subject No: 10131229

Subject Initials: ---

Generated By: pfe.lewissc

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: TREATMENT UNBLINDED

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1013

Site Name: (1013) Clinical Neuroscience Solutions Inc.

Subject No: 10131229

Subject Initials: ---

Generated By: pfe.levisse

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

[eCRF Audit Trail History](#)

Treatment Unblinded

1.	Date Treatment Unblinded :	Jan/19/2021
2.	Primary Reason for Unblinding:	ASSESS ELIGIBILITY FOR ADDITIONAL VACCINATION

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: 10131229

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: 10131229

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: V101_VAX3

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: 10131229

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: V101_VAX3

Form: INFORMED CONSENT - FURTHER
VACCINATION

Form Version: 10-Dec-2020 02:31

Form Status: Not Started

Site No: 1013

Site Name: (1013) Clinical Neuroscience Solutions Inc.

Subject No: 10131229

Subject Initials: ---

Generated By: pfe.lewissc

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

Informed Consent - Further Vaccination

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

Header Text: c4591001

Visit: V101_VAX3

Form: INCLUSION/EXCLUSION CRITERIA - FURTHER VACCINATION

Form Version: 10-Dec-2020 02:30

Form Status: Not Started

Site No: 1013

Site Name: (1013) Clinical Neuroscience Solutions Inc.

Subject No: 10131229

Subject Initials: ---

Generated By: pfe.lewissc

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

Inclusion Criteria Not Met

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

Exclusion Criteria Met

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

090177e196ae2f59\Final\Final On: 01-Apr-2021 03:40 (GMT)

Header Text: c4591001

Visit: V101_VAX3

Form: DISPOSITION - SCREENING FOR FURTHER VACCINATION

Form Version: 10-Dec-2020 02:31

Form Status: Not Started

Site No: 1013

Site Name: (1013) Clinical Neuroscience Solutions Inc.

Subject No: 10131229

Subject Initials: ---

Generated By: pfe.levissc

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

Disposition - Screening for Further Vaccination

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

Header Text: c4591001

Visit: Subject Status - Unscheduled

Form: 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: 10131229

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/14/2020

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: 10131229

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
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Header Text: c4591001

Visit: Investigator Signature -
Unscheduled

Form: CASEBOOK SIGNATURE FORM

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Signed, Verified

Site No: 1013

Site Name: (1013) Clinical Neuroscience Solutions Inc.

Subject No: 10131229

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
Michael Dever	Approved	Mar-04-2021 07:15:53 (UTC-05:00) Eastern Time (US & Canada)	BOOK	Signed

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.

090177e196ae2f59\Final\Final On: 01-Apr-2021 03:40 (GMT)

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: 10131229

Subject Initials: ---

Generated By: pfe.lewissc

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

[Back to Form](#)

Item	Date	User	Comment
Form	Aug-19-2020 14:11:02 (UTC-05:00) Eastern Time (US & Canada)	Matthew Stephens (pfe.mstephens)	Not Applicable

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - Comments

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete

Site No: 1013

Site Name: (1013) Clinical Neuroscience Solutions Inc.

Subject No: 10131229

Subject Initials: ---

Generated By: pfe.levisse

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

[Back to Form](#)

Item	Date	User	Comment
6	Feb-01-2021 11:50:09 (UTC-05:00) Eastern Time (US & Canada)	Monica Cooper (pfe.mcooper)	Not Applicable

090177e196ae2f59\Final\Final On: 01-Apr-2021 03:40 (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: 10131229

Subject Initials: ---

Generated By: pfe.levissc

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
Michael Dever	Approved	Mar-04-2021 07:15:53 (UTC-05:00) Eastern Time (US & Canada)	BOOK	Signed

Affidavit:

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Pursuant to Section 11.100 of Title 21 of the Code of Federal Regulations, this is to certify that I intend that this electronic signature is to be the legally binding equivalent of my handwritten signature.

To this I do attest by supplying my user name and password and clicking the button marked Submit below.

Scott Salmon	N/A	Mar-02-2021 16:32:20 (UTC-05:00) Eastern Time (US & Canada)		Edit - All signatures invalidated
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Affidavit:

N/A

Michael Dever	Approved	Feb-02-2021 10:45:21 (UTC-05:00) Eastern Time (US & Canada)	BOOK	Signed
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090177e196ae2f59\Final\Final On: 01-Apr-2021 03:40 (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: 10131229

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.

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To this I do attest by supplying my user name and password and clicking the button marked Submit below.

Monica Cooper	N/A	Feb-01-2021 11:49:57 (UTC-05:00) Eastern Time (US & Canada)		Edit - All signatures invalidated
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Affidavit:

N/A

Michael Dever	Approved	Feb-01-2021 09:49:25 (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.

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090177e196ae2f59\Final\Final On: 01-Apr-2021 03:40 (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: 10131229

Subject Initials: ---

Generated By: pfe.levissc

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

Scott Salmon	N/A	Jan-28-2021 19:52:55 (UTC-05:00) Eastern Time (US & Canada)		Edit - All signatures invalidated
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Affidavit:

N/A

Michael Dever	Approved	Jan-22-2021 06:41:41 (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	Jan-20-2021 13:42:51 (UTC-05:00) Eastern Time (US & Canada)		Edit - All signatures invalidated
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Affidavit:

N/A

Michael Dever	Approved	Oct-21-2020 12:22:53 (UTC-05:00) Eastern Time (US & Canada)	BOOK	Signed
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090177e196ae2f59\Final\Final On: 01-Apr-2021 03:40 (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: 10131229

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.

Scott Salmon	N/A	Oct-14-2020 14:42:12 (UTC-05:00) Eastern Time (US & Canada)		Edit - All signatures invalidated
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Affidavit:

N/A

Michael Dever	Approved	Oct-05-2020 13:02:31 (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.

090177e196ae2f59\Final\Final On: 01-Apr-2021 03:40 (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: 10131229

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
Aug-19-2020 14:10:23 (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
Aug-19-2020 14:10:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe.mstephens)	Data Entry: STAGE 3 COHOR TS	Initial Entry

090177e196ae2f59\Final\Final On: 01-Apr-2021 03:40 (GMT)

Header Text: c4591001

Visit: COHORT_SELECTION

Form: MAIN INFORMED CONSENT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1013

Site Name: (1013) Clinical Neuroscience Solutions Inc.

Subject No: 10131229

Subject Initials: ---

Generated By: pfe.lewissc

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

[Back to Form](#)

1. Consent Was:

Date	Location	User	Value	Reason
Aug-19-2020 14:10:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe.mstephens)	Data Entry: OBTAINED Date Written Consent Obtained Aug/19/2020	Initial Entry

090177e196ae2f59\Final\Final On: 01-Apr-2021 03:40 (GMT)

Header Text: c4591001

Visit: COHORT_SELECTION

Form Version: 06-Jul-2020 21:55

Site No: 1013

Subject No: 10131229

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
Aug-19-2020 14:10:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 10131229	Item copied from previous form

2. Birth Date:

Date	Location	User	Value	Reason
Aug-19-2020 14:10:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: (b) (6)/1995	Enrollment Entry

3. Sex:

Date	Location	User	Value	Reason
Aug-19-2020 14:10:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe.mstephens)	Data Entry: FEMALE	Initial Entry

4. Ethnicity:

Date	Location	User	Value	Reason
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090177e196ae2f59\Final\Final On: 01-Apr-2021 03:40 (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: 10131229

Subject Initials: ---

Generated By: pfe.levissc

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

Aug-19-2020 14:10:42 (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
Aug-19-2020 14:10:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe.mstephens)	Data Entry: ASIAN	Initial Entry

090177e196ae2f59\Final\Final On: 01-Apr-2021 03:40 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:02

Site No: 1013

Subject No: 10131229

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
Aug-19-2020 14:10:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe.mstephens)	Data Entry: Aug/19/2020	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1013

Subject No: 10131229

Generated By: pfe.lewissc

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
Aug-19-2020 14:11:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe.mstephens)	Data Entry: Aug/19/2020	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Aug-19-2020 14:11:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SCREENING	Initial Entry

3. Status:

Date	Location	User	Value	Reason
Aug-19-2020 14:11:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe.mstephens)	Data Entry: COMPLETED	Initial Entry

090177e196ae2f59\Final\Final On: 01-Apr-2021 03:40 (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: 10131229

Subject Initials: ---

Generated By: pfe.lewissc

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

[Back to Form](#)

1.a

Date	Location	User	Value	Reason
Aug-19-2020 14:11:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/ 1 MH N umber : Medic ATTENTION al Hist DEFICIT HY ory Te PERACTIVIT rm: Y DISORDE R Start UNK/UNK/20 Date: 10 Ongoi YES ng:	Initial Entry

1.a Line/MH Number:

Date	Location	User	Value	Reason
Aug-19-2020 14:11:42 (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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090177e196ae2f59\Final\Final On: 01-Apr-2021 03:40 (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: 10131229

Subject Initials: ---

Generated By: pfe.lewissc

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

Aug-19-2020 14:11:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe.mstephens)	Data Entry: ATTENTION DEFICIT HYPERACTIVITY DISORDER	Initial Entry
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1.a Start Date:

Date	Location	User	Value	Reason
Aug-19-2020 14:11:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe.mstephens)	Data Entry: UNK/UNK/2010	Initial Entry

1.a Ongoing:

Date	Location	User	Value	Reason
Aug-19-2020 14:11:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe.mstephens)	Data Entry: YES	Initial Entry

1.b

Date	Location	User	Value	Reason
Aug-19-2020 14:12:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/M 2 H Number:	Initial Entry

090177e196ae2f59\Final\Final On: 01-Apr-2021 03:40 (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: 10131229

Subject Initials: ---

Generated By: pfe.lewissc

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

			Medical History Term: BREAST AUGMENTATION Start Date: Jun/UNK/2020 Ongoing: NO End Date: Jun/UNK/2020	
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090177e196ae2f59\Final\Final On: 01-Apr-2021 03:40 (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: 10131229

Subject Initials: ---

Generated By: pfe.lewissc

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

1.b Line/MH Number:

Date	Location	User	Value	Reason
Aug-19-2020 14:12:01 (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
Aug-19-2020 14:12:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe.mstephens)	Data Entry: BREAST AUGMENTATION	Initial Entry

1.b Start Date:

Date	Location	User	Value	Reason
Aug-19-2020 14:12:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe.mstephens)	Data Entry: Jun/UNK/2020	Initial Entry

1.b Ongoing:

Date	Location	User	Value	Reason
Aug-19-2020 14:12:01	ACV0PFEINFP6000	Matthew Stephens	Data Entry: NO	Initial Entry

090177e196ae2f59\Final\Final On: 01-Apr-2021 03:40 (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: 10131229

Subject Initials: ---

Generated By: pfe.lewissc

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

(UTC-05:00) Eastern Time (US & Canada)		(pfe.mstephens)	End Date: Jun/UNK/2020	
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I.c

Date	Location	User	Value	Reason
Aug-19-2020 14:12:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH N 3 umber: Medical His OBESIT tory Term: Y Start Date: UNK/U NK/201 6 Ongoing: YES	Initial Entry

090177e196ae2f59\Final\Final On: 01-Apr-2021 03:40 (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: 10131229

Subject Initials: ---

Generated By: pfe.lewissc

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

1.c Line/MH Number:

Date	Location	User	Value	Reason
Aug-19-2020 14:12:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 3	Initial Entry

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

Date	Location	User	Value	Reason
Aug-19-2020 14:12:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe.mstephens)	Data Entry: OBESITY	Initial Entry

1.c Start Date:

Date	Location	User	Value	Reason
Aug-19-2020 14:12:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe.mstephens)	Data Entry: UNK/UNK/2016	Initial Entry

1.c Ongoing:

Date	Location	User	Value	Reason
Aug-19-2020 14:12:11	ACV0PFEINFP6000	Matthew Stephens	Data Entry: YES	Initial Entry

090177e196ae2f59\Final\Final On: 01-Apr-2021 03:40 (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: 10131229

Subject Initials: ---

Generated By: pfe.levissc

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

(UTC-05:00) Eastern Time (US & Canada)		(pfe.mstephens)		
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Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 30-Jul-2020 21:28

Site No: 1013

Subject No: 10131229

Generated By: pfe.lewissc

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
Aug-19-2020 14:12:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe.mstephens)	Data Entry: Aug/19/2020	Initial Entry

2. Weight:

Date	Location	User	Value	Reason
Aug-19-2020 14:12:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe.mstephens)	Data Entry: 79.3	Initial Entry

3. Unit:

Date	Location	User	Value	Reason
Aug-19-2020 14:12:35 (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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090177e196ae2f59\Final\Final On: 01-Apr-2021 03:40 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: VITAL SIGNS - BASELINE - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:28

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1013

Site Name: (1013) Clinical Neuroscience Solutions Inc.

Subject No: 10131229

Subject Initials: ---

Generated By: pfe.levisse

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

Aug-19-2020 14:12:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe.mstephens)	Data Entry: 162.6	Initial Entry
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5. Unit:

Date	Location	User	Value	Reason
Aug-19-2020 14:12:35 (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
Aug-19-2020 14:12:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 30.0	Initial Entry

7.a

Date	Location	User	Value	Reason
Aug-19-2020 14:12:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe.mstephens)	Data Entry: Record Id 1 entifier:: Temperat 37.1 ure:	Initial Entry

090177e196ae2f59\Final\Final On: 01-Apr-2021 03:40 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: VITAL SIGNS - BASELINE - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:28

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1013

Site Name: (1013) Clinical Neuroscience Solutions Inc.

Subject No: 10131229

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
Aug-19-2020 14:12:35 (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
Aug-19-2020 14:12:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe.mstephens)	Data Entry: 37.1	Initial Entry

7.a Unit:

Date	Location	User	Value	Reason
Aug-19-2020 14:12:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe.mstephens)	Data Entry: C	Initial Entry

090177e196ae2f59\Final\Final On: 01-Apr-2021 03:40 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: VITAL SIGNS - BASELINE - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:28

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1013

Site Name: (1013) Clinical Neuroscience Solutions Inc.

Subject No: 10131229

Subject Initials: ---

Generated By: pfe.levissc

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

7.a Temperature Location:

Date	Location	User	Value	Reason
Aug-19-2020 14:12:35 (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: 30-Jul-2020 21:27

Site No: 1013

Subject No: 10131229

Generated By: pfe.lewissc

Form: LAB URINALYSIS - PREGNANCY TEST -
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. Lab Panel:

Date	Location	User	Value	Reason
Aug-19-2020 14:12:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: URINALYSIS	Initial Entry

2. Lab Sub-Panel:

Date	Location	User	Value	Reason
Aug-19-2020 14:12:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: PREGNANCY	Initial Entry

3. Collection Date:

Date	Location	User	Value	Reason
Aug-19-2020 14:12:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe.mstephens)	Data Entry: Aug/19/2020	Initial Entry

4. Laboratory Name and Address (Derived)

Date	Location	User	Value	Reason
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090177e196ae2f59\Final\Final On: 01-Apr-2021 03:40 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

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

Form Version: 30-Jul-2020 21:27

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1013

Site Name: (1013) Clinical Neuroscience Solutions Inc.

Subject No: 10131229

Subject Initials: ---

Generated By: pfe.levissc

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

Aug-19-2020 14:12:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: STUDY SITE	Initial Entry
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5. Specimen Type:

Date	Location	User	Value	Reason
Aug-19-2020 14:12:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: URINE	Initial Entry

6.a

Date	Location	User	Value	Reason
Aug-19-2020 14:12:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sponsor- 113 Defined I dentifier: Test:: Choriogon adotropin Beta_PX11 3 Result:: NEGATIV E Not Done ::	Initial Entry

6.a Sponsor ID:

090177e196ae2f59\Final\Final On: 01-Apr-2021 03:40 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

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

Form Version: 30-Jul-2020 21:27

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1013

Site Name: (1013) Clinical Neuroscience Solutions Inc.

Subject No: 10131229

Subject Initials: ---

Generated By: pfe.lewissc

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

Date	Location	User	Value	Reason
Aug-19-2020 14:12:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 113	Initial Entry

6.a Test:

Date	Location	User	Value	Reason
Aug-19-2020 14:12:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe.mstephens)	Data Entry: Choriogonadotropin Beta_PX113	Initial Entry

6.a Result:

Date	Location	User	Value	Reason
Aug-19-2020 14:12:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe.mstephens)	Data Entry: NEGATIVE	Initial Entry

090177e196ae2f59\Final\Final On: 01-Apr-2021 03:40 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1013

Subject No: 10131229

Generated By: pfe.lewissc

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

[Back to Form](#)

1. Randomization Date :

Date	Location	User	Value	Reason
Aug-19-2020 14:13:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe.mstephens)	Data Entry: Aug/19/2020	Initial Entry

2. Randomization Number:

Date	Location	User	Value	Reason
Aug-19-2020 14:13:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe.mstephens)	Data Entry: 55842	Initial Entry

090177e196ae2f59\Final\Final On: 01-Apr-2021 03:40 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1013

Subject No: 10131229

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

[Back to Form](#)

1. Data Origin

Date	Location	User	Value	Reason
Aug-19-2020 14:13:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Aug-19-2020 14:13:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SERUM	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Aug-19-2020 17:56:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Aug-19-2020 14:13:13 (UTC-05:00)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however

090177e196ae2f59\Final\Final On: 01-Apr-2021 03:40 (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: 10131229

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.
Aug-19-2020 14:13:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe.mstephens)	Data Entry: YES Date of Collection: Aug/19/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Aug-19-2020 17:56:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe.mstephens)	Data Entry: Sample I BPYX9 D: 1	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Aug-19-2020 17:56:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe.mstephens)	Data Entry: BPYX91	Initial Entry

5.b

090177e196ae2f59\Final\Final On: 01-Apr-2021 03:40 (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: 10131229

Subject Initials: ---

Generated By: pfe.lewissc

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

Date	Location	User	Value	Reason
Aug-19-2020 17:56:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe.mstephens)	Data Entry: Sample I BPYX9 D: 2	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Aug-19-2020 17:56:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe.mstephens)	Data Entry: BPYX92	Initial Entry

5.c

Date	Location	User	Value	Reason
Aug-19-2020 17:56:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe.mstephens)	Data Entry: Sample I BPYX9 D: 3	Initial Entry

090177e196ae2f59\Final\Final On: 01-Apr-2021 03:40 (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: 10131229

Subject Initials: ---

Generated By: pfe.lewissc

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

5.c Sample ID

Date	Location	User	Value	Reason
Aug-19-2020 17:56:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe.mstephens)	Data Entry: BPYX93	Initial Entry

5.d

Date	Location	User	Value	Reason
Aug-19-2020 17:56:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe.mstephens)	Data Entry: Sample BNWH ID: MD	Initial Entry

5.d Sample ID

Date	Location	User	Value	Reason
Aug-19-2020 17:56:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe.mstephens)	Data Entry: BNWHMD	Initial Entry

5.e

Date	Location	User	Value	Reason
Aug-19-2020 17:56:33	ACV0PFEINFP6000	Matthew Stephens	Data Entry: Sample I BNWH	Initial Entry

090177e196ae2f59\Final\Final On: 01-Apr-2021 03:40 (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: 10131229

Subject Initials: ---

Generated By: pfe.lewissc

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

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

Date	Location	User	Value	Reason
Aug-19-2020 17:56:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe.mstephens)	Data Entry: BNWHMF	Initial Entry

090177e196ae2f59\Final\Final On: 01-Apr-2021 03:40 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1013

Subject No: 10131229

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
Aug-19-2020 14:13:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Aug-19-2020 14:13:19 (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
Aug-19-2020 17:56:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Aug-19-2020 14:13:19 (UTC-05:00)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however

090177e196ae2f59\Final\Final On: 01-Apr-2021 03:40 (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: 10131229

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.
Aug-19-2020 14:13:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe.mstephens)	Data Entry: YES Date of Collection: Aug/19/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Aug-19-2020 17:56:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe.mstephens)	Data Entry: Sample I BM8S6 D: Z	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Aug-19-2020 17:56:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe.mstephens)	Data Entry: BM8S6Z	Initial Entry

090177e196ae2f59\Final\Final On: 01-Apr-2021 03:40 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:04

Site No: 1013

Subject No: 10131229

Generated By: pfe.levissc

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

[Back to Form](#)

1. Was there a temporary delay of vaccination?

Date	Location	User	Value	Reason
Aug-19-2020 14:13:31 (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
Aug-19-2020 14:13:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: BLINDED THERAPY	Initial Entry

3. Formulation:

Date	Location	User	Value	Reason
Aug-19-2020 14:13:31 (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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090177e196ae2f59\Final\Final On: 01-Apr-2021 03:40 (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: 10131229

Subject Initials: ---

Generated By: pfe.levissc

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

Aug-19-2020 14:13:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe.mstephens)	Data Entry: Aug/19/2020 09:40	Initial Entry
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5. Anatomical Location:

Date	Location	User	Value	Reason
Aug-19-2020 14:13:31 (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
Aug-19-2020 14:13:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe.mstephens)	Data Entry: LEFT	Initial Entry

7. Route:

Date	Location	User	Value	Reason
Aug-19-2020 14:13:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INTRAMUSCULAR	Initial Entry

090177e196ae2f59\Final\Final On: 01-Apr-2021 03:40 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:04

Site No: 1013

Subject No: 10131229

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
Aug-19-2020 14:13:31 (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
Aug-19-2020 14:13:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe.mstephens)	Data Entry: YES	Initial Entry

090177e196ae2f59\Final\Final On: 01-Apr-2021 03:40 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 06-Jul-2020 21:53

Site No: 1013

Subject No: 10131229

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

[Back to Form](#)

1. Select appropriate response - Reactogenicity diary collection

Date	Location	User	Value	Reason
Aug-20-2020 10:21:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe.mstephens)	Data Entry: NO - REACTOGENICITY E-DIARY NOT COLLECTED FOR THIS SUBJECT	Transcription Error
Aug-19-2020 14:13:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe.mstephens)	Data Entry: YES - REACTOGENICITY E-DIARY COLLECTED FOR THIS SUBJECT	Initial Entry

090177e196ae2f59\Final\Final On: 01-Apr-2021 03:40 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 1013

Subject No: 10131229

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-10-2020 15:59:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe.mstephens)	Data Entry: Sep/10/2020	Initial Entry

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 21-Aug-2020 02:51

Site No: 1013

Subject No: 10131229

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

[Back to Form](#)

1. Date:

Date	Location	User	Value	Reason
Sep-10-2020 15:59:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe.mstephens)	Data Entry: Sep/10/2020	Initial Entry

2.a

Date	Location	User	Value	Reason
Sep-10-2020 15:59:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe.mstephens)	Data Entry: Record Id 1 entifier:: Temperat 37.1 ure: Temperat C ure Unit: Temperat ORAL ure Locati CAVIT on:: Y	Initial Entry

2.a Record Identifier:

Date	Location	User	Value	Reason
Sep-10-2020 15:59:52 (UTC-05:00) Eastern Time (US	ACV0PFEINFP6000	Matthew Stephens (pfe.mstephens)	Data Entry: 1	Initial Entry

090177e196ae2f59\Final\Final On: 01-Apr-2021 03:40 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form: VITAL SIGNS - TEMP - 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: 10131229

Subject Initials: ---

Generated By: pfe.levisse

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

& Canada)

2.a Temperature:

Date	Location	User	Value	Reason
Sep-10-2020 15:59:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe.mstephens)	Data Entry: 37.1	Initial Entry

2.a Unit:

Date	Location	User	Value	Reason
Sep-10-2020 15:59:52 (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-10-2020 15:59:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe.mstephens)	Data Entry: ORAL CAVITY	Initial Entry

090177e196ae2f59\Final\Final On: 01-Apr-2021 03:40 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

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

Form Version: 30-Jul-2020 21:27

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1013

Site Name: (1013) Clinical Neuroscience Solutions Inc.

Subject No: 10131229

Subject Initials: ---

Generated By: pfe.lewissc

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

[Back to Form](#)

1. Lab Panel:

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

2. Lab Sub-Panel:

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

3. Collection Date:

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

4. Laboratory Name and Address (Derived)

Date	Location	User	Value	Reason
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090177e196ae2f59\Final\Final On: 01-Apr-2021 03:40 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

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

Form Version: 30-Jul-2020 21:27

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1013

Site Name: (1013) Clinical Neuroscience Solutions Inc.

Subject No: 10131229

Subject Initials: ---

Generated By: pfe.levissc

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

Sep-10-2020 16:00:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: STUDY SITE	Initial Entry
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5. Specimen Type:

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

6.a

Date	Location	User	Value	Reason
Sep-10-2020 16:00:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sponsor- 113 Defined I dentifier: Test:: Choriogon adotropin Beta_PX11 3 Result:: NEGATIV E Not Done ::	Initial Entry

6.a Sponsor ID:

090177e196ae2f59\Final\Final On: 01-Apr-2021 03:40 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

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

Form Version: 30-Jul-2020 21:27

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1013

Site Name: (1013) Clinical Neuroscience Solutions Inc.

Subject No: 10131229

Subject Initials: ---

Generated By: pfe.lewissc

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

Date	Location	User	Value	Reason
Sep-10-2020 16:00:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 113	Initial Entry

6.a Test:

Date	Location	User	Value	Reason
Sep-10-2020 16:00:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe.mstephens)	Data Entry: Choriogonadotropin Beta_PX113	Initial Entry

6.a Result:

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

090177e196ae2f59\Final\Final On: 01-Apr-2021 03:40 (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: 10131229

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-10-2020 16:00:13 (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-10-2020 16:00:13 (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-10-2020 17:05:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Sep-10-2020 16:00:13 (UTC-05:00)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidat e	'Sample Collected?' is Yes, however

090177e196ae2f59\Final\Final On: 01-Apr-2021 03:40 (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: 10131229

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-10-2020 16:00:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe.mstephens)	Data Entry: YES Date of Collection: Sep/10/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Sep-10-2020 17:05:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe.mstephens)	Data Entry: Sample I BPC2W D: L	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Sep-10-2020 17:05:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe.mstephens)	Data Entry: BPC2WL	Initial Entry

090177e196ae2f59\Final\Final On: 01-Apr-2021 03:40 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1013

Subject No: 10131229

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

[Back to Form](#)

1. Was there a temporary delay of vaccination?

Date	Location	User	Value	Reason
Sep-10-2020 16:00:25 (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-10-2020 16:00:25 (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-10-2020 16:00:25 (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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090177e196ae2f59\Final\Final On: 01-Apr-2021 03:40 (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: 10131229

Subject Initials: ---

Generated By: pfe.lewissc

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

Sep-10-2020 16:00:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe.mstephens)	Data Entry: Sep/10/2020 14:50	Initial Entry
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5. Anatomical Location:

Date	Location	User	Value	Reason
Sep-10-2020 16:00:25 (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-10-2020 16:00:25 (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-10-2020 16:00:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INTRAMUSCULAR	Initial Entry

090177e196ae2f59\Final\Final On: 01-Apr-2021 03:40 (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: 10131229

Subject Initials: ---

Generated By: pfe.levissc

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

10. Timeframe Subject Was Observed

Date	Location	User	Value	Reason
Sep-10-2020 16:00:25 (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-10-2020 16:00:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe.mstephens)	Data Entry: YES	Initial Entry

090177e196ae2f59\Final\Final On: 01-Apr-2021 03:40 (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: 10131229 **Subject Initials:** ---

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

[Back to Form](#)

1. Date of Visit

Date	Location	User	Value	Reason
Oct-14-2020 14:42:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Scott Salmon (pfe.ssalmon)	Data Entry: Oct/14/2020	Initial Entry

090177e196ae2f59\Final\Final On: 01-Apr-2021 03:40 (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: 10131229 **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
Oct-14-2020 14:42:27 (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-14-2020 14:42:27 (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-15-2020 08:17:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Oct-15-2020 04:44:55 (UTC-05:00)	ACV0PFEINFP6000	Roshni Nair (pfe.nairr29)	Query 1: Opened	'Sample Collected?' is Yes, however

090177e196ae2f59\Final\Final On: 01-Apr-2021 03:40 (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:** 10131229**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.
Oct-14-2020 14:42:27 (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-14-2020 14:42:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Scott Salmon (pfe.ssalmon)	Data Entry: YES Date of Collection : Oct/14/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Oct-15-2020 08:17:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe.mstephens)	Data Entry: Sample I BR9TR D: R	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
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Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L **Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF Audit Trail History

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

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

Subject No: 10131229 **Subject Initials:** ---

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

Oct-15-2020 08:17:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe.mstephens)	Data Entry: BR9TRR	Initial Entry
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5.b

Date	Location	User	Value	Reason
Oct-15-2020 08:17:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe.mstephens)	Data Entry: Sample I BR9TR D: S	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Oct-15-2020 08:17:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe.mstephens)	Data Entry: BR9TRS	Initial Entry

5.c

Date	Location	User	Value	Reason
Oct-15-2020 08:17:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe.mstephens)	Data Entry: Sample I BR9TR D: T	Initial Entry

090177e196ae2f59\Final\Final On: 01-Apr-2021 03:40 (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: 10131229 **Subject Initials:** ---

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

5.c Sample ID

Date	Location	User	Value	Reason
Oct-15-2020 08:17:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe.mstephens)	Data Entry: BR9TRT	Initial Entry

5.d

Date	Location	User	Value	Reason
Oct-15-2020 08:17:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe.mstephens)	Data Entry: Sample I BMN58 D: G	Initial Entry

5.d Sample ID

Date	Location	User	Value	Reason
Oct-15-2020 08:17:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe.mstephens)	Data Entry: BMN58G	Initial Entry

5.e

Date	Location	User	Value	Reason
Oct-15-2020 08:17:42	ACV0PFEINFP6000	Matthew Stephens	Data Entry: Sample I BMN58	Initial Entry

090177e196ae2f59\Final\Final On: 01-Apr-2021 03:40 (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: 10131229 **Subject Initials:** ---

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

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

Date	Location	User	Value	Reason
Oct-15-2020 08:17:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe.mstephens)	Data Entry: BMN58H	Initial Entry

090177e196ae2f59\Final\Final On: 01-Apr-2021 03:40 (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: 10131229 **Subject Initials:** ---

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

[Back to Form](#)

1. Date of Completion/Discontinuation/Death :

Date	Location	User	Value	Reason
Oct-14-2020 14:42:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Scott Salmon (pfe.ssalmon)	Data Entry: Oct/14/2020	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Oct-14-2020 14:42:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: VACCINATION	Initial Entry

3. Status:

Date	Location	User	Value	Reason
Oct-14-2020 14:42:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Scott Salmon (pfe.ssalmon)	Data Entry: COMPLETED	Initial Entry

090177e196ae2f59\Final\Final On: 01-Apr-2021 03:40 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - Audit Trail

Form Version: 22-Apr-2020 21:02

Form Status:

Site No: 1013

Site Name: (1013) Clinical Neuroscience Solutions Inc.

Subject No: 10131229

Subject Initials: ---

Generated By: pfe.levissc

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

[Back to Form](#)

Date	Location	User	Value	Reason
Jan-28-2021 19:52:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Scott Salmon (pfe.ssalmon)	Form Created	

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete

Site No: 1013

Site Name: (1013) Clinical Neuroscience Solutions Inc.

Subject No: 10131229

Subject Initials: ---

Generated By: pfe.levissc

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

[Back to Form](#)

1. Category:

Date	Location	User	Value	Reason
Jan-28-2021 19:52:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: ADVERSE EVENT	Initial Entry

2. AE ID:

Date	Location	User	Value	Reason
Jan-28-2021 19:52:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 1	Initial Entry

3. Adverse Event:

(If possible specify diagnosis, not individual symptoms)

Date	Location	User	Value	Reason
Mar-04-2021 11:34:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 1: Closed	Response satisfies query
Feb-25-2021 11:01:05 (UTC-05:00)	ACV0PFEINFP6000	Scott Salmon (pfe.ssalmon)	Query 1: Answered	CORRECT AS CHARTED AND WAS

090177e196ae2f59\Final\Final On: 01-Apr-2021 03:40 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete

Site No: 1013

Site Name: (1013) Clinical Neuroscience Solutions Inc.

Subject No: 10131229

Subject Initials: ---

Generated By: pfe.lewissc

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

Eastern Time (US & Canada)				SUBMITTED.
Feb-23-2021 15:58:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 2: Closed	Query closed; will follow for requested miscarriage history year information.
Feb-23-2021 15:57:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 3: Closed	Query closed; will follow for requested Father information.
Feb-18-2021 18:36:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 1: Reissued :Opened	Clinical - no further records required to match the SAE with the AE; please submit correct term per Pregnancy reporting instructions 'Exposure during Pregnancy' to the PG Safety report as well
Feb-17-2021 15:03:47 (UTC-05:00)	ACV0PFEINFP6000	Scott Salmon (pfe.ssalmon)	Query 3: Answered	CRC is still attempting to contact subject

090177e196ae2f59\Final\Final On: 01-Apr-2021 03:40 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete

Site No: 1013

Site Name: (1013) Clinical Neuroscience Solutions Inc.

Subject No: 10131229

Subject Initials: ---

Generated By: pfe.lewissc

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

Eastern Time (US & Canada)				for additional details.
Feb-17-2021 15:03:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Scott Salmon (pfe.ssalmon)	Query 2: Answered	CRC still attempting to contact subject for additional details.
Feb-17-2021 15:02:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Scott Salmon (pfe.ssalmon)	Query 1: Answered	CRC is still trying to contact subject for additional details.
Feb-17-2021 09:13:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 2: Reissued :Opened	Clinical As of 17Feb21, the most recent safety update was the 08Feb21 submission; year of prior delivery still remains missing on PG safety report
Feb-17-2021 09:07:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 3: Reissued :Opened	Clinical As of 17Feb21, the most recent safety update was the 08Feb21 submission; no

090177e196ae2f59\Final\Final On: 01-Apr-2021 03:40 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete

Site No: 1013

Site Name: (1013) Clinical Neuroscience Solutions Inc.

Subject No: 10131229

Subject Initials: ---

Generated By: pfe.lewissc

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

				father info still on PG safety report other than takes MVI
Feb-17-2021 09:06:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 1: Reissued :Opened	Clinical As of 17Feb21, the most recent safety update was the 08Feb21 submission; pregnancy is still the event term on PG safety report
Feb-11-2021 16:13:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Scott Salmon (pfe.ssalmon)	Query 3: Answered	UPDATED BY CRC
Feb-11-2021 16:12:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Scott Salmon (pfe.ssalmon)	Query 2: Answered	UPDATED BY CRC
Feb-11-2021 16:10:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Scott Salmon (pfe.ssalmon)	Query 1: Answered	UPDATE SUBMITTED BY CRC

090177e196ae2f59\Final\Final On: 01-Apr-2021 03:40 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete

Site No: 1013

Site Name: (1013) Clinical Neuroscience Solutions Inc.

Subject No: 10131229

Subject Initials: ---

Generated By: pfe.lewissc

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

Feb-09-2021 02:00:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 3: Opened	Clinical Thank you; however PG safety update (08Feb) did not report Father information
Feb-09-2021 01:59:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 2: Reissued :Opened	CLINICAL Thank you; PG safety update (08Feb) did not report year of subject's prior pregnancy, and if the outcome was miscarriage (in Med Hx)
Feb-09-2021 01:55:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 1: Reissued :Opened	Clinical Thank you; however safety update (08Feb21) continues with event term 'Pregnancy'. Please submit a PG safety update reporting the modified event term EDP
Feb-01-2021 11:50:56 (UTC-05:00)	ACV0PFEINFP6000	Monica Cooper (pfe.mcooper)	Query 2: Answered	Safety update has been submitted by

090177e196ae2f59\Final\Final On: 01-Apr-2021 03:40 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete

Site No: 1013

Site Name: (1013) Clinical Neuroscience Solutions Inc.

Subject No: 10131229

Subject Initials: ---

Generated By: pfe.lewissc

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

Eastern Time (US & Canada)				CRC
Feb-01-2021 11:50:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Monica Cooper (pfe.mcooper)	Query 1: Answered	Safety update has been submitted by CRC
Jan-29-2021 13:23:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 2: Opened	Clinical Please submit a safety update (#2021058335) with the year for subject's previous miscarriage and Father info (age, meds, social hx) on the Pregnancy form
Jan-29-2021 13:22:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 1: Opened	Event term is Exposure during Pregnancy; however, event term in Safety report is Pregnancy. Please submit a Safety update to report the full term 'Exposure during Pregnancy'

090177e196ae2f59\Final\Final On: 01-Apr-2021 03:40 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete

Site No: 1013

Site Name: (1013) Clinical Neuroscience Solutions Inc.

Subject No: 10131229

Subject Initials: ---

Generated By: pfe.lewissc

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

Jan-29-2021 10:53:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Monica Cooper (pfe.mcooper)	Data Entry: Exposure During Pregnancy	changed information per email query instructions
Jan-28-2021 19:52:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Scott Salmon (pfe.ssalmon)	Data Entry: PREGNANCY	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason
Feb-26-2021 00:17:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 1: Closed	Response satisfies query
Feb-25-2021 11:06:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Scott Salmon (pfe.ssalmon)	Query 1: Answered	PER CRC; CORRECT AS IT IS THE SAME ON AE AND SAE FORMS SUBMITTED.
Feb-23-2021 15:56:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 1: Reissued :Opened	Clinical - the correct date is desired for both AE and PG safety report, & must be the

090177e196ae2f59\Final\Final On: 01-Apr-2021 03:40 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete

Site No: 1013

Site Name: (1013) Clinical Neuroscience Solutions Inc.

Subject No: 10131229

Subject Initials: ---

Generated By: pfe.lewissc

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

				same in both locations. Please report either 10Dec20 or ??Dec20 in both locations
Feb-17-2021 14:59:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Scott Salmon (pfe.ssalmon)	Query 1: Answered	Correct as charted per CRC.
Feb-17-2021 09:08:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 1: Reissued :Opened	Clinical As of 17Feb21, the most recent safety update was the 08Feb21 submission; start date still remains ??Dec20 on PG safety report
Feb-11-2021 16:11:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Scott Salmon (pfe.ssalmon)	Query 1: Answered	UPDATE SUBMITTED BY CRC
Feb-09-2021 02:01:56 (UTC-05:00) Eastern Time	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 1: Reissued :Opened	Clinical Thank you; start date of 10Dec20 is Estimated date

090177e196ae2f59\Final\Final On: 01-Apr-2021 03:40 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete

Site No: 1013

Site Name: (1013) Clinical Neuroscience Solutions Inc.

Subject No: 10131229

Subject Initials: ---

Generated By: pfe.lewissc

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

(US & Canada)				of Conception; however, most recent PG safety report still has ??Dec20
Feb-01-2021 12:04:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Monica Cooper (pfe.mcooper)	Query 1: Answered	correct as recorded; Safety update has been submitted by CRC
Jan-29-2021 13:26:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 1: Opened	Clinical Event start date is 10Dec20 (estimated date of conception); however, safety report for pregnancy has start date of ??Dec20. Please submit a safety update to report the full start date
Jan-28-2021 19:52:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Scott Salmon (pfe.ssalmon)	Data Entry: Dec/10/2020 UN K:UNK	Initial Entry

090177e196ae2f59\Final\Final On: 01-Apr-2021 03:40 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete

Site No: 1013

Site Name: (1013) Clinical Neuroscience Solutions Inc.

Subject No: 10131229

Subject Initials: ---

Generated By: pfe.lewissc

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

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Mar-04-2021 11:38:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 1: Closed	Response satisfies query
Feb-25-2021 11:02:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Scott Salmon (pfe.ssalmon)	Query 1: Answered	PER CRC, FORMS ARE BEING SUBMITTED 25/FEB/2021.
Feb-18-2021 18:37:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 1: Reissued:Opened	Clinical Please report Subject's statement as to whether she is still pregnant or has experienced a miscarriage (information from subject does not require medical records)
Feb-17-2021 15:04:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Scott Salmon (pfe.ssalmon)	Query 1: Answered	CRC is still attempting to contact subject for additional details.
Feb-17-2021 09:12:10 (UTC-05:00)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 1: Reissued:Opened	Clinical As of 17Feb21, the most recent safety update

090177e196ae2f59\Final\Final On: 01-Apr-2021 03:40 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete

Site No: 1013

Site Name: (1013) Clinical Neuroscience Solutions Inc.

Subject No: 10131229

Subject Initials: ---

Generated By: pfe.lewissc

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

Eastern Time (US & Canada)				was the 08Feb21 submission (current status is Ongoing). Please clarify in query response - was there a miscarriage? If so, please record this pregnancy adverse outcome on AE CRF
Feb-11-2021 16:11:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Scott Salmon (pfe.ssalmon)	Query 1: Answered	UPDATED FORMS PER CRC
Feb-09-2021 02:06:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 1: Opened	Clinical - Current status is Ongoing/no stop date; however, recent PG safety update reported 'outcome of spontaneous abortion/miscarriage'. If a PG adverse outcome has occurred, please record it on the AE CRF
Jan-28-2021 19:52:55 (UTC-05:00) Eastern Time	ACV0PFEINFP6000	Scott Salmon (pfe.ssalmon)	Data Entry: YES	Initial Entry

090177e196ae2f59\Final\Final On: 01-Apr-2021 03:40 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete

Site No: 1013

Site Name: (1013) Clinical Neuroscience Solutions Inc.

Subject No: 10131229

Subject Initials: ---

Generated By: pfe.lewissc

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

(US & Canada)

6. Toxicity Grade:

Date	Location	User	Value	Reason
Feb-02-2021 09:58:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 1: Closed	Response satisfies query
Feb-01-2021 11:50:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Monica Cooper (pfe.mcooper)	Data Entry: Not Applicable	Initial Entry
Feb-01-2021 11:49:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Transcription Error
Feb-01-2021 11:49:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Monica Cooper (pfe.mcooper)	Data Entry:	Transcription Error
Jan-29-2021 13:20:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 1: Opened	Clinical As per CRF CG 8.50.2.5, the toxicity grade for "Exposure During

090177e196ae2f59\Final\Final On: 01-Apr-2021 03:40 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete

Site No: 1013

Site Name: (1013) Clinical Neuroscience Solutions Inc.

Subject No: 10131229

Subject Initials: ---

Generated By: pfe.lewissc

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

				Pregnancy” is reported as Not Applicable
Jan-28-2021 19:52:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Scott Salmon (pfe.ssalmon)	Data Entry: 1	Initial Entry

7. Is the adverse event serious?

If Yes, NOTIFY PFIZER IMMEDIATELY.

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

Date	Location	User	Value	Reason
Jan-28-2021 19:52:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Scott Salmon (pfe.ssalmon)	Data Entry: NO	Initial Entry

090177e196ae2f59\Final\Final On: 01-Apr-2021 03:40 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete

Site No: 1013

Site Name: (1013) Clinical Neuroscience Solutions Inc.

Subject No: 10131229

Subject Initials: ---

Generated By: pfe.lewissc

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

[Back to Form](#)

8. Is this adverse event the result of a study Medication Error?

If Yes, record the type of medication error on the Medication Error Log.

Date	Location	User	Value	Reason
Jan-28-2021 19:52:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Scott Salmon (pfe.ssalmon)	Data Entry: NO	Initial Entry

9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Jan-28-2021 19:52:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Scott Salmon (pfe.ssalmon)	Data Entry: NOT RELATED If Not Related to study treatment(s), this event is due to: OTHER <i>If Other, specify:</i> PREGNANCY	Initial Entry

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Jan-28-2021 19:52:55	ACV0PFEINFP6000	Scott Salmon (pfe.ssalmon)	Data Entry: NOT APPLICABLE	Initial Entry

090177e196ae2f59\Final\Final On: 01-Apr-2021 03:40 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete

Site No: 1013

Site Name: (1013) Clinical Neuroscience Solutions Inc.

Subject No: 10131229

Subject Initials: ---

Generated By: pfe.lewissc

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

(UTC-05:00) Eastern Time (US & Canada)				
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11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
Jan-28-2021 19:52:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Scott Salmon (pfe.ssalmon)	Data Entry: NO	Initial Entry

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Jan-28-2021 19:52:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Scott Salmon (pfe.ssalmon)	Data Entry: NO	Initial Entry

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

Date	Location	User	Value	Reason
Jan-28-2021 19:52:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Scott Salmon (pfe.ssalmon)	Data Entry: RECOVERING/RE SOLVING	Initial Entry

090177e196ae2f59\Final\Final On: 01-Apr-2021 03:40 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete

Site No: 1013

Site Name: (1013) Clinical Neuroscience Solutions Inc.

Subject No: 10131229

Subject Initials: ---

Generated By: pfe.lewissc

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

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

Date	Location	User	Value	Reason
Jan-28-2021 19:52:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Scott Salmon (pfe.ssalmon)	Data Entry: NO	Initial Entry

Header Text: c4591001

Visit: Potential ReVax Initial Contact - **Form:** DATE OF VISIT - eCRF Audit Trail History
Unscheduled

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: 10131229 **Subject Initials:** ---

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

[Back to Form](#)

1. Date of Visit

Date	Location	User	Value	Reason
Jan-20-2021 13:43:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Scott Salmon (pfe.ssalmon)	Data Entry: Jan/19/2021	Initial Entry

090177e196ae2f59\Final\Final On: 01-Apr-2021 03:40 (GMT)

Header Text: c4591001

Visit: Potential ReVax Initial Contact - **Form:** FURTHER VACCINATION CONFIRMATION -
Unscheduled eCRF Audit Trail History

Form Version: 10-Dec-2020 02:25 **Form Status:** Data Complete, Frozen

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

Subject No: 10131229 **Subject Initials:** ---

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

[Back to Form](#)

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

Date	Location	User	Value	Reason
Mar-03-2021 06:25:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Ajit Malode (pfe.maloda)	Query 1: Closed	Site has updated the response to 'have received only placebo at Vaccination 1/2 '.
Mar-02-2021 16:32:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Transcription Error
Mar-02-2021 16:32:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Scott Salmon (pfe.ssalmon)	Data Entry: Participant is willing to return for Vaccination 3 Participant is: eligible and NOT confirmed to have received only placebo at Vaccination 1/2	Transcription Error
Mar-02-2021 09:55:02	ACV0PFEINFP6000	Pratiksha Mahadik	Query 1: Opened	DM: Participant is

090177e196ae2f59\Final\Final On: 01-Apr-2021 03:40 (GMT)

Header Text: c4591001

Visit: Potential ReVax Initial Contact - **Form:** FURTHER VACCINATION CONFIRMATION -
Unscheduled eCRF Audit Trail History

Form Version: 10-Dec-2020 02:25 **Form Status:** Data Complete, Frozen

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

Subject No: 10131229 **Subject Initials:** ---

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

(UTC-05:00) Eastern Time (US & Canada)		(pfe.mahadp07)		eligible and confirmed to have received Placebo on the Further Vaccination Confirmation CRF, However Date Written Consent Obtained is missing in Informed Consent - Further Vaccination CRF. Kindly review and update, else clarify.
Jan-20-2021 13:43:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Scott Salmon (pfe.ssalmon)	Data Entry: Participant is willing to return for Vaccination 3 Participant is: eligible per local/national recommendations and confirmed to have received only placebo at Vaccination 1/2	Initial Entry

090177e196ae2f59\Final\Final On: 01-Apr-2021 03:40 (GMT)

Header Text: c4591001

Visit: Disposition - Unscheduled

Form: TREATMENT UNBLINDED - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1013

Site Name: (1013) Clinical Neuroscience Solutions Inc.

Subject No: 10131229

Subject Initials: ---

Generated By: pfe.lewissc

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

[Back to Form](#)

1. Date Treatment Unblinded :

Date	Location	User	Value	Reason
Jan-20-2021 13:42:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Scott Salmon (pfe.ssalmon)	Data Entry: Jan/19/2021	Initial Entry

2. Primary Reason for Unblinding:

Date	Location	User	Value	Reason
Jan-20-2021 13:42:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Scott Salmon (pfe.ssalmon)	Data Entry: ASSESS ELIGIBILI TY FOR ADDITION AL VACCINATION	Initial Entry

Header Text: c4591001

Visit: Subject Status - Unscheduled

Form: SUBJECT STATUS - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Verified

Site No: 1013

Site Name: (1013) Clinical Neuroscience Solutions Inc.

Subject No: 10131229

Subject Initials: ---

Generated By: pfe.lewissc

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

[Back to Form](#)

1. Subject Status

Date	Location	User	Value	Reason
Oct-14-2020 14:42:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: FOLLOW-UP	Initial Entry
Aug-19-2020 14:13:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: ENROLLED/RANDOMIZED	Initial Entry
Aug-19-2020 14:11:16 (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
Feb-02-2021 18:33:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 1: Closed	Response satisfies query
Jan-28-2021 19:48:09	ACV0PFEINFP6000	Scott Salmon (pfe.ssalmon)	Query 1: Answered	UPDATED

090177e196ae2f59\Final\Final On: 01-Apr-2021 03:40 (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: 10131229

Subject Initials: ---

Generated By: pfe.lewissc

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

(UTC-05:00) Eastern Time (US & Canada)				
Jan-25-2021 11:46:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 1: Opened	Clinical Please enter the event 'Pregnancy' on the AE CRF
Oct-14-2020 14:42:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Oct/14/2020	Initial Entry
Aug-19-2020 14:13:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Aug/19/2020	Initial Entry
Aug-19-2020 14:11:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Aug/19/2020	Initial Entry

090177e196ae2f59\Final\Final On: 01-Apr-2021 03:40 (GMT)

Header Text: c4591001

Visit: Investigator Signature -
Unscheduled

Form Version: 22-Apr-2020 21:04

Site No: 1013

Subject No: 10131229

Generated By: pfe.lewissc

Form: CASEBOOK SIGNATURE FORM - eCRF Audit
Trail History

Form Status: Data Complete, Signed, Verified

Site Name: (1013) Clinical Neuroscience Solutions Inc.

Subject Initials: ---

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

[Back to Form](#)

1. Casebook Signature

Date	Location	User	Value	Reason
Sep-15-2020 10:36:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Monica Cooper (pfe.mcooper)	Data Entry: Click Here to Enable	Initial Entry

090177e196ae2f59\Final\Final On: 01-Apr-2021 03:40 (GMT)