

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: 10131255

Subject Initials: ---

Generated By: pfe.levisse

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

[eCRF Audit Trail History](#)

Cohort Selection

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

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

Header Text: c4591001

Visit: COHORT_SELECTION

Form: MAIN INFORMED CONSENT

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1013

Site Name: (1013) Clinical Neuroscience Solutions Inc.

Subject No: 10131255

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/20/2020
----	--------------	--

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: 10131255

Subject Initials: ---

Generated By: pfe.levissc

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

[eCRF Audit Trail History](#)

Demography

1.	Subject ID	[10131255]
2.	Birth Date:	(b) (6)/1990
3.	Sex:	FEMALE
4.	Ethnicity:	NOT HISPANIC OR LATINO(A) OR OF SPANISH ORIGIN
5.	Race: (Check X all that apply):	WHITE
6.	Racial Designation:	

090177e196ae2f58\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: 10131255

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/20/2020
2.	Erroneous Visit	

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 30-Jul-2020 21:29

Site No: 1013

Subject No: 10131255

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 _____
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Exclusion Criteria Met

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

090177e196ae2f58\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: 10131255

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/20/2020
2.	Phase of Disposition:	SCREENING
3.	Status:	COMPLETED
4.	Specify Status:	[]

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1013

Subject No: 10131255

Generated By: pfe.levissc

Form: GENERAL MEDICAL HISTORY

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1013) Clinical Neuroscience Solutions Inc.

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Medical History Details

1.a	Line/MH Number:	[1]
	Disease/Syndrome /Surgery/Non-Drug Allergies/Drug Allergies:	[WISDOM TEETH REMOVAL]
	Start Date:	May/UNK/2016
	Ongoing:	NO
		End Date: May/UNK/2016

090177e196ae2f58\Final\Final On: 01-Apr-2021 03:40 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: VITAL SIGNS - BASELINE

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: 10131255

Subject Initials: ---

Generated By: pfe.levissc

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

eCRF Audit Trail History

Vital Signs

1.	Date:	Aug/20/2020
2.	Weight:	[60.5]
3.	Unit:	kg
4.	Height:	[178.0]
5.	Unit:	cm
6.	Body Mass Index:	[19.1]

Vital Signs Details

7.a	Record Identifier:	1
	Temperature:	[35.7]
	Unit:	C
	Temperature Location:	ORAL CAVITY

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 30-Jul-2020 21:27

Site No: 1013

Subject No: 10131255

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/20/2020
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:	

090177e196ae2f58\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: 10131255

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/20/2020
2.	Randomization Number:	[58170]
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: 10131255

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

Aliquot

Please enter barcode for each aliquot.

5.a	Sample ID	[BPYXBB]
5.b	Sample ID	[BPYXBC]
5.c	Sample ID	[BPYXBD]
5.d	Sample ID	[BNWHN8]
5.e	Sample ID	[BNWHN9]

090177e196ae2f58\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:** 10131255**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/20/2020
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[]

Aliquot

Please enter barcode for each aliquot.

5.a	Sample ID	[BM8S83]
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Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:04

Site No: 1013

Subject No: 10131255

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/20/2020 10:10
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

090177e196ae2f58\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: 10131255

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
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Header Text: c4591001

Visit: V2_VAX2_L

Form: DATE OF VISIT

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1013

Site Name: (1013) Clinical Neuroscience Solutions Inc.

Subject No: 10131255

Subject Initials: ---

Generated By: pfe.levisse

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

[eCRF Audit Trail History](#)

Date of Visit

1.	Date of Visit	Sep/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: 10131255

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

090177e196ae2f58\Final\Final On: 01-Apr-2021 03:40 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 30-Jul-2020 21:27

Site No: 1013

Subject No: 10131255

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:	

090177e196ae2f58\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: 10131255

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	[BPC2WJ]
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090177e196ae2f58\Final\Final On: 01-Apr-2021 03:40 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form: VACCINATION

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1013

Site Name: (1013) Clinical Neuroscience Solutions Inc.

Subject No: 10131255

Subject Initials: ---

Generated By: pfe.levissc

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 15:50
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

090177e196ae2f58\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: 10131255 **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: 10131255 **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	[BR9TT7]
5.b	Sample ID	[BR9TT8]
5.c	Sample ID	[BR9TT9]
5.d	Sample ID	[BMN59G]
5.e	Sample ID	[BMN59H]

090177e196ae2f58\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: 10131255

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:	
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Header Text: c4591001

Visit: POT_COVID_ILL - New
Unscheduled Visit

Form Version: 20-Feb-2021 02:17

Site No: 1013

Subject No: 10131255

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:	[]
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090177e196ae2f58\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: 10131255

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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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: 10131255

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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090177e196ae2f58\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: 10131255

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:	[]
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Health Care Utilization

3.	Has the subject been hospitalized due to potential COVID-19 illness?	
----	--	--

090177e196ae2f58\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: 10131255

Subject Initials: ---

Generated By: pfe.lewissc

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: 10131255

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: 10131255

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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090177e196ae2f58\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: 10131255 **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: 10131255 **Subject Initials:** ---

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

Unplanned Assessments

1.	Assessments	
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090177e196ae2f58\Final\Final On: 01-Apr-2021 03:40 (GMT)

Header Text: c4591001

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

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

Site No: 1013

Site Name: (1013) Clinical Neuroscience Solutions Inc.

Subject No: 10131255

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: 10131255

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: 10131255

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: 10131255 **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	[]
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090177e196ae2f58\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: 10131255

Subject Initials: ---

Generated By: pfe.levisse

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	Sep/UNK/2020 UNK:UNK	NO End Date Time: Oct/UNK/2020 UNK:UNK	Repeating Pages
2.	ADVERSE EVENT	2	MISCARRIAGE	Oct/UNK/2020 UNK:UNK	NO End Date Time: Oct/UNK/2020 UNK:UNK	Repeating Pages

090177e196ae2f58\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, Frozen

Site No: 1013

Site Name: (1013) Clinical Neuroscience Solutions Inc.

Subject No: 10131255

Subject Initials: ---

Generated By: pfe.levisse

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

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[eCRF Audit Trail History](#)

[Form Audit Trail](#)

Adverse Event Report

1.	Category:	ADVERSE EVENT	
2.	AE ID:	[1]	
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[EXPOSURE DURING PREGNANCY]	
4.	Start Date Time:	Sep/UNK/2020 UNK:UNK	
5.	Is the adverse event still ongoing?	NO End Date Time: Oct/UNK/2020 UNK:UNK	
6.	Toxicity Grade:	Not Applicable	Comments

090177e196ae2f58\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, Frozen

Site No: 1013

Site Name: (1013) Clinical Neuroscience Solutions Inc.

Subject No: 10131255

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 WITH MISCARRIAGE]
10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE

090177e196ae2f58\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, Frozen

Site No: 1013

Site Name: (1013) Clinical Neuroscience Solutions Inc.

Subject No: 10131255

Subject Initials: ---

Generated By: pfe.levisse

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

090177e196ae2f58\Final\Final On: 01-Apr-2021 03:40 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1013

Subject No: 10131255

Generated By: pfe.levissc

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Frozen

Site Name: (1013) Clinical Neuroscience Solutions Inc.

Subject Initials: ---

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

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[eCRF Audit Trail History](#)

[Form Audit Trail](#)

Adverse Event Report

1.	Category:	ADVERSE EVENT
2.	AE ID:	[2]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[MISCARRIAGE]
4.	Start Date Time:	Oct/UNK/2020 UNK:UNK
5.	Is the adverse event still ongoing?	NO End Date Time: Oct/UNK/2020 UNK:UNK
6.	Toxicity Grade:	3

Header Text: c4591001**Visit:** Logs - Unscheduled**Form Version:** 22-Apr-2020 21:02**Site No:** 1013**Subject No:** 10131255**Generated By:** pfe.levisse**Form:** ADVERSE EVENT REPORT**Form Status:** Data Complete, Frozen**Site Name:** (1013) Clinical Neuroscience Solutions Inc.**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 04:21

7.	<p>Is the adverse event serious?</p> <p>If Yes, NOTIFY PFIZER IMMEDIATELY.</p> <p>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).</p>	<p>YES</p> <p>Is this serious event associated with congenital anomaly or birth defect? NO</p> <p>Did this serious event result in death? NO</p> <p>Did this serious event require or prolong hospitalization? NO</p> <p>Did this serious event result in persistent or significant disability/incapacity? NO</p> <p>Is this serious event life threatening? NO</p> <p>Other medically important serious event YES</p>
8.	<p>Is this adverse event the result of a study Medication Error?</p> <p>If Yes, record the type of medication error on the Medication Error Log.</p>	NO
9.	<p>Is this event related to study treatment:</p>	<p>NOT RELATED</p> <p>If Not Related to study treatment(s), this event is due to: OTHER</p> <p>If Other, specify: [MISCARRIAGE]</p>
10.	<p>Latest Action Taken with Study Treatment:</p>	NOT APPLICABLE

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen

Site No: 1013

Site Name: (1013) Clinical Neuroscience Solutions Inc.

Subject No: 10131255

Subject Initials: ---

Generated By: pfe.levisse

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?:	RECOVERED/RESOLVED
14.	Did the adverse event cause the subject to be discontinued from the study?	NO
15.	Serious Adverse Event Number: For Pfizer Use Only	[2020503978]

090177e196ae2f58\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: 10131255

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: 10131255

Subject Initials: ---

Generated By: pfe.levisse

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

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Medication Error

1.	Category:	
2.	Medication Error (Type of Medication Error):	[]
3.	Start Date:	//
4.	Is the medication error still ongoing?	
5.	Latest Action Taken with Study Treatment:	
6.	Was a Concomitant Medication given?	
7.	Was a Non-Drug Treatment given?	
8.	Did the Medication Error cause the subject to be discontinued from the study?	
9.	Was this medication error associated with any adverse events?	
10.	Serious Adverse Event Number: For Pfizer Use Only	[]

090177e196ae2f58\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: 10131255

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	Start Date	Form Instance
1.						Repeating Pages

090177e196ae2f58\Final\Final On: 01-Apr-2021 03:40 (GMT)

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: 10131255

Subject Initials: ---

Generated By: pfe.lewissc

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

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Concomitant Medications

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

090177e196ae2f58\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: 10131255

Subject Initials: ---

Generated By: pfe.lewissc

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

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

Header Text: c4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - PROHIBITED

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1013

Site Name: (1013) Clinical Neuroscience Solutions Inc.

Subject No: 10131255

Subject Initials: ---

Generated By: pfe.lewissc

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

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Concomitant Medications

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

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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: 10131255

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

090177e196ae2f58\Final\Final On: 01-Apr-2021 03:40 (GMT)

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: 10131255

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?	

090177e196ae2f58\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: 10131255

Subject Initials: ---

Generated By: pfe.levisse

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

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

090177e196ae2f58\Final\Final On: 01-Apr-2021 03:40 (GMT)

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: 10131255

Subject Initials: ---

Generated By: pfe.levisse

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

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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: 10131255

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: 10131255

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:	

090177e196ae2f58\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: 10131255

Subject Initials: ---

Generated By: pfe.levisse

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:	

090177e196ae2f58\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: 10131255

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?	

090177e196ae2f58\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: 10131255

Subject Initials: ---

Generated By: pfe.lewissc

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

Contact Outcome

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

Header Text: c4591001

Visit: Unplanned Vaccination -
Unscheduled

Form: CONTACT OUTCOME - MONTH 6

Form Version: 10-Oct-2020 16:01

Form Status: Not Started

Site No: 1013

Site Name: (1013) Clinical Neuroscience Solutions Inc.

Subject No: 10131255

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

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

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

Subject No: 10131255 **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	Mar/10/2021
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

Site No: 1013

Site Name: (1013) Clinical Neuroscience Solutions Inc.

Subject No: 10131255

Subject Initials: ---

Generated By: pfe.levissc

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

[eCRF Audit Trail History](#)

Further Vaccination Confirmation

1.	Select appropriate response - Is participant willing to return for Vaccination 3?	Participant is willing to return for Vaccination 3 Participant is: eligible per other protocol allowance(s) and 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, Verified

Site No: 1013

Site Name: (1013) Clinical Neuroscience Solutions Inc.

Subject No: 10131255

Subject Initials: ---

Generated By: pfe.levisse

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

[eCRF Audit Trail History](#)

Treatment Unblinded

1.	Date Treatment Unblinded :	Mar/10/2021
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: 10131255

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: 10131255

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: Data Complete, Verified

Site No: 1013

Site Name: (1013) Clinical Neuroscience Solutions Inc.

Subject No: 10131255

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	Mar/10/2021
2.	Erroneous Visit	

Header Text: c4591001

Visit: V101_VAX3

Form: INFORMED CONSENT - FURTHER VACCINATION

Form Version: 10-Dec-2020 02:31

Form Status: Data Complete, Verified

Site No: 1013

Site Name: (1013) Clinical Neuroscience Solutions Inc.

Subject No: 10131255

Subject Initials: ---

Generated By: pfe.lewissc

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

[eCRF Audit Trail History](#)

Informed Consent - Further Vaccination

1.	Consent Was:	OBTAINED Date Written Consent Obtained Mar/10/2021
----	--------------	--

090177e196ae2f58\Final\Final On: 01-Apr-2021 03:40 (GMT)

Header Text: c4591001

Visit: V101_VAX3

Form: INCLUSION/EXCLUSION CRITERIA - FURTHER VACCINATION

Form Version: 10-Dec-2020 02:30

Form Status: Data Complete, Verified

Site No: 1013

Site Name: (1013) Clinical Neuroscience Solutions Inc.

Subject No: 10131255

Subject Initials: ---

Generated By: pfe.lewissc

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

Header Text: c4591001

Visit: V101_VAX3

Form: DISPOSITION - SCREENING FOR FURTHER VACCINATION

Form Version: 10-Dec-2020 02:31

Form Status: Data Complete, Verified

Site No: 1013

Site Name: (1013) Clinical Neuroscience Solutions Inc.

Subject No: 10131255

Subject Initials: ---

Generated By: pfe.lewissc

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

[eCRF Audit Trail History](#)

Disposition - Screening for Further Vaccination

1.	Date of Completion/Discontinuation/Death :	Mar/10/2021
2.	Phase of Disposition:	REPEAT SCREENING 1
3.	Status:	COMPLETED
4.	Specify Status:	[]

090177e196ae2f58\Final\Final On: 01-Apr-2021 03:40 (GMT)

Header Text: c4591001**Visit:** V101_VAX3**Form Version:** 20-Feb-2021 02:14**Site No:** 1013**Subject No:** 10131255**Generated By:** pfe.levissc**Form:** LAB URINALYSIS - PREGNANCY TEST**Form Status:** Data Complete, Verified**Site Name:** (1013) Clinical Neuroscience Solutions Inc.**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 04:21[Form Comments](#)[eCRF Audit Trail History](#)**Lab Urinalysis**

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

Lab Result

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

Header Text: c4591001

Visit: V101_VAX3

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Verified

Site No: 1013

Site Name: (1013) Clinical Neuroscience Solutions Inc.

Subject No: 10131255

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: Mar/10/2021
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[]

Aliquot

Please enter barcode for each aliquot.

5.a	Sample ID	[BV0XPK]
5.b	Sample ID	[BV0XPL]
5.c	Sample ID	[BV0XPM]
5.d	Sample ID	[BVSYTW]
5.e	Sample ID	[BVSYTX]
5.f	Sample ID	[]
5.g	Sample ID	[]

090177e196ae2f58\Final\Final On: 01-Apr-2021 03:40 (GMT)

Header Text: c4591001

Visit: V101_VAX3

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Verified

Site No: 1013

Site Name: (1013) Clinical Neuroscience Solutions Inc.

Subject No: 10131255

Subject Initials: ---

Generated By: pfe.lewissc

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

5.h	Sample ID	[]
5.i	Sample ID	[]
5.j	Sample ID	[]

Header Text: c4591001

Visit: V101_VAX3

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Verified

Site No: 1013

Site Name: (1013) Clinical Neuroscience Solutions Inc.

Subject No: 10131255

Subject Initials: ---

Generated By: pfe.levisse

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

[eCRF Audit Trail History](#)

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Mar/10/2021
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[]

Aliquot

Please enter barcode for each aliquot.

5.a	Sample ID	[BV0PGC]
5.b	Sample ID	[]

090177e196ae2f58\Final\Final On: 01-Apr-2021 03:40 (GMT)

Header Text: c4591001

Visit: V101_VAX3

Form: VACCINATION

Form Version: 10-Dec-2020 02:26

Form Status: Incomplete, Verified

Site No: 1013

Site Name: (1013) Clinical Neuroscience Solutions Inc.

Subject No: 10131255

Subject Initials: ---

Generated By: pfe.levissc

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

eCRF Audit Trail History

Vaccination

1.	Was there a temporary delay of vaccination?	YES Date of First Delay: Mar/10/2021 Reason(s) for Temporary Delay of Vaccination RECENT NON-STUDY 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?	

090177e196ae2f58\Final\Final On: 01-Apr-2021 03:40 (GMT)

Header Text: c4591001

Visit: V102_VAX4

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: 10131255

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: V102_VAX4

Form Version: 20-Feb-2021 02:14

Site No: 1013

Subject No: 10131255

Generated By: pfe.levissc

Form: LAB URINALYSIS - PREGNANCY TEST

Form Status: Not Started

Site Name: (1013) Clinical Neuroscience Solutions Inc.

Subject Initials: ---

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:	

090177e196ae2f58\Final\Final On: 01-Apr-2021 03:40 (GMT)

Header Text: c4591001

Visit: V102_VAX4

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: 10131255

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

090177e196ae2f58\Final\Final On: 01-Apr-2021 03:40 (GMT)

Header Text: c4591001

Visit: V102_VAX4

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: 10131255

Subject Initials: ---

Generated By: pfe.levissc

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?	

090177e196ae2f58\Final\Final On: 01-Apr-2021 03:40 (GMT)

Header Text: c4591001

Visit: V103_MONTH1

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: 10131255

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: V103_MONTH1

Form Version: 22-Apr-2020 21:04

Site No: 1013

Subject No: 10131255

Generated By: pfe.levissc

Form: CONTACT OUTCOME

Form Status: Not Started

Site Name: (1013) Clinical Neuroscience Solutions Inc.

Subject Initials: ---

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

Contact Outcome

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

Header Text: c4591001

Visit: V104_MONTH6

Form Version: 22-Apr-2020 21:02

Site No: 1013

Subject No: 10131255

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: V104_MONTH6

Form Version: 22-Apr-2020 21:04

Site No: 1013

Subject No: 10131255

Generated By: pfe.levissc

Form: CONTACT OUTCOME

Form Status: Not Started

Site Name: (1013) Clinical Neuroscience Solutions Inc.

Subject Initials: ---

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

Contact Outcome

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

Header Text: c4591001

Visit: V105_MONTH18

Form Version: 22-Apr-2020 21:02

Site No: 1013

Subject No: 10131255

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: V105_MONTH18

Form Version: 22-Apr-2020 21:04

Site No: 1013

Subject No: 10131255

Generated By: pfe.levissc

Form: CONTACT OUTCOME

Form Status: Not Started

Site Name: (1013) Clinical Neuroscience Solutions Inc.

Subject Initials: ---

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

Contact Outcome

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

Header Text: c4591001

Visit:
FURTHER_VACCINATION_EOT -
Unscheduled

Form: DISPOSITION - TREATMENT

Form Version: 20-Feb-2021 02:26

Form Status: Not Started

Site No: 1013

Site Name: (1013) Clinical Neuroscience Solutions Inc.

Subject No: 10131255

Subject Initials: ---

Generated By: pfe.levissc

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

Disposition - Treatment

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

Header Text: c4591001

Visit: Subject Status - Unscheduled

Form: 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: 10131255

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, Verified

Site No: 1013

Site Name: (1013) Clinical Neuroscience Solutions Inc.

Subject No: 10131255

Subject Initials: ---

Generated By: pfe.lewissc

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

[eCRF Audit Trail History](#)

Casebook Signature Form

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

Header Text: c4591001

Visit: Investigator Signature -
Unscheduled

Form: CASEBOOK SIGNATURE FORM

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Verified

Site No: 1013

Site Name: (1013) Clinical Neuroscience Solutions Inc.

Subject No: 10131255

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
- CRF_Sign_1

Name	Signature Meaning	Date	Type	Action
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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: 10131255

Subject Initials: ---

Generated By: pfe.lewissc

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

[Back to Form](#)

Item	Date	User	Comment
Form	Aug-20-2020 13:14:28 (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, Frozen

Site No: 1013

Site Name: (1013) Clinical Neuroscience Solutions Inc.

Subject No: 10131255

Subject Initials: ---

Generated By: pfe.levisse

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

[Back to Form](#)

Item	Date	User	Comment
6	Feb-09-2021 09:58:07 (UTC-05:00) Eastern Time (US & Canada)	Scott Salmon (pfe.ssalmon)	Not Applicable

Header Text: c4591001

Visit: V101_VAX3

Form: INCLUSION/EXCLUSION CRITERIA - FURTHER VACCINATION - Comments

Form Version: 10-Dec-2020 02:30

Form Status: Data Complete, Verified

Site No: 1013

Site Name: (1013) Clinical Neuroscience Solutions Inc.

Subject No: 10131255

Subject Initials: ---

Generated By: pfe.lewissc

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

[Back to Form](#)

Item	Date	User	Comment
Form	Mar-12-2021 11:31:23 (UTC-05:00) Eastern Time (US & Canada)	Scott Salmon (pfe.ssalmon)	Not Applicable

Header Text: c4591001

Visit: V101_VAX3

Form: LAB URINALYSIS - PREGNANCY TEST -
Comments

Form Version: 20-Feb-2021 02:14

Form Status: Data Complete, Verified

Site No: 1013

Site Name: (1013) Clinical Neuroscience Solutions Inc.

Subject No: 10131255

Subject Initials: ---

Generated By: pfe.lewissc

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

[Back to Form](#)

Item	Date	User	Comment
Form	Mar-12-2021 11:32:00 (UTC-05:00) Eastern Time (US & Canada)	Scott Salmon (pfe.ssalmon)	Not Applicable

Header Text: c4591001

Visit: V101_VAX3

Form: LAB URINALYSIS - PREGNANCY TEST -
Comments

Form Version: 20-Feb-2021 02:14

Form Status: Data Complete, Verified

Site No: 1013

Site Name: (1013) Clinical Neuroscience Solutions Inc.

Subject No: 10131255

Subject Initials: ---

Generated By: pfe.lewissc

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

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Item	Date	User	Comment
1	Mar-12-2021 11:32:00 (UTC-05:00) Eastern Time (US & Canada)	Scott Salmon (pfe.ssalmon)	Not Applicable

090177e196ae2f58\Final\Final On: 01-Apr-2021 03:40 (GMT)

Header Text: c4591001

Visit: V101_VAX3

Form: LAB URINALYSIS - PREGNANCY TEST -
Comments

Form Version: 20-Feb-2021 02:14

Form Status: Data Complete, Verified

Site No: 1013

Site Name: (1013) Clinical Neuroscience Solutions Inc.

Subject No: 10131255

Subject Initials: ---

Generated By: pfe.lewissc

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

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Item	Date	User	Comment
2	Mar-12-2021 11:32:00 (UTC-05:00) Eastern Time (US & Canada)	Scott Salmon (pfe.ssalmon)	Not Applicable

Header Text: c4591001

Visit: V101_VAX3

Form: LAB URINALYSIS - PREGNANCY TEST -
Comments

Form Version: 20-Feb-2021 02:14

Form Status: Data Complete, Verified

Site No: 1013

Site Name: (1013) Clinical Neuroscience Solutions Inc.

Subject No: 10131255

Subject Initials: ---

Generated By: pfe.levissc

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

[Back to Form](#)

Item	Date	User	Comment
3	Mar-12-2021 11:32:00 (UTC-05:00) Eastern Time (US & Canada)	Scott Salmon (pfe.ssalmon)	Not Applicable

Header Text: c4591001

Visit: V101_VAX3

Form: LAB URINALYSIS - PREGNANCY TEST -
Comments

Form Version: 20-Feb-2021 02:14

Form Status: Data Complete, Verified

Site No: 1013

Site Name: (1013) Clinical Neuroscience Solutions Inc.

Subject No: 10131255

Subject Initials: ---

Generated By: pfe.lewissc

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

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Item	Date	User	Comment
4	Mar-12-2021 11:32:00 (UTC-05:00) Eastern Time (US & Canada)	Scott Salmon (pfe.ssalmon)	Not Applicable

Header Text: c4591001

Visit: V101_VAX3

Form: LAB URINALYSIS - PREGNANCY TEST -
Comments

Form Version: 20-Feb-2021 02:14

Form Status: Data Complete, Verified

Site No: 1013

Site Name: (1013) Clinical Neuroscience Solutions Inc.

Subject No: 10131255

Subject Initials: ---

Generated By: pfe.levissc

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

[Back to Form](#)

Item	Date	User	Comment
5	Mar-12-2021 11:32:00 (UTC-05:00) Eastern Time (US & Canada)	Scott Salmon (pfe.ssalmon)	Not Applicable

Header Text: c4591001

Visit: V101_VAX3

Form: LAB URINALYSIS - PREGNANCY TEST -
Comments

Form Version: 20-Feb-2021 02:14

Form Status: Data Complete, Verified

Site No: 1013

Site Name: (1013) Clinical Neuroscience Solutions Inc.

Subject No: 10131255

Subject Initials: ---

Generated By: pfe.lewissc

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

[Back to Form](#)

Item	Date	User	Comment
6.a	Mar-12-2021 11:32:00 (UTC-05:00) Eastern Time (US & Canada)	Scott Salmon (pfe.ssalmon)	Not Applicable

Header Text: c4591001

Visit: V101_VAX3

Form: LAB URINALYSIS - PREGNANCY TEST -
Comments

Form Version: 20-Feb-2021 02:14

Form Status: Data Complete, Verified

Site No: 1013

Site Name: (1013) Clinical Neuroscience Solutions Inc.

Subject No: 10131255

Subject Initials: ---

Generated By: pfe.lewissc

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

[Back to Form](#)

Item	Date	User	Comment
6.a	Mar-12-2021 11:32:00 (UTC-05:00) Eastern Time (US & Canada)	Scott Salmon (pfe.ssalmon)	Not Applicable

Header Text: c4591001

Visit: V101_VAX3

Form: LAB URINALYSIS - PREGNANCY TEST -
Comments

Form Version: 20-Feb-2021 02:14

Form Status: Data Complete, Verified

Site No: 1013

Site Name: (1013) Clinical Neuroscience Solutions Inc.

Subject No: 10131255

Subject Initials: ---

Generated By: pfe.lewissc

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

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Item	Date	User	Comment
6.a	Mar-12-2021 11:32:00 (UTC-05:00) Eastern Time (US & Canada)	Scott Salmon (pfe.ssalmon)	Not Applicable

Header Text: c4591001

Visit: Investigator Signature -
Unscheduled

Form: CASEBOOK SIGNATURE FORM - Signature
History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Verified

Site No: 1013

Site Name: (1013) Clinical Neuroscience Solutions Inc.

Subject No: 10131255

Subject Initials: ---

Generated By: pfe.lewissc

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

[Back to Form](#)

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

- CRF_Sign
- CRF_Sign_1

Name	Signature Meaning	Date	Type	Action
Scott Salmon	N/A	Mar-12-2021 11:29:44 (UTC-05:00) Eastern Time (US & Canada)		Edit - All signatures invalidated

Affidavit:
N/A

Patricia Brown	Approved	Feb-25-2021 13:48:54 (UTC-05:00) Eastern Time (US & Canada)	BOOK	Signed
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Affidavit:

By my dated signature below, I, PatriciaBrown, verify that all case report form pages accurately display the results of the examinations, tests, evaluations and treatments performed on this subject.

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

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

Scott Salmon	N/A	Feb-09-2021 09:57:57 (UTC-05:00) Eastern Time (US & Canada)		Edit - All signatures invalidated
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090177e196ae2f58\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, Verified**Site No:** 1013**Site Name:** (1013) Clinical Neuroscience Solutions Inc.**Subject No:** 10131255**Subject Initials:** ---**Generated By:** pfe.lewissc**Generated Time (GMT):** 29-Mar-2021 04:21**Affidavit:**

N/A

Michael Dever	Approved	Feb-04-2021 12:59:21 (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.

Pamela Benne prod	N/A	Feb-03-2021 09:29:06 (UTC-05:00) Eastern Time (US & Canada)		Edit - All signatures invalidated
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Affidavit:

N/A

Michael Dever	Approved	Feb-02-2021 11:05:14 (UTC-05:00) Eastern Time (US & Canada)	BOOK	Signed
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Header Text: c4591001

Visit: Investigator Signature -
Unscheduled

Form: CASEBOOK SIGNATURE FORM - Signature
History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Verified

Site No: 1013

Site Name: (1013) Clinical Neuroscience Solutions Inc.

Subject No: 10131255

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	Feb-01-2021 12:22:15 (UTC-05:00) Eastern Time (US & Canada)		Edit - All signatures invalidated
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Affidavit:

N/A

Michael Dever	Approved	Feb-01-2021 10:16:31 (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.

090177e196ae2f58\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, Verified

Site No: 1013

Site Name: (1013) Clinical Neuroscience Solutions Inc.

Subject No: 10131255

Subject Initials: ---

Generated By: pfe.levissc

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

Scott Salmon	N/A	Jan-27-2021 15:04:11 (UTC-05:00) Eastern Time (US & Canada)		Edit - All signatures invalidated
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Affidavit:

N/A

Michael Dever	Approved	Jan-21-2021 09:23:04 (UTC-05:00) Eastern Time (US & Canada)	BOOK	Signed
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Affidavit:

By my dated signature below, I, Michael Dever, verify that all case report form pages accurately display the results of the examinations, tests, evaluations and treatments performed on this subject.

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

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

Matthew Stephens	N/A	Dec-23-2020 11:13:15 (UTC-05:00) Eastern Time (US & Canada)		Edit - All signatures invalidated
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Affidavit:

N/A

Michael Dever	Approved	Oct-21-2020 12:39:18 (UTC-05:00) Eastern Time (US & Canada)	BOOK	Signed
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090177e196ae2f58\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, Verified

Site No: 1013

Site Name: (1013) Clinical Neuroscience Solutions Inc.

Subject No: 10131255

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.

Matthew Stephens	N/A	Oct-14-2020 17:18:39 (UTC-05:00) Eastern Time (US & Canada)		Edit - All signatures invalidated
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Affidavit:

N/A

Michael Dever	Approved	Oct-06-2020 06:39:05 (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.

090177e196ae2f58\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: 10131255

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-20-2020 13:13:50 (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-20-2020 13:13:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe.mstephens)	Data Entry: STAGE 3 COHOR TS	Initial Entry

090177e196ae2f58\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: 10131255

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-20-2020 13:13:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe.mstephens)	Data Entry: OBTAINED Date Written Cons ent Obtained Aug/20/2020	Initial Entry

090177e196ae2f58\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: 10131255

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-20-2020 13:13:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 10131255	Item copied from previous form

2. Birth Date:

Date	Location	User	Value	Reason
Aug-20-2020 13:13:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: (b) (6)/1990	Enrollment Entry

3. Sex:

Date	Location	User	Value	Reason
Aug-20-2020 13:14:08 (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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090177e196ae2f58\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: 10131255

Subject Initials: ---

Generated By: pfe.levissc

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

Aug-20-2020 13:14:08 (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-20-2020 13:14:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe.mstephens)	Data Entry: WHITE	Initial Entry

090177e196ae2f58\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: 10131255

Generated By: pfe.levisse

Form: DATE OF VISIT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1013) Clinical Neuroscience Solutions Inc.

Subject Initials: ---

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

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1. Date of Visit

Date	Location	User	Value	Reason
Aug-20-2020 13:14:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe.mstephens)	Data Entry: Aug/20/2020	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1013

Subject No: 10131255

Generated By: pfe.levisse

Form: DISPOSITION - SCREENING - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1013) Clinical Neuroscience Solutions Inc.

Subject Initials: ---

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

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1. Date of Completion/Discontinuation/Death

Date	Location	User	Value	Reason
Aug-20-2020 13:14:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe.mstephens)	Data Entry: Aug/20/2020	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Aug-20-2020 13:14:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SCREENING	Initial Entry

3. Status:

Date	Location	User	Value	Reason
Aug-20-2020 13:14:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe.mstephens)	Data Entry: COMPLETED	Initial Entry

090177e196ae2f58\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:** 10131255**Subject Initials:** ---**Generated By:** pfe.levisse**Generated Time (GMT):** 29-Mar-2021 04:21[Back to Form](#)*1.a*

Date	Location	User	Value	Reason
Aug-20-2020 13:15:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/M 1 H Num ber: Medical WISDOM T History EETH REM Term: OVAL Start Da May/UNK/2 te: 016 Ongoing NO : End Date: May/UN K/2016	Initial Entry

1.a Line/MH Number:

Date	Location	User	Value	Reason
Aug-20-2020 13:15:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 1	Initial Entry

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

Date	Location	User	Value	Reason
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Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1013

Site Name: (1013) Clinical Neuroscience Solutions Inc.

Subject No: 10131255

Subject Initials: ---

Generated By: pfe.levisse

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

Aug-20-2020 13:15:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe.mstephens)	Data Entry: WISDOM TEETH REMOVAL	Initial Entry
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1.a Start Date:

Date	Location	User	Value	Reason
Aug-20-2020 13:15:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe.mstephens)	Data Entry: May/UNK/2016	Initial Entry

1.a Ongoing:

Date	Location	User	Value	Reason
Aug-20-2020 13:15:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe.mstephens)	Data Entry: NO End Date: May/UNK/2016	Initial Entry

090177e196ae2f58\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: 10131255

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

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1. Date:

Date	Location	User	Value	Reason
Aug-20-2020 13:15:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe.mstephens)	Data Entry: Aug/20/2020	Initial Entry

2. Weight:

Date	Location	User	Value	Reason
Aug-20-2020 13:15:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe.mstephens)	Data Entry: 60.5	Initial Entry

3. Unit:

Date	Location	User	Value	Reason
Aug-20-2020 13:15:37 (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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090177e196ae2f58\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: 10131255

Subject Initials: ---

Generated By: pfe.levisse

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

Aug-20-2020 13:15:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe.mstephens)	Data Entry: 178.0	Initial Entry
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5. Unit:

Date	Location	User	Value	Reason
Aug-20-2020 13:15:37 (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-20-2020 13:15:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 19.1	Initial Entry

7.a

Date	Location	User	Value	Reason
Aug-20-2020 13:15:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe.mstephens)	Data Entry: Record Id 1 entifier:: Temperat 35.7 ure:	Initial Entry

090177e196ae2f58\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: 10131255

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-20-2020 13:15:37 (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-21-2020 03:08:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Ankita Thakur (pfe.thakua20)	Query 1: Closed	Closed by DM: AT.
Aug-20-2020 13:16:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe.mstephens)	Query 1: Answered	CORRECT AS RECORDED. PER INVESTIGATOR WITHIN NORMAL LIMITS
Aug-20-2020	ACV0PFEINFP6000	auto query	Query 1: Opened	Temperature 35.7

090177e196ae2f58\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: 10131255

Subject Initials: ---

Generated By: pfe.lewissc

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

13:15:37 (UTC-05:00) Eastern Time (US & Canada)		(autoquery)	d	C is outside of Normal Range 36.1 - 37.5 C.
Aug-20-2020 13:15:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe.mstephens)	Data Entry: 35.7	Initial Entry

7.a Unit:

Date	Location	User	Value	Reason
Aug-20-2020 13:15:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe.mstephens)	Data Entry: C	Initial Entry

7.a Temperature Location:

Date	Location	User	Value	Reason
Aug-20-2020 13:15:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe.mstephens)	Data Entry: ORAL CAVITY	Initial Entry

090177e196ae2f58\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: 10131255

Subject Initials: ---

Generated By: pfe.levisse

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

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1. Lab Panel:

Date	Location	User	Value	Reason
Aug-20-2020 13:16:18 (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-20-2020 13:16:18 (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-20-2020 13:16:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe.mstephens)	Data Entry: Aug/20/2020	Initial Entry

4. Laboratory Name and Address (Derived)

Date	Location	User	Value	Reason
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090177e196ae2f58\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: 10131255

Subject Initials: ---

Generated By: pfe.levisse

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

Aug-20-2020 13:16:18 (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-20-2020 13:16:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: URINE	Initial Entry

6.a

Date	Location	User	Value	Reason
Aug-20-2020 13:16:18 (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:

090177e196ae2f58\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: 10131255

Subject Initials: ---

Generated By: pfe.lewissc

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

Date	Location	User	Value	Reason
Aug-20-2020 13:16:18 (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-20-2020 13:16:18 (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-20-2020 13:16:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe.mstephens)	Data Entry: NEGATIVE	Initial Entry

090177e196ae2f58\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: 10131255

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

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1. Randomization Date :

Date	Location	User	Value	Reason
Aug-20-2020 13:16:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe.mstephens)	Data Entry: Aug/20/2020	Initial Entry

2. Randomization Number:

Date	Location	User	Value	Reason
Aug-20-2020 13:16:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe.mstephens)	Data Entry: 58170	Initial Entry

090177e196ae2f58\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: 10131255

Generated By: pfe.levisse

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

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1013) Clinical Neuroscience Solutions Inc.

Subject Initials: ---

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

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1. Data Origin

Date	Location	User	Value	Reason
Aug-20-2020 13:16:42 (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-20-2020 13:16:42 (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-20-2020 17:07:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Aug-20-2020 13:16:42 (UTC-05:00)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however

090177e196ae2f58\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: 10131255

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-20-2020 13:16:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe.mstephens)	Data Entry: YES Date of Collection: Aug/20/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Aug-20-2020 17:07:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe.mstephens)	Data Entry: Sample I BPYXB D: B	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Aug-20-2020 17:07:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe.mstephens)	Data Entry: BPYXBB	Initial Entry

5.b

090177e196ae2f58\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: 10131255

Subject Initials: ---

Generated By: pfe.lewissc

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

Date	Location	User	Value	Reason
Aug-20-2020 17:07:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe.mstephens)	Data Entry: Sample I BPYXB D: C	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Aug-20-2020 17:07:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe.mstephens)	Data Entry: BPYXBC	Initial Entry

5.c

Date	Location	User	Value	Reason
Aug-20-2020 17:07:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe.mstephens)	Data Entry: Sample I BPYXB D: D	Initial Entry

090177e196ae2f58\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: 10131255

Subject Initials: ---

Generated By: pfe.lewissc

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

5.c Sample ID

Date	Location	User	Value	Reason
Aug-20-2020 17:07:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe.mstephens)	Data Entry: BPYXBD	Initial Entry

5.d

Date	Location	User	Value	Reason
Aug-20-2020 17:07:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe.mstephens)	Data Entry: Sample I BNWH D: N8	Initial Entry

5.d Sample ID

Date	Location	User	Value	Reason
Aug-20-2020 17:07:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe.mstephens)	Data Entry: BNWHN8	Initial Entry

5.e

Date	Location	User	Value	Reason
Aug-20-2020 17:07:27	ACV0PFEINFP6000	Matthew Stephens	Data Entry: Sample I BNWH	Initial Entry

090177e196ae2f58\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: 10131255

Subject Initials: ---

Generated By: pfe.lewissc

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

(UTC-05:00) Eastern Time (US & Canada)		(pfe.mstephens)	D: N9	
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5.e Sample ID

Date	Location	User	Value	Reason
Aug-20-2020 17:07:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe.mstephens)	Data Entry: BNWHN9	Initial Entry

090177e196ae2f58\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: 10131255

Subject Initials: ---

Generated By: pfe.levisse

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

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1. Data Origin

Date	Location	User	Value	Reason
Aug-20-2020 13:16:49 (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-20-2020 13:16:49 (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-20-2020 17:07:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Aug-20-2020 13:16:49 (UTC-05:00)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however

090177e196ae2f58\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: 10131255

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-20-2020 13:16:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe.mstephens)	Data Entry: YES Date of Collection: Aug/20/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Aug-20-2020 17:07:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe.mstephens)	Data Entry: Sample I BM8S8 D: 3	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Aug-20-2020 17:07:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe.mstephens)	Data Entry: BM8S83	Initial Entry

090177e196ae2f58\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: 10131255

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

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1. Was there a temporary delay of vaccination?

Date	Location	User	Value	Reason
Aug-20-2020 13:17:00 (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-20-2020 13:17:00 (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-20-2020 13:17:00 (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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090177e196ae2f58\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: 10131255

Subject Initials: ---

Generated By: pfe.levissc

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

Aug-20-2020 13:17:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe.mstephens)	Data Entry: Aug/20/2020 10:10	Initial Entry
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5. Anatomical Location:

Date	Location	User	Value	Reason
Aug-20-2020 13:17:00 (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-20-2020 13:17:00 (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-20-2020 13:17:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INTRAMUSCULAR	Initial Entry

090177e196ae2f58\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: 10131255

Subject Initials: ---

Generated By: pfe.levissc

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

10. Timeframe Subject Was Observed

Date	Location	User	Value	Reason
Aug-20-2020 13:17:00 (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-20-2020 13:17:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe.mstephens)	Data Entry: YES	Initial Entry

090177e196ae2f58\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: 10131255

Generated By: pfe.levissc

Form: REACTOGENICITY DIARY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1013) Clinical Neuroscience Solutions Inc.

Subject Initials: ---

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

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1. Select appropriate response - Reactogenicity diary collection

Date	Location	User	Value	Reason
Aug-20-2020 13:17:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe.mstephens)	Data Entry: NO - REACTOGE NICITY E-DIARY NOT COLLECTE D FOR THIS SUBJ ECT	Initial Entry

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 1013

Subject No: 10131255

Generated By: pfe.lewissc

Form: DATE OF VISIT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1013) Clinical Neuroscience Solutions Inc.

Subject Initials: ---

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

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1. Date of Visit

Date	Location	User	Value	Reason
Sep-10-2020 16:34:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Monica Cooper (pfe.mcooper)	Data Entry: Sep/10/2020	Initial Entry

090177e196ae2f58\Final\Final On: 01-Apr-2021 03:40 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 21-Aug-2020 02:51

Site No: 1013

Subject No: 10131255

Generated By: pfe.lewissc

Form: VITAL SIGNS - TEMP - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1013) Clinical Neuroscience Solutions Inc.

Subject Initials: ---

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

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1. Date:

Date	Location	User	Value	Reason
Sep-10-2020 16:34:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Monica Cooper (pfe.mcooper)	Data Entry: Sep/10/2020	Initial Entry

2.a

Date	Location	User	Value	Reason
Sep-10-2020 16:34:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Monica Cooper (pfe.mcooper)	Data Entry: Record Identifier:: Temperature: Temperature Unit: Temperature Location: Y	Initial Entry

2.a Record Identifier:

Date	Location	User	Value	Reason
Sep-10-2020 16:34:26 (UTC-05:00) Eastern Time (US	ACV0PFEINFP6000	Monica Cooper (pfe.mcooper)	Data Entry: 1	Initial Entry

090177e196ae2f58\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: 10131255

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 16:34:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Monica Cooper (pfe.mcooper)	Data Entry: 37.1	Initial Entry

2.a Unit:

Date	Location	User	Value	Reason
Sep-10-2020 16:34:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Monica Cooper (pfe.mcooper)	Data Entry: C	Initial Entry

2.a Temperature Location:

Date	Location	User	Value	Reason
Sep-10-2020 16:34:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Monica Cooper (pfe.mcooper)	Data Entry: ORAL CAVITY	Initial Entry

090177e196ae2f58\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: 10131255

Subject Initials: ---

Generated By: pfe.lewissc

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

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1. Lab Panel:

Date	Location	User	Value	Reason
Sep-10-2020 16:34:39 (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 16:34:39 (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 16:34:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Monica Cooper (pfe.mcooper)	Data Entry: Sep/10/2020	Initial Entry

4. Laboratory Name and Address (Derived)

Date	Location	User	Value	Reason
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090177e196ae2f58\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: 10131255

Subject Initials: ---

Generated By: pfe.lewissc

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

Sep-10-2020 16:34:39 (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 16:34:39 (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 16:34:39 (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:

090177e196ae2f58\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: 10131255

Subject Initials: ---

Generated By: pfe.lewissc

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

Date	Location	User	Value	Reason
Sep-10-2020 16:34:39 (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 16:34:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Monica Cooper (pfe.mcooper)	Data Entry: Choriogonadotropin Beta_PX113	Initial Entry

6.a Result:

Date	Location	User	Value	Reason
Sep-10-2020 16:34:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Monica Cooper (pfe.mcooper)	Data Entry: NEGATIVE	Initial Entry

090177e196ae2f58\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: 10131255

Subject Initials: ---

Generated By: pfe.levisse

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

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1. Data Origin

Date	Location	User	Value	Reason
Sep-10-2020 16:34:47 (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 16:34:47 (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 17:04:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Sep-10-2020 16:34:47 (UTC-05:00)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however

090177e196ae2f58\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: 10131255

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 16:34:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Monica Cooper (pfe.mcooper)	Data Entry: YES Date of Collection : Sep/10/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Sep-10-2020 17:04:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe.mstephens)	Data Entry: Sample I BPC2 D: WJ	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Sep-10-2020 17:04:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe.mstephens)	Data Entry: BPC2WJ	Initial Entry

090177e196ae2f58\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: 10131255

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

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1. Was there a temporary delay of vaccination?

Date	Location	User	Value	Reason
Sep-10-2020 16:35:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Monica Cooper (pfe.mcooper)	Data Entry: NO	Initial Entry

2. Treatment Name

Date	Location	User	Value	Reason
Sep-10-2020 16:35:07 (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 16:35:07 (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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090177e196ae2f58\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: 10131255

Subject Initials: ---

Generated By: pfe.lewissc

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

Sep-10-2020 16:35:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Monica Cooper (pfe.mcooper)	Data Entry: Sep/10/2020 15:50	Initial Entry
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5. Anatomical Location:

Date	Location	User	Value	Reason
Sep-10-2020 16:35:07 (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 16:35:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Monica Cooper (pfe.mcooper)	Data Entry: LEFT	Initial Entry

7. Route:

Date	Location	User	Value	Reason
Sep-10-2020 16:35:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INTRAMUSCULAR	Initial Entry

090177e196ae2f58\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: 10131255

Subject Initials: ---

Generated By: pfe.lewissc

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

10. Timeframe Subject Was Observed

Date	Location	User	Value	Reason
Sep-10-2020 16:35:07 (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 16:35:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Monica Cooper (pfe.mcooper)	Data Entry: YES	Initial Entry

090177e196ae2f58\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: 10131255 **Subject Initials:** ---

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

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1. Date of Visit

Date	Location	User	Value	Reason
Oct-14-2020 17:18:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe.mstephens)	Data Entry: Oct/14/2020	Initial Entry

090177e196ae2f58\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: 10131255 **Subject Initials:** ---

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

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1. Data Origin

Date	Location	User	Value	Reason
Oct-14-2020 17:18:50 (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 17:18:50 (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 08:33:11 (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

090177e196ae2f58\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:** 10131255**Subject Initials:** ---**Generated By:** pfe.levissc**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 17:18:50 (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 17:18:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe.mstephens)	Data Entry: YES Date of Collection: Oct/14/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Oct-15-2020 08:33:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe.mstephens)	Data Entry: Sample ID: BR9TT 7	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: 10131255 **Subject Initials:** ---

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

Oct-15-2020 08:33:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe.mstephens)	Data Entry: BR9TT7	Initial Entry
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5.b

Date	Location	User	Value	Reason
Oct-15-2020 08:33:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe.mstephens)	Data Entry: Sample I BR9TT D: 8	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Oct-15-2020 08:33:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe.mstephens)	Data Entry: BR9TT8	Initial Entry

5.c

Date	Location	User	Value	Reason
Oct-15-2020 08:33:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe.mstephens)	Data Entry: Sample I BR9TT D: 9	Initial Entry

090177e196ae2f58\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: 10131255 **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 08:33:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe.mstephens)	Data Entry: BR9TT9	Initial Entry

5.d

Date	Location	User	Value	Reason
Oct-15-2020 08:33:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe.mstephens)	Data Entry: Sample I BMN59 D: G	Initial Entry

5.d Sample ID

Date	Location	User	Value	Reason
Oct-15-2020 08:33:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe.mstephens)	Data Entry: BMN59G	Initial Entry

5.e

Date	Location	User	Value	Reason
Oct-15-2020 08:33:39	ACV0PFEINFP6000	Matthew Stephens	Data Entry: Sample I BMN59	Initial Entry

090177e196ae2f58\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: 10131255 **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 08:33:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe.mstephens)	Data Entry: BMN59H	Initial Entry

090177e196ae2f58\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: 10131255 **Subject Initials:** ---

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

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1. Date of Completion/Discontinuation/Death :

Date	Location	User	Value	Reason
Oct-14-2020 17:19:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe.mstephens)	Data Entry: Oct/14/2020	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Oct-14-2020 17:19:04 (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 17:19:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe.mstephens)	Data Entry: COMPLETED	Initial Entry

090177e196ae2f58\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: 10131255

Subject Initials: ---

Generated By: pfe.lewissc

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

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Date	Location	User	Value	Reason
Dec-23-2020 11:13:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe.mstephens)	Form Created	

090177e196ae2f58\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: 10131255

Subject Initials: ---

Generated By: pfe.levisse

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

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Date	Location	User	Value	Reason
Feb-01-2021 12:26:08 (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, Frozen

Site No: 1013

Site Name: (1013) Clinical Neuroscience Solutions Inc.

Subject No: 10131255

Subject Initials: ---

Generated By: pfe.levissc

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

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1. Category:

Date	Location	User	Value	Reason
Dec-23-2020 11:13:15 (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
Dec-23-2020 11:13:15 (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
Feb-23-2021 16:04:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 3: Closed	Clinical - thank you; however date of contact / notification of event was not added in the most recent SAE update, e.g at "During this call, the subject mentioned". Please submit a safety update reporting this date

090177e196ae2f58\Final\Final On: 01-Apr-2021 03:40 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

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Form Status: Data Complete, Frozen

Site No: 1013

Site Name: (1013) Clinical Neuroscience Solutions Inc.

Subject No: 10131255

Subject Initials: ---

Generated By: pfe.lewissc

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Feb-17-2021 08:17:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe.mstephens)	Query 3: Answered	CRC WILL UPDATE ACCORDINGLY.
Feb-15-2021 22:24:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 3: Opened	CLINICAL Please submit a SAE update reporting the date when site contacted the subject (to review diary compliance) and the subject informed the site re pregnancy and miscarriage
Feb-03-2021 09:34:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Pamela Benne prod (pfe.bennep07)	Query 2: Closed	Response satisfies query
Feb-01-2021 12:22:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Answered	Changed Information
Feb-01-2021 12:22:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Scott Salmon (pfe.ssalmon)	Data Entry: EXPOS URE D URING PREGN	Changed Information

090177e196ae2f58\Final\Final On: 01-Apr-2021 03:40 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

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Form Status: Data Complete, Frozen

Site No: 1013

Site Name: (1013) Clinical Neuroscience Solutions Inc.

Subject No: 10131255

Subject Initials: ---

Generated By: pfe.lewissc

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

			ANCY	
Feb-01-2021 10:49:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Pamela Benne prod (pfe.bennep07)	Query 2: Opened	SAE RECON:AER#2020503978, the term in AE CRF was recorded as 'PREGNANCY WITH MISCARRIAGE' while reported as MISCARRIAGE in SDB. Please confirm correct term. If safety update is required, please submit a follow-up form.
Jan-29-2021 13:31:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 1: Closed	Clinical Thank you; however the event terms need to be split on 2 lines: Miscarriage (SAE) and Exposure during Pregnancy (not a SAE). Info currently is correct for EDP section.
Jan-27-2021 15:00:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Scott Salmon (pfe.ssalmon)	Query 1: Answered	UPDATED AE
Jan-12-2021 14:23:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 1: Opened	CLINICAL Event term is Pregnancy with Miscarriage; however, SAE event term is Miscarriage. As pregnancy is not an AE (although reported on AE

090177e196ae2f58\Final\Final On: 01-Apr-2021 03:40 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

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Form Status: Data Complete, Frozen

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Subject Initials: ---

Generated By: pfe.lewissc

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				log), please harmonize on SAE term of miscarriage; earlier PG info will be retained
Dec-23-2020 11:13:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe.mstephens)	Data Entry: PREGNANCY WITH MISARRIAGE	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason
Feb-09-2021 01:31:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 1: Closed	Safety specifications include EDP (non-serious event) with Miscarriage SAE
Feb-03-2021 09:38:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Pamela Benne prod (pfe.bennep07)	Query 1: Reissued :Opened	EXPOSURE DURING PREGNANCY not in SDB only miscarriage
Feb-02-2021 10:09:24 (UTC-05:00) Eastern Time	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 2: Closed	Response satisfies query

090177e196ae2f58\Final\Final On: 01-Apr-2021 03:40 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

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Form Status: Data Complete, Frozen

Site No: 1013

Site Name: (1013) Clinical Neuroscience Solutions Inc.

Subject No: 10131255

Subject Initials: ---

Generated By: pfe.lewissc

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(US & Canada)				
Feb-01-2021 12:28:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Scott Salmon (pfe.ssalmon)	Query 1: Answered	UPDATED
Jan-28-2021 10:01:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Gladys Noi (pfe.noig)	Query 1: Reissued :Opened	SAE RECON 1: Thanks for the response. Please consider submitting an updated SAE form to update the Onset date in safety database with the Month since its recorded as only 2020 in Safety database.
Jan-27-2021 15:04:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Scott Salmon (pfe.ssalmon)	Data Entry: Sep/UNK/2020 UNK:UNK	Changed Information
Jan-27-2021 15:01:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Scott Salmon (pfe.ssalmon)	Query 2: Answered	AE UPDATED
Jan-27-2021 14:56:13	ACV0PFEINFP6000	Scott Salmon (pfe.ssalmon)	Query 1: Answered	SEPTEMBER 2020

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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, Frozen**Site No:** 1013**Site Name:** (1013) Clinical Neuroscience Solutions Inc.**Subject No:** 10131255**Subject Initials:** ---**Generated By:** pfe.levissc**Generated Time (GMT):** 29-Mar-2021 04:21

(UTC-05:00) Eastern Time (US & Canada)			d	
Jan-12-2021 14:20:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 2: Opened	CLINICAL Start date is UNK; however, SAE report for event Miscarriage reports Start of event on 22Dec20. Please review, harmonize reporting and update where applicable
Jan-08-2021 07:25:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Ricell Ann Piojo (pfe.quitor)	Query 1: Opened	SAE RECON:AER#2020503978, the onset date is blank in Safety database while recorded as UNK/UNK /2020. Please confirm if the month and year at least can be provided for the onset date.
Dec-23-2020 11:13:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe.mstephens)	Data Entry: UNK/UNK/2020 UNK:UNK	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Feb-02-2021 10:09:00	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 2: Closed	Response satisfies query

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Visit: Logs - Unscheduled

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Subject No: 10131255

Subject Initials: ---

Generated By: pfe.lewissc

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

(UTC-05:00) Eastern Time (US & Canada)				
Jan-27-2021 15:04:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Scott Salmon (pfe.ssalmon)	Data Entry: NO End Date Time: Oct/UNK/2020 UNK:UNK	Changed Information
Jan-27-2021 14:59:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Scott Salmon (pfe.ssalmon)	Query 2: Answered	UPDATED AE FORM
Jan-26-2021 11:47:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 2: Opened	CLINICAL End date is UNK; however, original SAE report for event Miscarriage was on 18Dec20, so End date before that. Please review and update End Month if possible in both AE/SAE

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Subject Initials: ---

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Jan-26-2021 11:46:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 1: Closed	rewording
Jan-12-2021 14:19:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 1: Opened	CLINICAL End date is UNK; however, SAE report for event Miscarriage reports end of event on 22Dec20. Please review, harmonize reporting and update where applicable
Dec-23-2020 12:49:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe.mstephens)	Data Entry: NO End Date Time: UNK/UNK/20 20 UNK:UNK	Transcription Error
Dec-23-2020 11:13:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe.mstephens)	Data Entry: YES	Initial Entry

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Site No: 1013

Site Name: (1013) Clinical Neuroscience Solutions Inc.

Subject No: 10131255

Subject Initials: ---

Generated By: pfe.lewissc

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

6. Toxicity Grade:

Date	Location	User	Value	Reason
Feb-09-2021 09:58:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Scott Salmon (pfe.ssalmon)	Data Entry: Not Applicable	Initial Entry
Feb-09-2021 09:57:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Scott Salmon (pfe.ssalmon)	Data Entry:	Changed Information
Dec-23-2020 11:13:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe.mstephens)	Data Entry: 2	Initial Entry

7. Is the adverse event serious?

If Yes, NOTIFY PFIZER IMMEDIATELY.

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

Date	Location	User	Value	Reason
Feb-04-2021 12:17:19 (UTC-05:00)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 2: Closed	Response satisfies query

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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, Frozen

Site No: 1013

Site Name: (1013) Clinical Neuroscience Solutions Inc.

Subject No: 10131255

Subject Initials: ---

Generated By: pfe.lewissc

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

Eastern Time (US & Canada)				
Feb-03-2021 09:35:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 3: Deleted	Close Auto Query
Feb-02-2021 10:08:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 2: Reissued:Opened	Clinical Thank you; however, SAE report #2020503978 reports the event as SERIOUS due to Medically important/significant criterion. Please review serious status, harmonize reporting, and update where appropriate
Feb-01-2021 12:22:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 3: Candidate	For AE EXPOSURE DURING PREGNANCY: Response to "Is the adverse event serious?" is 'No' but "Serious Adverse Event Number" is present.
Jan-27-2021 15:05:25	ACV0PFEINFP6000	auto query (autoquery)	Query 3: Candidate	For AE PREGNANCY

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Subject Initials: ---

Generated By: pfe.lewissc

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(UTC-05:00) Eastern Time (US & Canada)				WITH MISCARRIAGE: Response to "Is the adverse event serious?" is 'No' but "Serious Adverse Event Number" is present.
Jan-27-2021 15:05:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Scott Salmon (pfe.ssalmon)	Data Entry: NO	Changed Information
Jan-27-2021 14:54:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Scott Salmon (pfe.ssalmon)	Query 2: Ans wered	UPDATED AE
Jan-04-2021 07:17:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Dele ted	Close Auto Query
Dec-23-2020 15:38:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 2: Ope ned	Clinical - Event criteria for serious is Hospitalization; however, SAE report has event criteria for serious as Medically Important. Please

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Header Text: c4591001

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Subject No: 10131255

Subject Initials: ---

Generated By: pfe.lewissc

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				review, harmonize reporting, and update in the required location. Note, reporting 2 criteria is acceptable.
Dec-23-2020 12:49:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Can didate	For AE PREGNANCY WITH MISCARRIAGE: Response to "Is the adverse event serious?" is 'Yes' but "Serious Adverse Event Number" is blank.
Dec-23-2020 12:49:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe.mstephens)	Data Entry: YES Is this serious event associated with congenital anomaly or birth defect? NO Did this serious event result in death? NO	Transcription Error

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Site Name: (1013) Clinical Neuroscience Solutions Inc.

Subject No: 10131255

Subject Initials: ---

Generated By: pfe.lewissc

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			<p>Did this serious event require or prolong hospitalization?</p> <p>YES</p> <p>Did this serious event result in persistent or significant disability/incapacity?</p> <p>NO</p> <p>Is this serious event life threatening?</p> <p>NO</p> <p>Other medically important serious event</p> <p>NO</p>	
Dec-23-2020 11:13:15 (UTC-05:00)	ACV0PFEINFP6000	Matthew Stephens (pfe.mstephens)	Data Entry: NO	Initial Entry

090177e196ae2f58\Final\Final On: 01-Apr-2021 03:40 (GMT)

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Site No: 1013

Site Name: (1013) Clinical Neuroscience Solutions Inc.

Subject No: 10131255

Subject Initials: ---

Generated By: pfe.levissc

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

Eastern Time
(US & Canada)

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

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

Date	Location	User	Value	Reason
Dec-23-2020 11:13:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe.mstephens)	Data Entry: NO	Initial Entry

9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Jan-27-2021 13:20:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 2: Closed	contraception method submitted to SAE
Jan-12-2021 14:32:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 2: Opened	Clinical Please submit a SAE safety update specifying the contraceptive method(s) this subject was utilizing when conception occurred

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Header Text: c4591001

Visit: Logs - Unscheduled

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Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen

Site No: 1013

Site Name: (1013) Clinical Neuroscience Solutions Inc.

Subject No: 10131255

Subject Initials: ---

Generated By: pfe.lewissc

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

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9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Jan-12-2021 14:31:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 1: Closed	SAE update received with this info
Jan-08-2021 12:49:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 1: Opened	CLINICAL Please complete the supplement Exposure during Pregnancy form for information on subject prior to miscarriage, and Paternal information if available; also pregnancy outcome
Dec-23-2020 11:13:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe.mstephens)	Data Entry: NOT RELATED If Not Related to study treatment(s), this event is due to:	Initial Entry

090177e196ae2f58\Final\Final On: 01-Apr-2021 03:40 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

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Form Status: Data Complete, Frozen

Site No: 1013

Site Name: (1013) Clinical Neuroscience Solutions Inc.

Subject No: 10131255

Subject Initials: ---

Generated By: pfe.levissc

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

			OTHER <i>If Other, specify:</i> PREGNANCY WITH MISCARRIAGE	
--	--	--	--	--

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Dec-23-2020 11:13:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe.mstephens)	Data Entry: NOT APPLICABLE	Initial Entry

11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
Dec-23-2020 11:13:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe.mstephens)	Data Entry: NO	Initial Entry

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason

090177e196ae2f58\Final\Final On: 01-Apr-2021 03:40 (GMT)

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Site Name: (1013) Clinical Neuroscience Solutions Inc.

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Subject Initials: ---

Generated By: pfe.lewissc

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Dec-23-2020 11:13:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe.mstephens)	Data Entry: NO	Initial Entry
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13. What was the outcome of this adverse event?:

Date	Location	User	Value	Reason
Dec-23-2020 12:50:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Dec-23-2020 12:50:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe.mstephens)	Data Entry : RECOVERED/RESOLVED	Transcription Error
Dec-23-2020 12:49:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	For AE PREGNANCY WITH MISCARRIAGE: Response to "What was the outcome of this adverse event?" is 'Recovering/Resolving' but AE End Date/Time is present.
Dec-23-2020	ACV0PFEINFP6000	Matthew	Data Entry	Initial Entry

090177e196ae2f58\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, Frozen

Site No: 1013

Site Name: (1013) Clinical Neuroscience Solutions Inc.

Subject No: 10131255

Subject Initials: ---

Generated By: pfe.lewissc

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

11:13:15 (UTC-05:00) Eastern Time (US & Canada)		Stephens (pfe.mstephens)	RECOVER ING/RESO LVING	
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14. Did the adverse event cause the subject to be discontinued from the study?

Date	Location	User	Value	Reason
Dec-23-2020 11:13:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe.mstephens)	Data Entry: NO	Initial Entry

15. Serious Adverse Event Number: For Pfizer Use Only

Date	Location	User	Value	Reason
Feb-03-2021 09:35:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Pamela Benne prod (pfe.bennep07)	Data Entry:	New Information
Jan-04-2021 07:17:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Ricell Ann Piojo (pfe.quitor)	Data Entry: 2020503978	Initial Entry

090177e196ae2f58\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, Frozen

Site No: 1013

Site Name: (1013) Clinical Neuroscience Solutions Inc.

Subject No: 10131255

Subject Initials: ---

Generated By: pfe.lewissc

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

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1. Category:

Date	Location	User	Value	Reason
Feb-01-2021 12:26:08 (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
Feb-01-2021 12:26:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 2	Initial Entry

3. Adverse Event:

(If possible specify diagnosis, not individual symptoms)

Date	Location	User	Value	Reason
Mar-04-2021 11:38:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 1: Closed	Response satisfies query
Mar-01-2021 16:35:37	ACV0PFEINFP6000	Matthew Stephens	Query 1: Answer ed	CRC WILL UPDATE SAE

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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, Frozen

Site No: 1013

Site Name: (1013) Clinical Neuroscience Solutions Inc.

Subject No: 10131255

Subject Initials: ---

Generated By: pfe.lewissc

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

(UTC-05:00) Eastern Time (US & Canada)		(pfe.mstephens)		NARRATIVE.
Feb-26-2021 10:49:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Sathenapalli Suguna Srujan (pfe.srujas)	Query 1: Opened	Clinical - Miscarriage SAE narrative states that site RA contacted subject & was told about the miscarriage. Please update the SAE narrative with the date of this call
Feb-25-2021 09:37:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 1: Candida te	Clinical - Miscarriage SAE narrative states that site RA contacted subject & was told about the miscarriage. Please update the SAE narrative with the date of this call
Feb-01-2021 12:26:08 (UTC-05:00)	ACV0PFEINFP6000	Scott Salmon (pfe.ssalmon)	Data Entry: MISCARRIAGE	Initial Entry

090177e196ae2f58\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, Frozen

Site No: 1013

Site Name: (1013) Clinical Neuroscience Solutions Inc.

Subject No: 10131255

Subject Initials: ---

Generated By: pfe.levissc

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

Eastern Time
(US & Canada)

4. Start Date Time:

Date	Location	User	Value	Reason
Feb-22-2021 16:52:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Gladys Noi (pfe.noig)	Query 3: Closed	Onset date updated to UNK/OCT/2020 in SDB
Feb-18-2021 01:56:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Ricell Ann Piojo (pfe.quiror)	Query 3: Opened	SAE RECON:AER#2020503978, the onset date is updated to 10OCT2020 in Safety database while recorded as UNK/OCT/2020. Please confirm correct date. If safety update is required, please submit a follow-up form or update Inform.
Feb-09-2021 01:25:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 2: Closed	SAE start date updated to ??Oct2020
Feb-08-2021 08:12:32 (UTC-05:00) Eastern Time	ACV0PFEINFP6000	Pamela Benne prod (pfe.bennep07)	Query 1: Closed	updated dates

090177e196ae2f58\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, Frozen

Site No: 1013

Site Name: (1013) Clinical Neuroscience Solutions Inc.

Subject No: 10131255

Subject Initials: ---

Generated By: pfe.levissc

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

(US & Canada)				
Feb-04-2021 12:15:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 2: Opened	Clinical Start date is UNK/Oct/2020; however in Miscarriage SAE (#2020503978), event start date is UNK/Sep/2020. Please review start date; harmonize reporting, & update where required
Feb-03-2021 09:31:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Pamela Benne prod (pfe.bennep07)	Query 1: Opened	SAE RECON:AER#2020503978, the onset date is UNK/SEP/2020 in Safety database while recorded as UNK/OCT/2020. Please confirm dates. If safety update is required, please submit a follow-up form or update Inform.
Feb-01-2021 12:26:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Scott Salmon (pfe.ssalmon)	Data Entry: Oct/UNK /2020 U NK:UNK	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Feb-04-2021 12:14:06	ACV0PFEINFP6000	Kathryn Sewell	Query 1: Closed	rewording

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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, Frozen

Site No: 1013

Site Name: (1013) Clinical Neuroscience Solutions Inc.

Subject No: 10131255

Subject Initials: ---

Generated By: pfe.lewissc

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

(UTC-05:00) Eastern Time (US & Canada)		(pfe.sewelk02)		
Feb-04-2021 12:12:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 1: Opened	Clinical In Miscarriage SAE (#2020503978), event start/end dates are UNK/Nov/2020. Please review dates here & in SAE; harmonize reporting, & update where required
Feb-01-2021 12:26:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Scott Salmon (pfe.ssalmon)	Data Entry: NO End Date Time: Oct/UNK/202 0 UNK:UNK	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
Feb-01-2021 12:26:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Scott Salmon (pfe.ssalmon)	Data Entry: 3	Initial Entry

090177e196ae2f58\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, Frozen

Site No: 1013

Site Name: (1013) Clinical Neuroscience Solutions Inc.

Subject No: 10131255

Subject Initials: ---

Generated By: pfe.levissc

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).

Date	Location	User	Value	Reason
Feb-03-2021 09:29:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Feb-01-2021 12:26:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	For AE MISCARRIAGE: Response to "Is the adverse event serious?" is 'Yes' but "Serious Adverse Event Number" is blank.
Feb-01-2021 12:26:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Scott Salmon (pfe.ssalmon)	Data Entry: YES Is this serious event associated with congenital anomaly or birth defect?	Initial Entry

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Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen

Site No: 1013

Site Name: (1013) Clinical Neuroscience Solutions Inc.

Subject No: 10131255

Subject Initials: ---

Generated By: pfe.lewissc

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

			NO	
			Did this serious event result in death?	
			NO	
			Did this serious event require or prolong hospitalization?	
			NO	
			Did this serious event result in persistent or significant disability/incapacity?	
			NO	
			Is this serious event life threatening?	
			NO	
			Other medically important serious event	
			YES	

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Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

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Form Status: Data Complete, Frozen

Site No: 1013

Site Name: (1013) Clinical Neuroscience Solutions Inc.

Subject No: 10131255

Subject Initials: ---

Generated By: pfe.lewissc

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

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

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

Date	Location	User	Value	Reason
Feb-01-2021 12:26:08 (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
Feb-01-2021 12:26:08 (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> MISCARRIAGE	Initial Entry

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Feb-01-2021 12:26:08 (UTC-05:00) Eastern Time (US	ACV0PFEINFP6000	Scott Salmon (pfe.ssalmon)	Data Entry: NOT APPLICABLE	Initial Entry

090177e196ae2f58\Final\Final On: 01-Apr-2021 03:40 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

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Form Status: Data Complete, Frozen

Site No: 1013

Site Name: (1013) Clinical Neuroscience Solutions Inc.

Subject No: 10131255

Subject Initials: ---

Generated By: pfe.lewissc

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

& Canada)

11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
Feb-01-2021 12:26:08 (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
Feb-01-2021 12:26:08 (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
Feb-01-2021 12:26:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Scott Salmon (pfe.ssalmon)	Data Entry: RECOVERED/RES OLVED	Initial Entry

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

Date	Location	User	Value	Reason
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090177e196ae2f58\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, Frozen

Site No: 1013

Site Name: (1013) Clinical Neuroscience Solutions Inc.

Subject No: 10131255

Subject Initials: ---

Generated By: pfe.lewissc

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

Feb-01-2021 12:26:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Scott Salmon (pfe.ssalmon)	Data Entry: NO	Initial Entry
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15. Serious Adverse Event Number: For Pfizer Use Only

Date	Location	User	Value	Reason
Feb-03-2021 09:29:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Pamela Benne prod (pfe.bennep07)	Data Entry: 2020503978	Initial Entry

090177e196ae2f58\Final\Final On: 01-Apr-2021 03:40 (GMT)

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, Verified

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

Subject No: 10131255 **Subject Initials:** ---

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

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1. Date of Visit

Date	Location	User	Value	Reason
Mar-12-2021 11:30:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Scott Salmon (pfe.ssalmon)	Data Entry: Mar/10/2021	Initial Entry

090177e196ae2f58\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

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

Subject No: 10131255 **Subject Initials:** ---

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

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

Date	Location	User	Value	Reason
Mar-12-2021 11:30:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Scott Salmon (pfe.ssalmon)	Data Entry: Participant is willing to return for Vaccinat ion 3 Participant is: eligible per other protocol allowanc e(s) and confirme d to have received only placebo at Va ccination 1/2	Initial Entry

090177e196ae2f58\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, Verified

Site No: 1013

Site Name: (1013) Clinical Neuroscience Solutions Inc.

Subject No: 10131255

Subject Initials: ---

Generated By: pfe.lewissc

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

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1. Date Treatment Unblinded :

Date	Location	User	Value	Reason
Mar-12-2021 11:29:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Scott Salmon (pfe.ssalmon)	Data Entry: Mar/10/2021	Initial Entry

2. Primary Reason for Unblinding:

Date	Location	User	Value	Reason
Mar-12-2021 11:29:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Scott Salmon (pfe.ssalmon)	Data Entry: ASSESS ELIGIBILI TY FOR ADDITION AL VACCINATION	Initial Entry

090177e196ae2f58\Final\Final On: 01-Apr-2021 03:40 (GMT)

Header Text: c4591001

Visit: V101_VAX3

Form Version: 22-Apr-2020 21:02

Site No: 1013

Subject No: 10131255

Generated By: pfe.levisse

Form: DATE OF VISIT - eCRF Audit Trail History

Form Status: Data Complete, Verified

Site Name: (1013) Clinical Neuroscience Solutions Inc.

Subject Initials: ---

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

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1. Date of Visit

Date	Location	User	Value	Reason
Mar-12-2021 11:30:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Scott Salmon (pfe.ssalmon)	Data Entry: Mar/10/2021	Initial Entry

Header Text: c4591001

Visit: V101_VAX3

Form: INFORMED CONSENT - FURTHER
VACCINATION - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:31

Form Status: Data Complete, Verified

Site No: 1013

Site Name: (1013) Clinical Neuroscience Solutions Inc.

Subject No: 10131255

Subject Initials: ---

Generated By: pfe.lewissc

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

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1. Consent Was:

Date	Location	User	Value	Reason
Mar-12-2021 11:31:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Scott Salmon (pfe.ssalmon)	Data Entry: OBTAINED Date Written Consent Obtained Mar/10/2021	Initial Entry

090177e196ae2f58\Final\Final On: 01-Apr-2021 03:40 (GMT)

Header Text: c4591001

Visit: V101_VAX3

Form: DISPOSITION - SCREENING FOR FURTHER VACCINATION - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:31

Form Status: Data Complete, Verified

Site No: 1013

Site Name: (1013) Clinical Neuroscience Solutions Inc.

Subject No: 10131255

Subject Initials: ---

Generated By: pfe.lewissc

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

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1. Date of Completion/Discontinuation/Death :

Date	Location	User	Value	Reason
Mar-12-2021 11:31:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Scott Salmon (pfe.ssalmon)	Data Entry: Mar/10/2021	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Mar-12-2021 11:31:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: REPEAT SCREENING 1	Initial Entry

3. Status:

Date	Location	User	Value	Reason
Mar-12-2021 11:31:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Scott Salmon (pfe.ssalmon)	Data Entry: COMPLETED	Initial Entry

090177e196ae2f58\Final\Final On: 01-Apr-2021 03:40 (GMT)

Header Text: c4591001

Visit: V101_VAX3

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

Form Version: 20-Feb-2021 02:14

Form Status: Data Complete, Verified

Site No: 1013

Site Name: (1013) Clinical Neuroscience Solutions Inc.

Subject No: 10131255

Subject Initials: ---

Generated By: pfe.lewissc

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

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1. Lab Panel:

Date	Location	User	Value	Reason
Mar-12-2021 11:32:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Scott Salmon (pfe.ssalmon)	Data Entry: Not Applicable	Initial Entry

2. Lab Sub-Panel:

Date	Location	User	Value	Reason
Mar-12-2021 11:32:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Scott Salmon (pfe.ssalmon)	Data Entry: Not Applicable	Initial Entry

3. Collection Date:

Date	Location	User	Value	Reason
Mar-12-2021 11:32:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Scott Salmon (pfe.ssalmon)	Data Entry: Not Applicable	Initial Entry

4. Laboratory Name and Address (Derived)

Date	Location	User	Value	Reason
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090177e196ae2f58\Final\Final On: 01-Apr-2021 03:40 (GMT)

Header Text: c4591001

Visit: V101_VAX3

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

Form Version: 20-Feb-2021 02:14

Form Status: Data Complete, Verified

Site No: 1013

Site Name: (1013) Clinical Neuroscience Solutions Inc.

Subject No: 10131255

Subject Initials: ---

Generated By: pfe.levisse

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

Mar-12-2021 11:32:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Scott Salmon (pfe.ssalmon)	Data Entry: Not Applicable	Initial Entry
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5. Specimen Type:

Date	Location	User	Value	Reason
Mar-12-2021 11:32:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Scott Salmon (pfe.ssalmon)	Data Entry: Not Applicable	Initial Entry

6.a

Date	Location	User	Value	Reason
Mar-12-2021 11:32:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Scott Salmon (pfe.ssalmon)	Data Entry: Sponsor-De Not A fined Identi pplica fier: ble Test:: Not A pplica ble Result:: Not A pplica ble Not Done:: Not A pplica ble	Initial Entry

090177e196ae2f58\Final\Final On: 01-Apr-2021 03:40 (GMT)

Header Text: c4591001

Visit: V101_VAX3

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

Form Version: 20-Feb-2021 02:14

Form Status: Data Complete, Verified

Site No: 1013

Site Name: (1013) Clinical Neuroscience Solutions Inc.

Subject No: 10131255

Subject Initials: ---

Generated By: pfe.lewissc

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

6.a Sponsor ID:

Date	Location	User	Value	Reason
Mar-12-2021 11:32:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Scott Salmon (pfe.ssalmon)	Data Entry: Not Applicable	Initial Entry

6.a Test:

Date	Location	User	Value	Reason
Mar-12-2021 11:32:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Scott Salmon (pfe.ssalmon)	Data Entry: Not Applicable	Initial Entry

6.a Result:

Date	Location	User	Value	Reason
Mar-12-2021 11:32:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Scott Salmon (pfe.ssalmon)	Data Entry: Not Applicable	Initial Entry

6.a Not Done:

Date	Location	User	Value	Reason
Mar-12-2021 11:32:00	ACV0PFEINFP6000	Scott Salmon (pfe.ssalmon)	Data Entry: Not Applicable	Initial Entry

090177e196ae2f58\Final\Final On: 01-Apr-2021 03:40 (GMT)

Header Text: c4591001

Visit: V101_VAX3

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

Form Version: 20-Feb-2021 02:14

Form Status: Data Complete, Verified

Site No: 1013

Site Name: (1013) Clinical Neuroscience Solutions Inc.

Subject No: 10131255

Subject Initials: ---

Generated By: pfe.levisse

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

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

Visit: V101_VAX3

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Verified

Site No: 1013

Site Name: (1013) Clinical Neuroscience Solutions Inc.

Subject No: 10131255

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
Mar-12-2021 11:32:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Mar-12-2021 11:32:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SERUM	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Mar-12-2021 14:03:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Mar-12-2021 11:32:19 (UTC-05:00)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however

090177e196ae2f58\Final\Final On: 01-Apr-2021 03:40 (GMT)

Header Text: c4591001

Visit: V101_VAX3

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Verified

Site No: 1013

Site Name: (1013) Clinical Neuroscience Solutions Inc.

Subject No: 10131255

Subject Initials: ---

Generated By: pfe.levisse

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

Eastern Time (US & Canada)				no barcodes are entered. Please review and correct as appropriate.
Mar-12-2021 11:32:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Scott Salmon (pfe.ssalmon)	Data Entry: YES Date of Collection : Mar/10/2021	Initial Entry

5.a

Date	Location	User	Value	Reason
Mar-12-2021 14:03:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Scott Salmon (pfe.ssalmon)	Data Entry: Sample I BV0XP D: K	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Mar-12-2021 14:03:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Scott Salmon (pfe.ssalmon)	Data Entry: BV0XPK	Initial Entry

5.b

090177e196ae2f58\Final\Final On: 01-Apr-2021 03:40 (GMT)

Header Text: c4591001

Visit: V101_VAX3

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Verified

Site No: 1013

Site Name: (1013) Clinical Neuroscience Solutions Inc.

Subject No: 10131255

Subject Initials: ---

Generated By: pfe.lewissc

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

Date	Location	User	Value	Reason
Mar-12-2021 14:03:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Scott Salmon (pfe.ssalmon)	Data Entry: Sample ID BV0XP : L	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Mar-12-2021 14:03:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Scott Salmon (pfe.ssalmon)	Data Entry: BV0XPL	Initial Entry

5.c

Date	Location	User	Value	Reason
Mar-12-2021 14:03:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Scott Salmon (pfe.ssalmon)	Data Entry: Sample I BV0XP D: M	Initial Entry

090177e196ae2f58\Final\Final On: 01-Apr-2021 03:40 (GMT)

Header Text: c4591001

Visit: V101_VAX3

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Verified

Site No: 1013

Site Name: (1013) Clinical Neuroscience Solutions Inc.

Subject No: 10131255

Subject Initials: ---

Generated By: pfe.lewissc

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

5.c Sample ID

Date	Location	User	Value	Reason
Mar-12-2021 14:03:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Scott Salmon (pfe.ssalmon)	Data Entry: BVOXPM	Initial Entry

5.d

Date	Location	User	Value	Reason
Mar-12-2021 14:04:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Scott Salmon (pfe.ssalmon)	Data Entry: Sample I BVSYT D: W	Initial Entry

5.d Sample ID

Date	Location	User	Value	Reason
Mar-12-2021 14:04:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Scott Salmon (pfe.ssalmon)	Data Entry: BVSYTW	Initial Entry

5.e

Date	Location	User	Value	Reason
Mar-12-2021 14:05:10	ACV0PFEINFP6000	Scott Salmon (pfe.ssalmon)	Data Entry: Sample I BVSYT	Initial Entry

090177e196ae2f58\Final\Final On: 01-Apr-2021 03:40 (GMT)

Header Text: c4591001

Visit: V101_VAX3

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Verified

Site No: 1013

Site Name: (1013) Clinical Neuroscience Solutions Inc.

Subject No: 10131255

Subject Initials: ---

Generated By: pfe.lewissc

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

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

Date	Location	User	Value	Reason
Mar-12-2021 14:05:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Scott Salmon (pfe.ssalmon)	Data Entry: BVSYTX	Initial Entry

090177e196ae2f58\Final\Final On: 01-Apr-2021 03:40 (GMT)

Header Text: c4591001

Visit: V101_VAX3

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Verified

Site No: 1013

Site Name: (1013) Clinical Neuroscience Solutions Inc.

Subject No: 10131255

Subject Initials: ---

Generated By: pfe.levisse

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

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1. Data Origin

Date	Location	User	Value	Reason
Mar-12-2021 11:32:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Mar-12-2021 11:32:35 (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
Mar-12-2021 14:16:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Mar-12-2021 11:32:35 (UTC-05:00)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however

090177e196ae2f58\Final\Final On: 01-Apr-2021 03:40 (GMT)

Header Text: c4591001

Visit: V101_VAX3

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Verified

Site No: 1013

Site Name: (1013) Clinical Neuroscience Solutions Inc.

Subject No: 10131255

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.
Mar-12-2021 11:32:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Scott Salmon (pfe.ssalmon)	Data Entry: YES Date of Collection : Mar/10/2021	Initial Entry

5.a

Date	Location	User	Value	Reason
Mar-12-2021 14:16:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Scott Salmon (pfe.ssalmon)	Data Entry: Sample I BV0PG D: C	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Mar-12-2021 14:16:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Scott Salmon (pfe.ssalmon)	Data Entry: BV0PGC	Initial Entry

090177e196ae2f58\Final\Final On: 01-Apr-2021 03:40 (GMT)

Header Text: c4591001

Visit: V101_VAX3

Form Version: 10-Dec-2020 02:26

Site No: 1013

Subject No: 10131255

Generated By: pfe.levissc

Form: VACCINATION - eCRF Audit Trail History

Form Status: Incomplete, Verified

Site Name: (1013) Clinical Neuroscience Solutions Inc.

Subject Initials: ---

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

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1. Was there a temporary delay of vaccination?

Date	Location	User	Value	Reason
Mar-12-2021 11:34:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Scott Salmon (pfe.ssalmon)	Data Entry: YES Date of First Delay: Mar/10/2021 Reason(s) for Temp orary Delay of Vacc ination RECENT NON-S TUDY VACCINA TION	Initial Entry

090177e196ae2f58\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: 10131255

Subject Initials: ---

Generated By: pfe.lewissc

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

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1. Subject Status

Date	Location	User	Value	Reason
Oct-14-2020 17:19:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: FOLLOW-UP	Initial Entry
Aug-20-2020 13:16:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: ENROLLED/RANDOMIZED	Initial Entry
Aug-20-2020 13:14:40 (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
Jan-27-2021 13:09:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 3: Closed	DSU querying date of phone call, with is date PI is first aware of event
Jan-27-2021	ACV0PFEINFP6000	Kathryn Sewell	Query	Response satisfies query

090177e196ae2f58\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:** 10131255**Subject Initials:** ---**Generated By:** pfe.levisse**Generated Time (GMT):** 29-Mar-2021 04:21

13:07:33 (UTC-05:00) Eastern Time (US & Canada)		(pfe.sewelk02)	4: Clos ed	
Jan-06-2021 15:05:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Erik Sundgaard (pfe.sundgaardea)	Query 1: Clos ed	Response satisfies query
Jan-05-2021 15:13:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe.mstephens)	Query 1: Ans wered	PER CRC, SUBJECT REPORTED IN ERROR.
Jan-05-2021 00:37:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Nancy Vedamuthu (pfe.vedamn)	Query 1: Reis sued:O pened	RQ: Thank you for the response. Please consider to follow-up and confirm for reported Illness eDiary response of 01DEC2020. Please update or clarify.
Dec-31-2020 04:35:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Swapna Varikuti (pfe.variks)	Query 1: Reis sued:C andidat e	RQ1: Thank you for the response, please confirm if the COVID visit is scheduled for symptoms reported on 01DEC2020 and update the details accordingly , else clarify.
Dec-30-2020 14:04:36	ACV0PFEINFP6000	Scott Salmon (pfe.ssalmon)	Query 1: Ans	Attempting to contact

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:** 10131255**Subject Initials:** ---**Generated By:** pfe.levisse**Generated Time (GMT):** 29-Mar-2021 04:21

(UTC-05:00) Eastern Time (US & Canada)			wered	
Dec-30-2020 04:37:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Sonal K (pfe.ks66)	Query 1: Reis sued:O pened	RQ1: Thank you for the response, please confirm if the COVID visit is scheduled for symptoms reported on 01DEC2020 and update the details accordingly , else clarify.
Dec-23-2020 17:32:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 4: Reis sued:O pened	Clinical Please send the parent pregnancy info in a SAE update FAX (LMP date, prior pregnancies & outcome, father age, mother & father smoke/alcohol/illicit drugs, contraceptive method, other info)
Dec-23-2020 17:26:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 3: Reis sued:O pened	Clinical Thank you; please send the information on the date of the notification phone call in a SAE update FAX
Dec-23-2020 17:24:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 5: Clos ed	event entered on AE CRF

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: 10131255

Subject Initials: ---

Generated By: pfe.levisse

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

Dec-23-2020 17:23:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 2: Clos ed	Response satisfies query
Dec-23-2020 11:14:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe.mstephens)	Query 5: Ans wered	Changed data per query
Dec-23-2020 11:13:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe.mstephens)	Query 4: Ans wered	Changed data per query
Dec-23-2020 11:13:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe.mstephens)	Query 3: Ans wered	Changed data per query
Dec-23-2020 11:13:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe.mstephens)	Query 2: Ans wered	Changed data per query
Dec-22-2020 09:24:33	ACV0PFEINFP6000	Ricell Ann Piojo (pfe.quitor)	Query 5: Ope	SAE RECON:AER#2020503978

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Header Text: c4591001

Visit: Subject Status - Unscheduled

Form: SUBJECT STATUS - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Verified

Site No: 1013

Site Name: (1013) Clinical Neuroscience Solutions Inc.

Subject No: 10131255

Subject Initials: ---

Generated By: pfe.lewissc

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

(UTC-05:00) Eastern Time (US & Canada)			ned	pregnany resulting in miscarriage was reported as serious in Safety database but missing in AE CRF. Please confirm and update CRF. If safety update is required, submit a follow-up SAE Form.
Dec-21-2020 16:10:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 4: Ope ned	Clinical Please complete the Parent Pregnancy Information section on the SAE form, to clarify previous obstetric and delivery history.
Dec-21-2020 16:08:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 3: Ope ned	CLINICAL SAE report states that subject informed the site of the event on a phone call, when research asst called about diary compliance. However, date of the call is missing; please submit a SAE update with the date of the phone contact.
Dec-21-2020 16:05:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 2: Ope ned	CLINICAL SAE report (#2020503978) states subject had a miscarriage 'between visit 2 and visit 3'. Please enter the event on the AE CRF.
Dec-16-2020 03:48:31	ACV0PFEINFP6000	Nancy Vedamuthu	Query 1: Reis	Query response indicate NOT BEEN ABLE GET

090177e196ae2f58\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:** 10131255**Subject Initials:** ---**Generated By:** pfe.levisse**Generated Time (GMT):** 29-Mar-2021 04:21

(UTC-05:00) Eastern Time (US & Canada)		(pfe.vedamn)	sued:C andidat e	IN CONTACT. Please query after 2 days to confirm whether Cov ill visit done or not.
Dec-15-2020 08:51:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe.mstephens)	Query 1: Ans wered	CRC CANNOT CONFIRM WITH SUBJECT AS THEY HAVE NOT BEEN ABLE GET IN CONTACT WITH.
Dec-15-2020 00:42:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Nancy Vedamuthu (pfe.vedamn)	Query 1: Reis sued:O pened	RQ1: Thank you for the response. Please consider to follow-up and confirm for reported Illness eDiary response of 01DEC2020. Please update or clarify.
Dec-14-2020 10:04:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe.mstephens)	Query 1: Ans wered	PER CRC, STILL TRYING TO GET IN CONTACT WITH SUBJECT TO CONFIRM SYMPTOMS.
Dec-08-2020 08:08:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Sharat Nair (pfe.nairs51)	Query 1: Ope ned	Illness ed diary: As per Illness ed diary records, subject reported "Yes" for the question "Have you experienced any of the following?" for the COVID-19 symptoms or diagnosis on 01DEC2020. But corresponding COVID Illness visit not reported.

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: 10131255

Subject Initials: ---

Generated By: pfe.levisse

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

				Please clarify.
Oct-14-2020 17:19:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Oct/14/ 2020	Initial Entry
Aug-20-2020 13:16:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Aug/20 /2020	Initial Entry
Aug-20-2020 13:14:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Aug/20 /2020	Initial Entry

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Header Text: c4591001

Visit: Investigator Signature -
Unscheduled

Form Version: 22-Apr-2020 21:04

Site No: 1013

Subject No: 10131255

Generated By: pfe.lewissc

Form: CASEBOOK SIGNATURE FORM - eCRF Audit
Trail History

Form Status: Data Complete, Verified

Site Name: (1013) Clinical Neuroscience Solutions Inc.

Subject Initials: ---

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

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1. Casebook Signature

Date	Location	User	Value	Reason
Sep-15-2020 10:47:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Monica Cooper (pfe.mcooper)	Data Entry: Click Here to Enable	Initial Entry

090177e196ae2f58\Final\Final On: 01-Apr-2021 03:40 (GMT)