

Header Text: c4591001

Visit: COHORT_SELECTION

Form Version: 30-Jul-2020 21:29

Site No: 1013

Subject No: 10131176

Generated By: pfe.levisse

Form: COHORT SELECTION

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](#)

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 Version: 22-Apr-2020 21:02

Site No: 1013

Subject No: 10131176

Generated By: pfe.levissc

Form: MAIN INFORMED CONSENT

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](#)

Informed Consent

1.	Consent Was:	OBTAINED Date Written Consent Obtained Aug/13/2020
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Header Text: c4591001

Visit: COHORT_SELECTION

Form Version: 06-Jul-2020 21:55

Site No: 1013

Subject No: 10131176

Generated By: pfe.levissc

Form: DEMOGRAPHY

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1013) Clinical Neuroscience Solutions Inc.

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Demography

1.	Subject ID	[10131176]
2.	Birth Date:	(b) (6) 1944
3.	Sex:	MALE
4.	Ethnicity:	NOT HISPANIC OR LATINO(A) OR OF SPANISH ORIGIN
5.	Race: (Check X all that apply):	WHITE
6.	Racial Designation:	

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:02

Site No: 1013

Subject No: 10131176

Generated By: pfe.levisse

Form: DATE OF VISIT

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1013) Clinical Neuroscience Solutions Inc.

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Date of Visit

1.	Date of Visit	Aug/13/2020
2.	Erroneous Visit	

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 30-Jul-2020 21:29

Site No: 1013

Subject No: 10131176

Generated By: pfe.levissc

Form: INCLUSION/EXCLUSION CRITERIA

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1013) Clinical Neuroscience Solutions Inc.

Subject Initials: ---

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

[Form Comments](#)

Inclusion Criteria Not Met

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

Exclusion Criteria Met

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

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1013

Subject No: 10131176

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/13/2020
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: 10131176

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:	[HYPERTENSION]
	Start Date:	UNK/UNK/2015
	Ongoing:	YES
1.b	Line/MH Number:	[2]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[HYPERCHOLESTEROLEMIA]
	Start Date:	UNK/UNK/2014
	Ongoing:	YES
1.c	Line/MH Number:	[3]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[GASTROESOPHAGEAL REFLUX DISEASE]
	Start Date:	UNK/UNK/2005
	Ongoing:	YES
1.d	Line/MH Number:	[4]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[CONSTIPATION]
	Start Date:	UNK/UNK/2018
	Ongoing:	YES

090177e196ae2f66\Final\Final On: 01-Apr-2021 03:42 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1013

Subject No: 10131176

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

1.e	Line/MH Number:	[5]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[SMALL BOWEL RESECTION]
	Start Date:	UNK/UNK/2016
	Ongoing:	NO End Date: UNK/UNK/2016
1.f	Line/MH Number:	[6]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[SMALL BOWEL PERFORATION]
	Start Date:	UNK/UNK/2016
	Ongoing:	NO End Date: UNK/UNK/2016
1.g	Line/MH Number:	[7]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[HIATAL HERNIA]
	Start Date:	UNK/UNK/2005
	Ongoing:	YES
1.h	Line/MH Number:	[8]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[INGUINAL HERNIA]
	Start Date:	UNK/UNK/2016
	Ongoing:	NO End Date: UNK/UNK/2017

090177e196ae2f66\Final\Final On: 01-Apr-2021 03:42 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1013

Subject No: 10131176

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

1.i	Line/MH Number:	[9]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[INGUINAL HERNIA REPAIR]
	Start Date:	UNK/UNK/2017
	Ongoing:	NO End Date: UNK/UNK/2017
1.j	Line/MH Number:	[10]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[RIGHT KNEE REPLACEMENT]
	Start Date:	UNK/UNK/2009
	Ongoing:	NO End Date: UNK/UNK/2009
1.k	Line/MH Number:	[11]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[LEFT KNEE REPLACEMENT]
	Start Date:	UNK/UNK/2000
	Ongoing:	NO End Date: UNK/UNK/2000
1.l	Line/MH Number:	[12]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[RIGHT KNEE OSTEOARTHRITIS]
	Start Date:	UNK/UNK/1990
	Ongoing:	NO End Date: UNK/UNK/2009

090177e196ae2f66\Final\Final On: 01-Apr-2021 03:42 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1013

Subject No: 10131176

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

1 m	Line/MH Number:	[13]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[LEFT KNEE OSTEOARTHRITIS]
	Start Date:	UNK/UNK/1990
	Ongoing:	NO End Date: UNK/UNK/2000

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 30-Jul-2020 21:28

Site No: 1013

Subject No: 10131176

Generated By: pfe.levissc

Form: VITAL SIGNS - BASELINE

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1013) Clinical Neuroscience Solutions Inc.

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Vital Signs

1.	Date:	Aug/13/2020
2.	Weight:	[72.2]
3.	Unit:	kg
4.	Height:	[174.9]
5.	Unit:	cm
6.	Body Mass Index:	[23.6]

Vital Signs Details

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

090177e196ae2f66\Final\Final On: 01-Apr-2021 03:42 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1013

Subject No: 10131176

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/13/2020
2.	Randomization Number:	[227629]
3.	Randomization Group:	[]

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1013

Subject No: 10131176

Generated By: pfe.levissc

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1013) Clinical Neuroscience Solutions Inc.

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	SERUM
3.	Sample Collected?	YES Date of Collection: Aug/13/2020
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	[BPYWBS]
5.b	Sample ID	[BPYWBT]
5.c	Sample ID	[BPYWBV]
5.d	Sample ID	[BNWHH0]
5.e	Sample ID	[BNWHH1]

090177e196ae2f66\Final\Final On: 01-Apr-2021 03:42 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1013

Subject No: 10131176

Generated By: pfe.levissc

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1013) Clinical Neuroscience Solutions Inc.

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Aug/13/2020
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	[BM8S47]
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Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:04

Site No: 1013

Subject No: 10131176

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/13/2020 12:35
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

090177e196ae2f66\Final\Final On: 01-Apr-2021 03:42 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 06-Jul-2020 21:53

Site No: 1013

Subject No: 10131176

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	YES - REACTOGENICITY E-DIARY COLLECTED FOR THIS SUBJECT
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Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 1013

Subject No: 10131176

Generated By: pfe.levisse

Form: DATE OF VISIT

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1013) Clinical Neuroscience Solutions Inc.

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Date of Visit

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

Header Text: c4591001

Visit: V2_VAX2_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES

Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1013

Site Name: (1013) Clinical Neuroscience Solutions Inc.

Subject No: 10131176

Subject Initials: ---

Generated By: pfe.levissc

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

[eCRF Audit Trail History](#)

Vaccination Symptoms Diary - Symptom Resolved Dates

1.	Were medications to treat fever/pain given on the last day the Subject Diary was completed?	NO
2.a	Symptom:	FEVER
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO
2.b	Symptom:	FATIGUE
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO
2.c	Symptom:	HEADACHE
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO
2.d	Symptom:	CHILLS
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO
2.e	Symptom:	VOMITING
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO
2.f	Symptom:	DIARRHEA
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO
2.g	Symptom:	NEW OR WORSENERED MUSCLE PAIN
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO

090177e196ae2f66\Final\Final On: 01-Apr-2021 03:42 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES

Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1013

Site Name: (1013) Clinical Neuroscience Solutions Inc.

Subject No: 10131176

Subject Initials: ---

Generated By: pfe.levissc

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

2.h	Symptom:	NEW OR WORSENERD JOINT PAIN
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO
3.	Injection Site Location:	DELTOID MUSCLE
4.	Injection Site Body Side:	LEFT
5.a	Injection Site Reaction:	REDNESS
	Were injection site reactions present on the last day the Subject Diary was completed?	NO
5.b	Injection Site Reaction:	SWELLING
	Were injection site reactions present on the last day the Subject Diary was completed?	NO
5.c	Injection Site Reaction:	PAIN AT INJECTION SITE
	Were injection site reactions present on the last day the Subject Diary was completed?	NO

090177e196ae2f66\Final\Final On: 01-Apr-2021 03:42 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 15-Sep-2020 21:54

Site No: 1013

Subject No: 10131176

Generated By: pfe.levisse

Form: VITAL SIGNS - TEMP

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1013) Clinical Neuroscience Solutions Inc.

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Vital Signs

1.	Date:	Oct/7/2020
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Vital Signs Details

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

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:03

Site No: 1013

Subject No: 10131176

Generated By: pfe.levissc

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1013) Clinical Neuroscience Solutions Inc.

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Oct/7/2020
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[]

Aliquot

Please enter barcode for each aliquot.

5.a	Sample ID	[BRG2V7]
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090177e196ae2f66\Final\Final On: 01-Apr-2021 03:42 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1013

Subject No: 10131176

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:	Oct/7/2020 15:10
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

090177e196ae2f66\Final\Final On: 01-Apr-2021 03:42 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 1013

Subject No: 10131176

Generated By: pfe.levisse

Form: DATE OF VISIT

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1013) Clinical Neuroscience Solutions Inc.

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Date of Visit

1.	Date of Visit	Nov/4/2020
2.	Erroneous Visit	

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES

Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1013

Site Name: (1013) Clinical Neuroscience Solutions Inc.

Subject No: 10131176

Subject Initials: ---

Generated By: pfe.levissc

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

[eCRF Audit Trail History](#)

Vaccination Symptoms Diary - Symptom Resolved Dates

1.	Were medications to treat fever/pain given on the last day the Subject Diary was completed?	NO
2.a	Symptom:	FEVER
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO
2.b	Symptom:	FATIGUE
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO
2.c	Symptom:	HEADACHE
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO
2.d	Symptom:	CHILLS
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO
2.e	Symptom:	VOMITING
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO
2.f	Symptom:	DIARRHEA
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO
2.g	Symptom:	NEW OR WORSENERED MUSCLE PAIN
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO

090177e196ae2f66\Final\Final On: 01-Apr-2021 03:42 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES

Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1013

Site Name: (1013) Clinical Neuroscience Solutions Inc.

Subject No: 10131176

Subject Initials: ---

Generated By: pfe.levissc

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

2.h	Symptom:	NEW OR WORSENERD JOINT PAIN
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO
3.	Injection Site Location:	DELTOID MUSCLE
4.	Injection Site Body Side:	LEFT
5.a	Injection Site Reaction:	REDNESS
	Were injection site reactions present on the last day the Subject Diary was completed?	NO
5.b	Injection Site Reaction:	SWELLING
	Were injection site reactions present on the last day the Subject Diary was completed?	NO
5.c	Injection Site Reaction:	PAIN AT INJECTION SITE
	Were injection site reactions present on the last day the Subject Diary was completed?	NO

090177e196ae2f66\Final\Final On: 01-Apr-2021 03:42 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form Version: 22-Apr-2020 21:03

Site No: 1013

Subject No: 10131176

Generated By: pfe.levissc

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1013) Clinical Neuroscience Solutions Inc.

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	SERUM
3.	Sample Collected?	YES Date of Collection: Nov/4/2020
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	[BS0J7D]
5.b	Sample ID	[BS0J7F]
5.c	Sample ID	[BRHVB9]
5.d	Sample ID	[BRHVBB]
5.e	Sample ID	[BRHVBC]

090177e196ae2f66\Final\Final On: 01-Apr-2021 03:42 (GMT)

Header Text: c4591001

Visit: V4_MONTH6_L

Form Version: 22-Apr-2020 21:02

Site No: 1013

Subject No: 10131176

Generated By: pfe.levisse

Form: DATE OF VISIT

Form Status: Not Started

Site Name: (1013) Clinical Neuroscience Solutions Inc.

Subject Initials: ---

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

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

Header Text: c4591001

Visit: V4_MONTH6_L

Form Version: 22-Apr-2020 21:03

Site No: 1013

Subject No: 10131176

Generated By: pfe.levissc

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Status: Not Started

Site Name: (1013) Clinical Neuroscience Solutions Inc.

Subject Initials: ---

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

Electronic Sample Tracking

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

Aliquot

Please enter barcode for each aliquot.

5.	Sample ID	[]
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Header Text: c4591001

Visit: V5_MONTH12_L

Form Version: 22-Apr-2020 21:02

Site No: 1013

Subject No: 10131176

Generated By: pfe.levisse

Form: DATE OF VISIT

Form Status: Not Started

Site Name: (1013) Clinical Neuroscience Solutions Inc.

Subject Initials: ---

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

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

Header Text: c4591001

Visit: V5_MONTH12_L

Form Version: 22-Apr-2020 21:03

Site No: 1013

Subject No: 10131176

Generated By: pfe.levissc

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Status: Not Started

Site Name: (1013) Clinical Neuroscience Solutions Inc.

Subject Initials: ---

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

Electronic Sample Tracking

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

Aliquot

Please enter barcode for each aliquot.

5.	Sample ID	[]
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Header Text: c4591001

Visit: V6_MONTH24_L

Form Version: 22-Apr-2020 21:02

Site No: 1013

Subject No: 10131176

Generated By: pfe.levisse

Form: DATE OF VISIT

Form Status: Not Started

Site Name: (1013) Clinical Neuroscience Solutions Inc.

Subject Initials: ---

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

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

Header Text: c4591001

Visit: V6_MONTH24_L

Form Version: 22-Apr-2020 21:03

Site No: 1013

Subject No: 10131176

Generated By: pfe.levissc

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Status: Not Started

Site Name: (1013) Clinical Neuroscience Solutions Inc.

Subject Initials: ---

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

Electronic Sample Tracking

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

Aliquot

Please enter barcode for each aliquot.

5.	Sample ID	[]
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Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on **Form:** DATE OF VISIT - ILLNESS ONSET
Nov/09/2020

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1013

Site Name: (1013) Clinical Neuroscience Solutions Inc.

Subject No: 10131176

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	Nov/9/2020
2.	Erroneous Visit	

COVID-19 Illness Visit

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

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/09/2020 Form: SIGNS AND SYMPTOMS OF POTENTIAL COVID-19

Form Version: 10-Oct-2020 16:02

Form Status: Data Complete, Frozen, Not Complete

Site No: 1013

Site Name: (1013) Clinical Neuroscience Solutions Inc.

Subject No: 10131176

Subject Initials: ---

Generated By: pfe.levissc

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

[eCRF Audit Trail History](#)

Signs and Symptoms

1.	Date of Assessment:	Nov/9/2020	
2.	Date of First Symptom Started:	Not Applicable _____ //	Comments
3.	Symptoms Ongoing?	Not Applicable _____	Comments

Symptoms

4.a	Symptoms:	FEVER
	Was symptom present?	NO
4.b	Symptoms:	NEW OR INCREASED COUGH
	Was symptom present?	NO
4.c	Symptoms:	NEW OR INCREASED SHORTNESS OF BREATH
	Was symptom present?	NO
4.d	Symptoms:	CHILLS
	Was symptom present?	NO
4.e	Symptoms:	NEW OR INCREASED MUSCLE PAIN
	Was symptom present?	NO
4.f	Symptoms:	NEW LOSS OF TASTE OR SMELL
	Was symptom present?	NO
4.g	Symptoms:	NEW OR INCREASED SORE THROAT
	Was symptom present?	NO
4.h	Symptoms:	DIARRHEA
	Was symptom present?	NO
4.i	Symptoms:	VOMITING
	Was symptom present?	NO

Symptoms - Other

090177e196ae2f66\Final\Final On: 01-Apr-2021 03:42 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on **Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19
Nov/09/2020

Form Version: 10-Oct-2020 16:02

Form Status: Data Complete, Frozen, Not Complete

Site No: 1013

Site Name: (1013) Clinical Neuroscience Solutions Inc.

Subject No: 10131176

Subject Initials: ---

Generated By: pfe.levissc

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

5.a

Symptoms - Other Text:

[]

Header Text: c4591001

Visit: POT_COVID_ILL 1

Form: MICROBIOLOGY SPECIMEN

Form Version: 06-Jul-2020 21:54

Site No: 1013

Site Name: (1013) Clinical Neuroscience Solutions Inc.

Subject No: 10131176

Subject Initials: ---

Generated By: pfe.levissc

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

#	Date of Collection	Specimen Type	Specimen Collection Location	Assay Code and Description	Device Type	Form Instance
1.	Not Applicable	Not Applicable	Not Applicable	Not Applicable	Not Applicable	Repeating Pages

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on **Form:** MICROBIOLOGY SPECIMEN
Nov/09/2020

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen, Verified

Site No: 1013

Site Name: (1013) Clinical Neuroscience Solutions Inc.

Subject No: 10131176

Subject Initials: ---

Generated By: pfe.levissc

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

[Back to Form](#)

[Form Comments](#)

[eCRF Audit Trail History](#)

Microbiology Specimen

1.	Actual Date of Collection:	Not Applicable _____ //	Comments
2.	Specimen Type:	Not Applicable _____	Comments
3.	Specimen Collection Location:	Not Applicable _____	Comments
4.	Assay Code and Description:	Not Applicable _____	Comments
5.	Device Type:	Not Applicable _____	Comments
6.	Trade Name:	Not Applicable _____	Comments
7.	Test Result:	Not Applicable _____	Comments
8.	Comments/Findings/Details:	Not Applicable _____ []	Comments
9.	Trade Name Other, Specify:	Not Applicable _____ []	Comments

090177e196ae2f66\Final\Final On: 01-Apr-2021 03:42 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on **Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB SELF
Nov/09/2020

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1013

Site Name: (1013) Clinical Neuroscience Solutions Inc.

Subject No: 10131176

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_SELF
3.	Sample Collected?	NO
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[NO SWAB COLLECTED. NO VISIT WAS COMPLETED FOR COVID ILLNESS.]

Aliquot

Please enter barcode for each aliquot.

5.	Sample ID	[]
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Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on **Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB
Nov/09/2020

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1013

Site Name: (1013) Clinical Neuroscience Solutions Inc.

Subject No: 10131176

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?	NO
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[NO SWAB COLLECTED AS THEIR WAS NO COVID ILLNESS VISIT.]

Aliquot

Please enter barcode for each aliquot.

5.	Sample ID	[]
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090177e196ae2f66\Final\Final On: 01-Apr-2021 03:42 (GMT)

Header Text: c4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit on **Form:** HEALTH CARE UTILIZATION
Nov/09/2020**Form Version:** 10-Oct-2020 15:59**Form Status:** Data Complete, Frozen, Verified**Site No:** 1013**Site Name:** (1013) Clinical Neuroscience Solutions Inc.**Subject No:** 10131176**Subject Initials:** ---**Generated By:** pfe.levissc**Generated Time (GMT):** 29-Mar-2021 04:21[Form Comments](#)[eCRF Audit Trail History](#)**Health Care Utilization**

1.a	Physician or Healthcare Professional:	SPECIALIST	
	Occurrence of Visits or Contacts:	NO	Comments
1.b	Physician or Healthcare Professional:	EMERGENCY ROOM	
	Occurrence of Visits or Contacts:	YES Number of Visits or Contacts: [1]	Comments
1.c	Physician or Healthcare Professional:	PRIMARY CARE PHYSICIAN	
	Occurrence of Visits or Contacts:	NO	Comments
1.d	Physician or Healthcare Professional:	URGENT CARE	
	Occurrence of Visits or Contacts:	NO	Comments
1.e	Physician or Healthcare Professional:	TELEPHONE CONSULTATION	
	Occurrence of Visits or Contacts:	NO	Comments
1.f	Physician or Healthcare Professional:	OTHER	
	Occurrence of Visits or Contacts:	YES Number of Visits or Contacts: [1]	Comments

Health Care Utilization Other

2.	Other Type of Practitioner Specify:	[INTENSIVE CARE UNIT]	Comments
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Health Care Utilization

3.	Has the subject been hospitalized due to potential COVID-19 illness?	NO	Comments
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Header Text: c4591001

Visit: POT_COVID_ILL 1

Form: RESPIRATORY TREATMENT

Form Version: 06-Jul-2020 21:53

Site No: 1013

Site Name: (1013) Clinical Neuroscience Solutions Inc.

Subject No: 10131176

Subject Initials: ---

Generated By: pfe.levissc

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

#	Treatment Identifier	Con Non-Drug Treatments Pre-specified	Treatment	Treatment	Start Date	Form Instance
1.	Not Applicable	Not Applicable	Not Applicable	Not Applicable	Not Applicable	Repeating Pages

090177e196ae2f66\Final\Final On: 01-Apr-2021 03:42 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on **Form:** RESPIRATORY TREATMENT

Nov/09/2020

Form Version: 06-Jul-2020 21:53

Form Status: Data Complete, Frozen, Verified

Site No: 1013

Site Name: (1013) Clinical Neuroscience Solutions Inc.

Subject No: 10131176

Subject Initials: ---

Generated By: pfe.levissc

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

[Back to Form](#)

[Form Comments](#)

[eCRF Audit Trail History](#)

Respiratory Treatment

1.	What is the treatment Identifier?	Not Applicable _____ []	Comments
2.	Concomitant Non-drug Treatment Pre-specified:	Not Applicable _____	Comments
3.	Treatment:	Not Applicable _____	Comments
4.	Treatment:	Not Applicable _____ []	Comments
5.	Start Date:	Not Applicable _____ //	Comments
6.	Ongoing?	Not Applicable _____	Comments

090177e196ae2f66\Final\Final On: 01-Apr-2021 03:42 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on **Form:** ILLNESS DETAILS
Nov/09/2020

Form Version: 06-Jul-2020 21:52

Form Status: Data Complete, Frozen, Verified

Site No: 1013

Site Name: (1013) Clinical Neuroscience Solutions Inc.

Subject No: 10131176

Subject Initials: ---

Generated By: pfe.levissc

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

[eCRF Audit Trail History](#)

Illness Details

1.	Category of Clinical Event:	POTENTIAL COVID-19 ILLNESS
2.	Was a diagnosis obtained for Potential COVID-19 Illness?	YES Respiratory Illness Diagnosis: [ASPIRATION PNEUMONIA] Date of Diagnosis: Aug/30/2020
3.	Toxicity Grade:	3

090177e196ae2f66\Final\Final On: 01-Apr-2021 03:42 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1

Form: ILLNESS DETAILS - SEVERE

Form Version: 17-Jul-2020 21:55

Site No: 1013

Site Name: (1013) Clinical Neuroscience Solutions Inc.

Subject No: 10131176

Subject Initials: ---

Generated By: pfe.levissc

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

#	Category of Clinical Event:	Subcategory of Clinical Event	Diagnosis Obtained	Toxicity Grade	Form Instance
1.	Not Applicable	Not Applicable	Not Applicable	Not Applicable	Repeating Pages

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on **Form:** ILLNESS DETAILS - SEVERE
Nov/09/2020

Form Version: 17-Jul-2020 21:55

Form Status: Data Complete, Frozen, Verified

Site No: 1013

Site Name: (1013) Clinical Neuroscience Solutions Inc.

Subject No: 10131176

Subject Initials: ---

Generated By: pfe.levissc

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

[Back to Form](#)

[Form Comments](#)

[eCRF Audit Trail History](#)

Illness Details

1.	Category of Clinical Event:	Not Applicable _____	Comments
2.	Subcategory of Clinical Event:	Not Applicable _____	Comments
3.	Was a diagnosis obtained?	Not Applicable _____	Comments
4.	Toxicity Grade:	Not Applicable _____	Comments

Header Text: c4591001

Visit: POT_COVID_ILL 1

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY

Form Version: 30-Jul-2020 21:27

Site No: 1013

Site Name: (1013) Clinical Neuroscience Solutions Inc.

Subject No: 10131176

Subject Initials: ---

Generated By: pfe.levissc

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

#	Category for Lab Test	Vendor Name	Collection Date:	Specimen Type	Lab Result			Form Instance
1.	Not Applicable	Not Applicable	Not Applicable	Not Applicable	Sponsor-Defined Identifier	Test:	Result:	Repeating Pages
					Not Applicable	Not Applicable	Not Applicable	
					Not Applicable	Not Applicable	Not Applicable	
					Not Applicable	Not Applicable	Not Applicable	
					Not Applicable	Not Applicable	Not Applicable	
					Not Applicable	Not Applicable	Not Applicable	
					Not Applicable	Not Applicable	Not Applicable	
					Not Applicable	Not Applicable	Not Applicable	

090177e196ae2f66\Final\Final On: 01-Apr-2021 03:42 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on **Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY
Nov/09/2020

Form Version: 30-Jul-2020 21:27

Form Status: Data Complete, Frozen, Verified

Site No: 1013

Site Name: (1013) Clinical Neuroscience Solutions Inc.

Subject No: 10131176

Subject Initials: ---

Generated By: pfe.levisse

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

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

Lab Chemistry Details

1.	Lab Panel:	Not Applicable _____	Comments
2.	Laboratory Name and Address	Not Applicable _____ []	Comments
3.	Collection Date:	Not Applicable _____ //	Comments
4.	Specimen Type:	Not Applicable _____	Comments

Lab Result

5.a	Sponsor ID:	Not Applicable _____ []	Comments
	Test:	C Reactive Protein_PX329	
	Result:	Not Applicable _____ []	Comments
	Not Done:	Not Applicable _____	Comments
	LNMT	Not Applicable _____ Low [] High [] Unit	Comments

090177e196ae2f66\Final\Final On: 01-Apr-2021 03:42 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on **Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY
Nov/09/2020

Form Version: 30-Jul-2020 21:27

Form Status: Data Complete, Frozen, Verified

Site No: 1013

Site Name: (1013) Clinical Neuroscience Solutions Inc.

Subject No: 10131176

Subject Initials: ---

Generated By: pfe.levissc

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

5.b	Sponsor ID:	Not Applicable _____ []	Comments
	Test:	Alanine Aminotransferase_PX30	
	Result:	Not Applicable _____ []	Comments
	Not Done:	Not Applicable _____ []	Comments
	LNMT	Not Applicable _____ Low [] High [] Unit	Comments
5.c	Sponsor ID:	Not Applicable _____ []	Comments
	Test:	Aspartate Aminotransferase_PX28	
	Result:	Not Applicable _____ []	Comments
	Not Done:	Not Applicable _____ []	Comments
	LNMT	Not Applicable _____ Low [] High [] Unit	Comments

090177e196ae2f66\Final\Final On: 01-Apr-2021 03:42 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY
Nov/09/2020

Form Version: 30-Jul-2020 21:27

Form Status: Data Complete, Frozen, Verified

Site No: 1013

Site Name: (1013) Clinical Neuroscience Solutions Inc.

Subject No: 10131176

Subject Initials: ---

Generated By: pfe.levissc

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

5.d	Sponsor ID:	Not Applicable _____ []	Comments
	Test:	Alkaline Phosphatase_PX35	
	Result:	Not Applicable _____ []	Comments
	Not Done:	Not Applicable _____ []	Comments
	LNMT	Not Applicable _____ Low [] High [] Unit	Comments
5.e	Sponsor ID:	Not Applicable _____ []	Comments
	Test:	Bilirubin_PX21	
	Result:	Not Applicable _____ []	Comments
	Not Done:	Not Applicable _____ []	Comments
	LNMT	Not Applicable _____ Low [] High [] Unit	Comments

090177e196ae2f66\Final\Final On: 01-Apr-2021 03:42 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on **Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY
Nov/09/2020

Form Version: 30-Jul-2020 21:27

Form Status: Data Complete, Frozen, Verified

Site No: 1013

Site Name: (1013) Clinical Neuroscience Solutions Inc.

Subject No: 10131176

Subject Initials: ---

Generated By: pfe.levissc

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

5 f	Sponsor ID:	Not Applicable _____ []	Comments
	Test:	Blood Urea Nitrogen_PX47	
	Result:	Not Applicable _____ []	Comments
	Not Done:	Not Applicable _____ []	Comments
	LNMT	Not Applicable _____ Low [] High [] Unit	Comments
5.g	Sponsor ID:	Not Applicable _____ []	Comments
	Test:	Creatinine_PX48	
	Result:	Not Applicable _____ []	Comments
	Not Done:	Not Applicable _____ []	Comments
	LNMT	Not Applicable _____ Low [] High [] Unit	Comments

090177e196ae2f66\Final\Final On: 01-Apr-2021 03:42 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1

Form: LOCAL LABORATORY DATA - REPEATING Hematology

Form Version: 30-Jul-2020 21:28

Site No: 1013

Site Name: (1013) Clinical Neuroscience Solutions Inc.

Subject No: 10131176

Subject Initials: ---

Generated By: pfe.levissc

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

#	Category for Lab Test	Vendor Name (DERIVED)	Collection Date:	Specimen Type	Lab Result			Form Instance
					Sponsor-Defined Identifier	Test:	Result:	
1.	Not Applicable	Not Applicable	Not Applicable	Not Applicable	Not Applicable	Not Applicable	Not Applicable	Repeating Pages
					Not Applicable	Not Applicable	Not Applicable	
					Not Applicable	Not Applicable	Not Applicable	
					Not Applicable	Not Applicable	Not Applicable	
					Not Applicable	Not Applicable	Not Applicable	
					Not Applicable	Not Applicable	Not Applicable	
					Not Applicable	Not Applicable	Not Applicable	
					Not Applicable	Not Applicable	Not Applicable	
					Not Applicable	Not Applicable	Not Applicable	
					Not Applicable	Not Applicable	Not Applicable	
					Not Applicable	Not Applicable	Not Applicable	

090177e196ae2f66\Final\Final On: 01-Apr-2021 03:42 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on **Form:** LOCAL LABORATORY DATA - REPEATING Hematology
Nov/09/2020

Form Version: 30-Jul-2020 21:28

Form Status: Data Complete, Frozen, Verified

Site No: 1013

Site Name: (1013) Clinical Neuroscience Solutions Inc.

Subject No: 10131176

Subject Initials: ---

Generated By: pfe.levissc

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

[Back to Form](#)

[Form Comments](#)

[eCRF Audit Trail History](#)

Laboratory Data Hematology

1.	Lab Panel:	Not Applicable _____	Comments
2.	Laboratory Name and Address	Not Applicable _____ []	Comments
3.	Collection Date:	Not Applicable _____ //	Comments
4.	Specimen Type:	Not Applicable _____	Comments

Lab Result

5.a	Sponsor ID:	Not Applicable _____ []	Comments
	Test:	Hemoglobin_PX1	
	Result:	Not Applicable _____ []	Comments
	Not Done:	Not Applicable _____	Comments
	LNMT	Not Applicable _____ Low [] High [] Unit	Comments

090177e196ae2f66\Final\Final On: 01-Apr-2021 03:42 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on **Form:** LOCAL LABORATORY DATA - REPEATING Hematology
Nov/09/2020

Form Version: 30-Jul-2020 21:28

Form Status: Data Complete, Frozen, Verified

Site No: 1013

Site Name: (1013) Clinical Neuroscience Solutions Inc.

Subject No: 10131176

Subject Initials: ---

Generated By: pfe.levissc

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

5.b	Sponsor ID:	Not Applicable _____ []	Comments
	Test:	Hematocrit_PX2	
	Result:	Not Applicable _____ []	Comments
	Not Done:	Not Applicable _____ []	Comments
	LNMT	Not Applicable _____ Low [] High [] Unit	Comments
5.c	Sponsor ID:	Not Applicable _____ []	Comments
	Test:	Erythrocytes_PX3	
	Result:	Not Applicable _____ []	Comments
	Not Done:	Not Applicable _____ []	Comments
	LNMT	Not Applicable _____ Low [] High [] Unit	Comments

090177e196ae2f66\Final\Final On: 01-Apr-2021 03:42 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on **Form:** LOCAL LABORATORY DATA - REPEATING Hematology
Nov/09/2020

Form Version: 30-Jul-2020 21:28

Form Status: Data Complete, Frozen, Verified

Site No: 1013

Site Name: (1013) Clinical Neuroscience Solutions Inc.

Subject No: 10131176

Subject Initials: ---

Generated By: pfe.levissc

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

5.d	Sponsor ID:	Not Applicable _____ []	Comments
	Test:	Platelets_PX5	
	Result:	Not Applicable _____ []	Comments
	Not Done:	Not Applicable _____ []	Comments
	LNMT	Not Applicable _____ Low [] High [] Unit	Comments
5.e	Sponsor ID:	Not Applicable _____ []	Comments
	Test:	Leukocytes_PX7	
	Result:	Not Applicable _____ []	Comments
	Not Done:	Not Applicable _____ []	Comments
	LNMT	Not Applicable _____ Low [] High [] Unit	Comments

090177e196ae2f66\Final\Final On: 01-Apr-2021 03:42 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on **Form:** LOCAL LABORATORY DATA - REPEATING Hematology
Nov/09/2020

Form Version: 30-Jul-2020 21:28

Form Status: Data Complete, Frozen, Verified

Site No: 1013

Site Name: (1013) Clinical Neuroscience Solutions Inc.

Subject No: 10131176

Subject Initials: ---

Generated By: pfe.levissc

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

5 f	Sponsor ID:	Not Applicable _____ []	Comments
	Test:	Neutrophils_PX608	
	Result:	Not Applicable _____ []	Comments
	Not Done:	Not Applicable _____ []	Comments
	LNMT	Not Applicable _____ Low [] High [] Unit	Comments
5.g	Sponsor ID:	Not Applicable _____ []	Comments
	Test:	Eosinophils_PX609	
	Result:	Not Applicable _____ []	Comments
	Not Done:	Not Applicable _____ []	Comments
	LNMT	Not Applicable _____ Low [] High [] Unit	Comments

090177e196ae2f66\Final\Final On: 01-Apr-2021 03:42 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on **Form:** LOCAL LABORATORY DATA - REPEATING Hematology
Nov/09/2020

Form Version: 30-Jul-2020 21:28

Form Status: Data Complete, Frozen, Verified

Site No: 1013

Site Name: (1013) Clinical Neuroscience Solutions Inc.

Subject No: 10131176

Subject Initials: ---

Generated By: pfe.levissc

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

5.h	Sponsor ID:	Not Applicable _____ []	Comments
	Test:	Monocytes_PX612	
	Result:	Not Applicable _____ []	Comments
	Not Done:	Not Applicable _____ []	Comments
	LNMT	Not Applicable _____ Low [] High [] Unit	Comments
5.i	Sponsor ID:	Not Applicable _____ []	Comments
	Test:	Basophils_PX610	
	Result:	Not Applicable _____ []	Comments
	Not Done:	Not Applicable _____ []	Comments
	LNMT	Not Applicable _____ Low [] High [] Unit	Comments

090177e196ae2f66\Final\Final On: 01-Apr-2021 03:42 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on **Form:** LOCAL LABORATORY DATA - REPEATING Hematology
Nov/09/2020

Form Version: 30-Jul-2020 21:28

Form Status: Data Complete, Frozen, Verified

Site No: 1013

Site Name: (1013) Clinical Neuroscience Solutions Inc.

Subject No: 10131176

Subject Initials: ---

Generated By: pfe.levissc

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

5.j	Sponsor ID:	Not Applicable _____ []	Comments
	Test:	Lymphocytes_PX611	
	Result:	Not Applicable _____ []	Comments
	Not Done:	Not Applicable _____ []	Comments
	LNMT	Not Applicable _____ Low [] High [] Unit	Comments

090177e196ae2f66\Final\Final On: 01-Apr-2021 03:42 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1

Form: VITAL SIGNS - COVID

Form Version: 30-Jul-2020 21:27

Site No: 1013

Site Name: (1013) Clinical Neuroscience Solutions Inc.

Subject No: 10131176

Subject Initials: ---

Generated By: pfe.levissc

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

#	Date:	Vital Signs Details			Form Instance
1.	Not Applicable	Record Identifier:	Systolic:	Diastolic:	Repeating Pages
		Not Applicable	Not Applicable	Not Applicable	

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on **Form:** VITAL SIGNS - COVID
Nov/09/2020

Form Version: 30-Jul-2020 21:27

Form Status: Data Complete, Frozen, Verified

Site No: 1013

Site Name: (1013) Clinical Neuroscience Solutions Inc.

Subject No: 10131176

Subject Initials: ---

Generated By: pfe.levissc

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

[Back to Form](#)

[Form Comments](#)

[eCRF Audit Trail History](#)

Vital Signs

1.	Date:	Not Applicable _____ //	Comments
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Vital Signs Details

2.a	Record Identifier:	Not Applicable _____ 1	
	Systolic:	Not Applicable _____ []	Comments
	Diastolic:	Not Applicable _____ []	Comments
	Respiratory Rate in respirations/minute:	Not Applicable _____ []	Comments
	Heart Rate in beats/minute:	Not Applicable _____ []	Comments

090177e196ae2f66\Final\Final On: 01-Apr-2021 03:42 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1

Form: VITAL SIGNS - PULSE OX ROOM AIR

Form Version: 30-Jul-2020 21:28

Site No: 1013

Site Name: (1013) Clinical Neuroscience Solutions Inc.

Subject No: 10131176

Subject Initials: ---

Generated By: pfe.levissc

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

#	Date:	Vital Signs Details		Form Instance
1.	Not Applicable	Record Identifier:	Oxygen Saturation	Repeating Pages
		Not Applicable	Not Applicable	

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on **Form:** VITAL SIGNS - PULSE OX ROOM AIR
Nov/09/2020

Form Version: 30-Jul-2020 21:28

Form Status: Data Complete, Frozen, Verified

Site No: 1013

Site Name: (1013) Clinical Neuroscience Solutions Inc.

Subject No: 10131176

Subject Initials: ---

Generated By: pfe.levissc

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

[Back to Form](#)

[Form Comments](#)

[eCRF Audit Trail History](#)

Vital Signs

1.	Date:	Not Applicable _____ //	Comments
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Vital Signs Details

2.a	Record Identifier:	Not Applicable _____ 1	
	SPO2 Pulse Oximetry %	Not Applicable _____ []	Comments

090177e196ae2f66\Final\Final On: 01-Apr-2021 03:42 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1

Form: OXYGENATION PARAMETERS

Form Version: 06-Jul-2020 21:52

Site No: 1013

Site Name: (1013) Clinical Neuroscience Solutions Inc.

Subject No: 10131176

Subject Initials: ---

Generated By: pfe.levissc

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

#	Date Time of Assessment	Arterial Blood Gases PaO2	FiO2 (Fraction of Inhaled Oxygen)	Form Instance
1.	Not Applicable	Not Applicable	Not Applicable	Repeating Pages

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on **Form:** OXYGENATION PARAMETERS

Nov/09/2020

Form Version: 06-Jul-2020 21:52

Form Status: Data Complete, Frozen, Verified

Site No: 1013

Site Name: (1013) Clinical Neuroscience Solutions Inc.

Subject No: 10131176

Subject Initials: ---

Generated By: pfe.levissc

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

[Back to Form](#)

[Form Comments](#)

[eCRF Audit Trail History](#)

Oxygenation Parameters

1.	Date Time of Assessment:	Not Applicable _____ //	Comments
2.	Arterial Blood Gases PaO2 (mmHg):	Not Applicable _____ []	Comments
3.	FiO2 (Fraction of Inhaled Oxygen):	Not Applicable _____ []	Comments

Header Text: c4591001

Visit: POT_COVID_ILL 1

Form: CONCOMITANT MEDICATIONS - VASOPRESSORS

Form Version: 06-Jul-2020 21:55

Site No: 1013

Site Name: (1013) Clinical Neuroscience Solutions Inc.

Subject No: 10131176

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.	Not Applicable	Not Applicable	Not Applicable	Not Applicable	Not Applicable	Repeating Pages

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on **Form:** CONCOMITANT MEDICATIONS - VASOPRESSORS
Nov/09/2020

Form Version: 06-Jul-2020 21:55

Form Status: Data Complete, Frozen, Verified

Site No: 1013

Site Name: (1013) Clinical Neuroscience Solutions Inc.

Subject No: 10131176

Subject Initials: ---

Generated By: pfe.levissc

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

[Back to Form](#)

[Form Comments](#)

[eCRF Audit Trail History](#)

Concomitant Medications

1.	What is the medication identifier?	Not Applicable _____ []	Comments
2.	Category:	Not Applicable _____	Comments
3.	Concomitant Medications Pre-specified:	Not Applicable _____	Comments
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).	Not Applicable _____ []	Comments
5.	Start Date:	Not Applicable _____ //	Comments
6.	Ongoing?	Not Applicable _____	Comments

090177e196ae2f66\Final\Final On: 01-Apr-2021 03:42 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1

Form: IMAGING

Form Version: 06-Jul-2020 21:53

Site No: 1013

Site Name: (1013) Clinical Neuroscience Solutions Inc.

Subject No: 10131176

Subject Initials: ---

Generated By: pfe.levissc

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

#	Date of Assessment	Location of Assessment	Imaging Method	Overall Assessment	Form Instance
1.	Not Applicable	Not Applicable	Not Applicable	Not Applicable	Repeating Pages

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on **Form:** IMAGING

Nov/09/2020

Form Version: 06-Jul-2020 21:53

Form Status: Data Complete, Frozen, Verified

Site No: 1013

Site Name: (1013) Clinical Neuroscience Solutions Inc.

Subject No: 10131176

Subject Initials: ---

Generated By: pfe.levissc

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

[Back to Form](#)

[Form Comments](#)

[eCRF Audit Trail History](#)

Imaging

1.	Date of Assessment:	Not Applicable _____ //	Comments
2.	Location of Assessment:	Not Applicable _____	Comments
3.	Type of Imaging Exam:	Not Applicable _____	Comments
4.	Assessment:	Not Applicable _____	Comments

090177e196ae2f66\Final\Final On: 01-Apr-2021 03:42 (GMT)

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: 10131176

Subject Initials: ---

Generated By: pfe.levisse

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

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

COVID-19 Illness Visit

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

Visit: POT_COVID_CONVA - New Unscheduled **Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY Visit

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1013

Site Name: (1013) Clinical Neuroscience Solutions Inc.

Subject No: 10131176

Subject Initials: ---

Generated By: pfe.levissc

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

Electronic Sample Tracking

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

Aliquot

Please enter barcode for each aliquot.

5.	Sample ID	[]
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Header Text: c4591001

Visit: Unplanned - New Unscheduled Visit

Form: DATE OF VISIT

Form Version: 22-Apr-2020 21:02

Form Status: Not Started

Site No: 1013

Site Name: (1013) Clinical Neuroscience Solutions Inc.

Subject No: 10131176

Subject Initials: ---

Generated By: pfe.levisse

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

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

Header Text: c4591001

Visit: Unplanned - 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: 10131176

Subject Initials: ---

Generated By: pfe.levissc

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

Unplanned Assessments

1.	Assessments	
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Header Text: c4591001

Visit: End of Treatment - Unscheduled

Form Version: 15-Sep-2020 21:55

Site No: 1013

Subject No: 10131176

Generated By: pfe.levisse

Form: DISPOSITION - TREATMENT

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 - Treatment

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

Header Text: c4591001

Visit: Follow-Up - Unscheduled

Form Version: 15-Sep-2020 21:53

Site No: 1013

Subject No: 10131176

Generated By: pfe.levisse

Form: DISPOSITION - FOLLOW-UP

Form Status: Not Started

Site Name: (1013) Clinical Neuroscience Solutions Inc.

Subject Initials: ---

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

Disposition - Follow-Up

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

Header Text: c4591001

Visit: POT_COVID_REPEAT_SWAB - New
Unscheduled Visit

Form: DATE OF VISIT - REPEAT SWAB

Form Version: 10-Oct-2020 15:57

Form Status: Not Started

Site No: 1013

Site Name: (1013) Clinical Neuroscience Solutions Inc.

Subject No: 10131176

Subject Initials: ---

Generated By: pfe.levisse

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

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

COVID-19 Repeat Swab

3.	COVID-19 Repeat Swab:	
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Header Text: c4591001

Visit: POT_COVID_REPEAT_SWAB - New
Unscheduled Visit

Form: ELECTRONIC SAMPLE TRACKING - REPEAT SWAB

Form Version: 10-Oct-2020 15:57

Form Status: Not Started

Site No: 1013

Site Name: (1013) Clinical Neuroscience Solutions Inc.

Subject No: 10131176

Subject Initials: ---

Generated By: pfe.levissc

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

Electronic Sample Tracking

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

Aliquot

Please enter barcode for each aliquot.

5.	Sample ID	[]
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Header Text: c4591001

Visit: Logs

Form: ADVERSE EVENT REPORT

Form Version: 22-Apr-2020 21:02

Site No: 1013

Site Name: (1013) Clinical Neuroscience Solutions Inc.

Subject No: 10131176

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	abdominal adhesions	Aug/29/2020 U NK:UNK	NO End Date Time: Aug/30/2020 UNK: UNK	Repeating Pages
2.	ADVERSE EVENT	2	altered mental status	Aug/29/2020 U NK:UNK	NO End Date Time: Sep/16/2020 UNK: UNK	Repeating Pages
3.	ADVERSE EVENT	3	acute hypoxic respiratory failure	Aug/30/2020 U NK:UNK	NO End Date Time: Sep/11/2020 UNK: UNK	Repeating Pages
4.	ADVERSE EVENT	4	CONGESTIVE HEART FAILURE	Aug/30/2020 U NK:UNK	NO End Date Time: Sep/16/2020 UNK: UNK	Repeating Pages
5.	ADVERSE EVENT	5	hypokalemia	Aug/30/2020 U NK:UNK	NO End Date Time: Sep/16/2020 UNK: UNK	Repeating Pages
6.	ADVERSE EVENT	6	anemia	Aug/30/2020 U NK:UNK	NO End Date Time: Sep/16/2020 UNK: UNK	Repeating Pages
7.	ADVERSE EVENT	7	acute renal failure	Aug/29/2020 U NK:UNK	NO End Date Time: Sep/16/2020 UNK: UNK	Repeating Pages

090177e196ae2f66\Final\Final On: 01-Apr-2021 03:42 (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: 10131176

Subject Initials: ---

Generated By: pfe.levissc

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

#	Category	AE Identifier	Adverse Event	Start Date	Is the Adverse Event Still Ongoing	Form Instance
8.	ADVERSE EVENT	8	sepsis	Aug/29/2020 UNK:UNK	NO End Date Time: Sep/16/2020 UNK:UNK	Repeating Pages
9.	ADVERSE EVENT	9	HYPONATREMIA	Aug/29/2020 UNK:UNK	NO End Date Time: Sep/7/2020 UNK:UNK	Repeating Pages
10.	ADVERSE EVENT	10	LEUKOPENIA	Aug/29/2020 UNK:UNK	NO End Date Time: Sep/7/2020 UNK:UNK	Repeating Pages
11.	ADVERSE EVENT	11	SMALL BOWEL OBSTRUCTION	Aug/29/2020 UNK:UNK	NO End Date Time: Aug/30/2020 UNK:UNK	Repeating Pages
12.	ADVERSE EVENT	12	ASPIRATION PNEUMONIA	Aug/30/2020 UNK:UNK	NO End Date Time: Sep/16/2020 UNK:UNK	Repeating Pages
13.	ADVERSE EVENT	13	MILD CONCENTRIC LEFT VENTRICULAR HYPERTROPHY	Sep/16/2020 UNK:UNK	YES	Repeating Pages
14.	ADVERSE EVENT	14	URINARY TRACT INFECTION	Jan/13/2021 UNK:UNK	NO End Date Time: Jan/22/2021 UNK:UNK	Repeating Pages

090177e196ae2f66\Final\Final On: 01-Apr-2021 03:42 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1013

Subject No: 10131176

Generated By: pfe.levissc

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Locked, Frozen

Site Name: (1013) Clinical Neuroscience Solutions Inc.

Subject Initials: ---

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

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

Adverse Event Report

1.	Category:	ADVERSE EVENT
2.	AE ID:	[1]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[abdominal adhesions]
4.	Start Date Time:	Aug/29/2020 UNK:UNK
5.	Is the adverse event still ongoing?	NO End Date Time: Aug/30/2020 UNK:UNK
6.	Toxicity Grade:	3
7.	Is the adverse event serious? If Yes, NOTIFY PFIZER IMMEDIATELY. Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).	YES Is this serious event associated with congenital anomaly or birth defect? NO Did this serious event result in death? NO Did this serious event require or prolong hospitalization? YES Did this serious event result in persistent or significant disability/incapacity? NO Is this serious event life threatening? NO Other medically important serious event 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: [PREVIOUS SURGERY]

090177e196ae2f66\Final\Final On: 01-Apr-2021 03:42 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1013

Subject No: 10131176

Generated By: pfe.levissc

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Locked, Frozen

Site Name: (1013) Clinical Neuroscience Solutions Inc.

Subject Initials: ---

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

10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE
11.	Was a Concomitant Medication given?	YES
12.	Was a Non-Drug Treatment given?	NO
13.	What was the outcome of this adverse event?:	RECOVERED/RESOLVED
14.	Did the adverse event cause the subject to be discontinued from the study?	NO
15.	Serious Adverse Event Number: For Pfizer Use Only	[2020339639]

090177e196ae2f66\Final\Final On: 01-Apr-2021 03:42 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1013

Subject No: 10131176

Generated By: pfe.levisse

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Locked, Frozen

Site Name: (1013) Clinical Neuroscience Solutions Inc.

Subject Initials: ---

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

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

Adverse Event Report

1.	Category:	ADVERSE EVENT
2.	AE ID:	[2]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[altered mental status]
4.	Start Date Time:	Aug/29/2020 UNK:UNK
5.	Is the adverse event still ongoing?	NO End Date Time: Sep/16/2020 UNK:UNK
6.	Toxicity Grade:	3
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: CONCOMITANT NON-DRUG TREATMENT
10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE
11.	Was a Concomitant Medication given?	NO
12.	Was a Non-Drug Treatment given?	NO

090177e196ae2f66\Final\Final On: 01-Apr-2021 03:42 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1013

Subject No: 10131176

Generated By: pfe.levissc

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Locked, Frozen

Site Name: (1013) Clinical Neuroscience Solutions Inc.

Subject Initials: ---

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

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	[]

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1013

Subject No: 10131176

Generated By: pfe.levisse

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Locked, Frozen

Site Name: (1013) Clinical Neuroscience Solutions Inc.

Subject Initials: ---

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

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

Adverse Event Report

1.	Category:	ADVERSE EVENT
2.	AE ID:	[3]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[acute hypoxic respiratory failure]
4.	Start Date Time:	Aug/30/2020 UNK:UNK
5.	Is the adverse event still ongoing?	NO End Date Time: Sep/11/2020 UNK:UNK
6.	Toxicity Grade:	3
7.	Is the adverse event serious? If Yes, NOTIFY PFIZER IMMEDIATELY. Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).	YES Is this serious event associated with congenital anomaly or birth defect? NO Did this serious event result in death? NO Did this serious event require or prolong hospitalization? YES Did this serious event result in persistent or significant disability/incapacity? NO Is this serious event life threatening? NO Other medically important serious event 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: [prior surgery]

090177e196ae2f66\Final\Final On: 01-Apr-2021 03:42 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1013

Subject No: 10131176

Generated By: pfe.levissc

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Locked, Frozen

Site Name: (1013) Clinical Neuroscience Solutions Inc.

Subject Initials: ---

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

10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE
11.	Was a Concomitant Medication given?	NO
12.	Was a Non-Drug Treatment given?	NO
13.	What was the outcome of this adverse event?:	RECOVERED/RESOLVED
14.	Did the adverse event cause the subject to be discontinued from the study?	NO
15.	Serious Adverse Event Number: For Pfizer Use Only	[2020339639]

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1013

Subject No: 10131176

Generated By: pfe.levisse

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Locked, Frozen

Site Name: (1013) Clinical Neuroscience Solutions Inc.

Subject Initials: ---

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

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

Adverse Event Report

1.	Category:	ADVERSE EVENT
2.	AE ID:	[4]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[CONGESTIVE HEART FAILURE]
4.	Start Date Time:	Aug/30/2020 UNK:UNK
5.	Is the adverse event still ongoing?	NO End Date Time: Sep/16/2020 UNK:UNK
6.	Toxicity Grade:	3
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: [prior surgery]
10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE
11.	Was a Concomitant Medication given?	NO

090177e196ae2f66\Final\Final On: 01-Apr-2021 03:42 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1013

Subject No: 10131176

Generated By: pfe.levissc

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Locked, Frozen

Site Name: (1013) Clinical Neuroscience Solutions Inc.

Subject Initials: ---

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

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

090177e196ae2f66\Final\Final On: 01-Apr-2021 03:42 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1013

Subject No: 10131176

Generated By: pfe.levisse

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Locked, Frozen

Site Name: (1013) Clinical Neuroscience Solutions Inc.

Subject Initials: ---

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

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

Adverse Event Report

1.	Category:	ADVERSE EVENT
2.	AE ID:	[5]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[hypokalemia]
4.	Start Date Time:	Aug/30/2020 UNK:UNK
5.	Is the adverse event still ongoing?	NO End Date Time: Sep/16/2020 UNK:UNK
6.	Toxicity Grade:	3
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: [prior surgery]
10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE
11.	Was a Concomitant Medication given?	NO

090177e196ae2f66\Final\Final On: 01-Apr-2021 03:42 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1013

Subject No: 10131176

Generated By: pfe.levissc

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Locked, Frozen

Site Name: (1013) Clinical Neuroscience Solutions Inc.

Subject Initials: ---

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

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

090177e196ae2f66\Final\Final On: 01-Apr-2021 03:42 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1013

Subject No: 10131176

Generated By: pfe.levisse

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Locked, Frozen

Site Name: (1013) Clinical Neuroscience Solutions Inc.

Subject Initials: ---

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

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

Adverse Event Report

1.	Category:	ADVERSE EVENT
2.	AE ID:	[6]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[anemia]
4.	Start Date Time:	Aug/30/2020 UNK:UNK
5.	Is the adverse event still ongoing?	NO End Date Time: Sep/16/2020 UNK:UNK
6.	Toxicity Grade:	3
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: [prior surgery]
10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE
11.	Was a Concomitant Medication given?	NO

090177e196ae2f66\Final\Final On: 01-Apr-2021 03:42 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1013

Subject No: 10131176

Generated By: pfe.levissc

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Locked, Frozen

Site Name: (1013) Clinical Neuroscience Solutions Inc.

Subject Initials: ---

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

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

090177e196ae2f66\Final\Final On: 01-Apr-2021 03:42 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1013

Subject No: 10131176

Generated By: pfe.levisse

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Locked, Frozen

Site Name: (1013) Clinical Neuroscience Solutions Inc.

Subject Initials: ---

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

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

Adverse Event Report

1.	Category:	ADVERSE EVENT
2.	AE ID:	[7]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[acute renal failure]
4.	Start Date Time:	Aug/29/2020 UNK:UNK
5.	Is the adverse event still ongoing?	NO End Date Time: Sep/16/2020 UNK:UNK
6.	Toxicity Grade:	3
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: [prior surgery]
10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE
11.	Was a Concomitant Medication given?	NO

090177e196ae2f66\Final\Final On: 01-Apr-2021 03:42 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1013

Subject No: 10131176

Generated By: pfe.levissc

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Locked, Frozen

Site Name: (1013) Clinical Neuroscience Solutions Inc.

Subject Initials: ---

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

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

090177e196ae2f66\Final\Final On: 01-Apr-2021 03:42 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1013

Subject No: 10131176

Generated By: pfe.levisse

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Locked, Frozen

Site Name: (1013) Clinical Neuroscience Solutions Inc.

Subject Initials: ---

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

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

Adverse Event Report

1.	Category:	ADVERSE EVENT
2.	AE ID:	[8]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[sepsis]
4.	Start Date Time:	Aug/29/2020 UNK:UNK
5.	Is the adverse event still ongoing?	NO End Date Time: Sep/16/2020 UNK:UNK
6.	Toxicity Grade:	3
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: [prior surgery]
10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE
11.	Was a Concomitant Medication given?	NO

090177e196ae2f66\Final\Final On: 01-Apr-2021 03:42 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1013

Subject No: 10131176

Generated By: pfe.levissc

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Locked, Frozen

Site Name: (1013) Clinical Neuroscience Solutions Inc.

Subject Initials: ---

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

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

090177e196ae2f66\Final\Final On: 01-Apr-2021 03:42 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1013

Subject No: 10131176

Generated By: pfe.levisse

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Locked, Frozen

Site Name: (1013) Clinical Neuroscience Solutions Inc.

Subject Initials: ---

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

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

Adverse Event Report

1.	Category:	ADVERSE EVENT
2.	AE ID:	[9]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[HYPONATREMIA]
4.	Start Date Time:	Aug/29/2020 UNK:UNK
5.	Is the adverse event still ongoing?	NO End Date Time: Sep/7/2020 UNK:UNK
6.	Toxicity Grade:	2
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: [BOWEL OBSTRUCTION]
10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE
11.	Was a Concomitant Medication given?	YES

090177e196ae2f66\Final\Final On: 01-Apr-2021 03:42 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1013

Subject No: 10131176

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Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Locked, Frozen

Site Name: (1013) Clinical Neuroscience Solutions Inc.

Subject Initials: ---

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

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

090177e196ae2f66\Final\Final On: 01-Apr-2021 03:42 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1013

Subject No: 10131176

Generated By: pfe.levisse

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Locked, Frozen

Site Name: (1013) Clinical Neuroscience Solutions Inc.

Subject Initials: ---

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

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

Adverse Event Report

1.	Category:	ADVERSE EVENT
2.	AE ID:	[10]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[LEUKOPENIA]
4.	Start Date Time:	Aug/29/2020 UNK:UNK
5.	Is the adverse event still ongoing?	NO End Date Time: Sep/7/2020 UNK:UNK
6.	Toxicity Grade:	2
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: [BOWEL OBSTRUCTION]
10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE
11.	Was a Concomitant Medication given?	NO

090177e196ae2f66\Final\Final On: 01-Apr-2021 03:42 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1013

Subject No: 10131176

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Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Locked, Frozen

Site Name: (1013) Clinical Neuroscience Solutions Inc.

Subject Initials: ---

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

12.	Was a Non-Drug Treatment given?	YES
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	[]

090177e196ae2f66\Final\Final On: 01-Apr-2021 03:42 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1013

Subject No: 10131176

Generated By: pfe.levisse

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Locked, Frozen

Site Name: (1013) Clinical Neuroscience Solutions Inc.

Subject Initials: ---

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

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

Adverse Event Report

1.	Category:	ADVERSE EVENT
2.	AE ID:	[11]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[SMALL BOWEL OBSTRUCTION]
4.	Start Date Time:	Aug/29/2020 UNK:UNK
5.	Is the adverse event still ongoing?	NO End Date Time: Aug/30/2020 UNK:UNK
6.	Toxicity Grade:	2
7.	Is the adverse event serious? If Yes, NOTIFY PFIZER IMMEDIATELY. Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).	YES Is this serious event associated with congenital anomaly or birth defect? NO Did this serious event result in death? NO Did this serious event require or prolong hospitalization? YES Did this serious event result in persistent or significant disability/incapacity? NO Is this serious event life threatening? NO Other medically important serious event 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: [ADHESIONS]

090177e196ae2f66\Final\Final On: 01-Apr-2021 03:42 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1013

Subject No: 10131176

Generated By: pfe.levissc

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Locked, Frozen

Site Name: (1013) Clinical Neuroscience Solutions Inc.

Subject Initials: ---

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

10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE
11.	Was a Concomitant Medication given?	NO
12.	Was a Non-Drug Treatment given?	YES
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	[2020339639]

090177e196ae2f66\Final\Final On: 01-Apr-2021 03:42 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1013

Subject No: 10131176

Generated By: pfe.levisse

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Locked, Frozen

Site Name: (1013) Clinical Neuroscience Solutions Inc.

Subject Initials: ---

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

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

Adverse Event Report

1.	Category:	ADVERSE EVENT
2.	AE ID:	[12]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[ASPIRATION PNEUMONIA]
4.	Start Date Time:	Aug/30/2020 UNK:UNK
5.	Is the adverse event still ongoing?	NO End Date Time: Sep/16/2020 UNK:UNK
6.	Toxicity Grade:	2
7.	Is the adverse event serious? If Yes, NOTIFY PFIZER IMMEDIATELY. Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).	YES Is this serious event associated with congenital anomaly or birth defect? NO Did this serious event result in death? NO Did this serious event require or prolong hospitalization? YES Did this serious event result in persistent or significant disability/incapacity? NO Is this serious event life threatening? NO Other medically important serious event 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: [ADHESIONS]

090177e196ae2f66\Final\Final On: 01-Apr-2021 03:42 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1013

Subject No: 10131176

Generated By: pfe.levissc

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Locked, Frozen

Site Name: (1013) Clinical Neuroscience Solutions Inc.

Subject Initials: ---

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

10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE
11.	Was a Concomitant Medication given?	NO
12.	Was a Non-Drug Treatment given?	YES
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	[2020339639]

090177e196ae2f66\Final\Final On: 01-Apr-2021 03:42 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1013

Subject No: 10131176

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Form: ADVERSE EVENT REPORT

Form Status: Data Complete

Site Name: (1013) Clinical Neuroscience Solutions Inc.

Subject Initials: ---

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

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

Adverse Event Report

1.	Category:	ADVERSE EVENT
2.	AE ID:	[13]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[MILD CONCENTRIC LEFT VENTRICULAR HYPERTROPHY]
4.	Start Date Time:	Sep/16/2020 UNK:UNK
5.	Is the adverse event still ongoing?	YES
6.	Toxicity Grade:	1
7.	Is the adverse event serious? If Yes, NOTIFY PFIZER IMMEDIATELY. Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).	NO
8.	Is this adverse event the result of a study Medication Error? If Yes, record the type of medication error on the Medication Error Log.	NO
9.	Is this event related to study treatment:	NOT RELATED If Not Related to study treatment(s), this event is due to: OTHER If Other, specify: [UNKNOWN]
10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE
11.	Was a Concomitant Medication given?	NO
12.	Was a Non-Drug Treatment given?	NO

090177e196ae2f66\Final\Final On: 01-Apr-2021 03:42 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1013

Subject No: 10131176

Generated By: pfe.levissc

Form: ADVERSE EVENT REPORT

Form Status: Data Complete

Site Name: (1013) Clinical Neuroscience Solutions Inc.

Subject Initials: ---

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

13.	What was the outcome of this adverse event?:	RECOVERING/RESOLVING
14.	Did the adverse event cause the subject to be discontinued from the study?	NO
15.	Serious Adverse Event Number: For Pfizer Use Only	[]

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1013

Subject No: 10131176

Generated By: pfe.levisse

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Frozen

Site Name: (1013) Clinical Neuroscience Solutions Inc.

Subject Initials: ---

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

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

Adverse Event Report

1.	Category:	ADVERSE EVENT
2.	AE ID:	[14]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[URINARY TRACT INFECTION]
4.	Start Date Time:	Jan/13/2021 UNK:UNK
5.	Is the adverse event still ongoing?	NO End Date Time: Jan/22/2021 UNK:UNK
6.	Toxicity Grade:	1
7.	Is the adverse event serious? If Yes, NOTIFY PFIZER IMMEDIATELY. Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).	NO
8.	Is this adverse event the result of a study Medication Error? If Yes, record the type of medication error on the Medication Error Log.	NO
9.	Is this event related to study treatment:	NOT RELATED If Not Related to study treatment(s), this event is due to: OTHER If Other, specify: [UNKNOWN]
10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE
11.	Was a Concomitant Medication given?	YES

090177e196ae2f66\Final\Final On: 01-Apr-2021 03:42 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1013

Subject No: 10131176

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

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	[]

090177e196ae2f66\Final\Final On: 01-Apr-2021 03:42 (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: 10131176

Subject Initials: ---

Generated By: pfe.levissc

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

#	Category	Medication Error	Start Date	Is the medication error Still On going	Study Medication Errors Action	Form Instance
1.						Repeating Pages

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 17-Jul-2020 21:54

Site No: 1013

Subject No: 10131176

Generated By: pfe.levissc

Form: MEDICATION ERROR

Form Status: Not Started

Site Name: (1013) Clinical Neuroscience Solutions Inc.

Subject Initials: ---

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

[Back to Form](#)

Medication Error

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

090177e196ae2f66\Final\Final On: 01-Apr-2021 03:42 (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: 10131176

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

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: 10131176

Subject Initials: ---

Generated By: pfe.levissc

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

[Back to Form](#)

Concomitant Medications

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

090177e196ae2f66\Final\Final On: 01-Apr-2021 03:42 (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: 10131176

Subject Initials: ---

Generated By: pfe.levissc

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

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

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1013

Subject No: 10131176

Generated By: pfe.levissc

Form: CONCOMITANT MEDICATIONS - PROHIBITED

Form Status: Not Started

Site Name: (1013) Clinical Neuroscience Solutions Inc.

Subject Initials: ---

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

[Back to Form](#)

Concomitant Medications

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

090177e196ae2f66\Final\Final On: 01-Apr-2021 03:42 (GMT)

Header Text: c4591001

Visit: Logs

Form: RADIATION TREATMENT

Form Version: 22-Apr-2020 21:02

Site No: 1013

Site Name: (1013) Clinical Neuroscience Solutions Inc.

Subject No: 10131176

Subject Initials: ---

Generated By: pfe.levissc

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

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

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1013

Subject No: 10131176

Generated By: pfe.levissc

Form: RADIATION TREATMENT

Form Status: Not Started

Site Name: (1013) Clinical Neuroscience Solutions Inc.

Subject Initials: ---

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?	

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: 10131176

Subject Initials: ---

Generated By: pfe.levissc

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

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

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1013

Subject No: 10131176

Generated By: pfe.levissc

Form: TRANSFUSIONS

Form Status: Not Started

Site Name: (1013) Clinical Neuroscience Solutions Inc.

Subject Initials: ---

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

[Back to Form](#)

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

Header Text: c4591001

Visit: Unplanned Vaccination - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1013

Subject No: 10131176

Generated By: pfe.levisse

Form: DATE OF VISIT

Form Status: Not Started

Site Name: (1013) Clinical Neuroscience Solutions Inc.

Subject Initials: ---

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

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

Header Text: c4591001

Visit: 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: 10131176

Subject Initials: ---

Generated By: pfe.levissc

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

Vital Signs

1.	Date:	//
----	-------	----

Vital Signs Details

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

Header Text: c4591001

Visit: Unplanned Vaccination - Unscheduled

Form: VACCINATION

Form Version: 10-Dec-2020 02:26

Form Status: Not Started

Site No: 1013

Site Name: (1013) Clinical Neuroscience Solutions Inc.

Subject No: 10131176

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?	

090177e196ae2f66\Final\Final On: 01-Apr-2021 03:42 (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: 10131176

Subject Initials: ---

Generated By: pfe.levissc

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

Contact Outcome

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

Header Text: c4591001

Visit: 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: 10131176

Subject Initials: ---

Generated By: pfe.levissc

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

Contact Outcome

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

Header Text: c4591001

Visit: V201_SURVEIL_CONSENT - 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: 10131176

Subject Initials: ---

Generated By: pfe.levisse

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

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

Header Text: c4591001

Visit: V201_SURVEIL_CONSENT - Unscheduled **Form:** INFORMED CONSENT - ASYMPTOMATIC SURVEILLANCE

Form Version: 14-Jan-2021 02:29

Form Status: Not Started

Site No: 1013

Site Name: (1013) Clinical Neuroscience Solutions Inc.

Subject No: 10131176

Subject Initials: ---

Generated By: pfe.levissc

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

Informed Consent - Asymptomatic Surveillance

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

Header Text: c4591001

Visit: V201_SURVEIL_CONSENT - Unscheduled **Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1013

Site Name: (1013) Clinical Neuroscience Solutions Inc.

Subject No: 10131176

Subject Initials: ---

Generated By: pfe.levissc

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

Electronic Sample Tracking

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

Aliquot

Please enter barcode for each aliquot.

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

Header Text: c4591001

Visit: V201_SURVEIL_CONSENT - Unscheduled **Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1013

Site Name: (1013) Clinical Neuroscience Solutions Inc.

Subject No: 10131176

Subject Initials: ---

Generated By: pfe.levissc

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

Electronic Sample Tracking

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

Aliquot

Please enter barcode for each aliquot.

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

Header Text: c4591001

Visit: Potential ReVax Initial Contact -
Unscheduled

Form: DATE OF VISIT

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen, Verified

Site No: 1013

Site Name: (1013) Clinical Neuroscience Solutions Inc.

Subject No: 10131176

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	Dec/30/2020
2.	Erroneous Visit	

Header Text: c4591001

Visit: Potential ReVax Initial Contact -
Unscheduled

Form: FURTHER VACCINATION CONFIRMATION

Form Version: 10-Dec-2020 02:25

Form Status: Data Complete, Frozen

Site No: 1013

Site Name: (1013) Clinical Neuroscience Solutions Inc.

Subject No: 10131176

Subject Initials: ---

Generated By: pfe.levissc

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

[eCRF Audit Trail History](#)

Further Vaccination Confirmation

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

Header Text: c4591001

Visit: Disposition - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1013

Subject No: 10131176

Generated By: pfe.levisse

Form: TREATMENT UNBLINDED

Form Status: Data Complete, Frozen, Verified

Site Name: (1013) Clinical Neuroscience Solutions Inc.

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Treatment Unblinded

1.	Date Treatment Unblinded :	Dec/30/2020
2.	Primary Reason for Unblinding:	ASSESS ELIGIBILITY FOR ADDITIONAL VACCINATION

Header Text: c4591001

Visit: Disposition - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1013

Subject No: 10131176

Generated By: pfe.levissc

Form: WITHDRAWAL OF CONSENT

Form Status: Not Started

Site Name: (1013) Clinical Neuroscience Solutions Inc.

Subject Initials: ---

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

Withdrawal Of Consent

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

Header Text: c4591001

Visit: Disposition - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1013

Subject No: 10131176

Generated By: pfe.levissc

Form: DEATH DETAILS CODED

Form Status: Not Started

Site Name: (1013) Clinical Neuroscience Solutions Inc.

Subject Initials: ---

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

Death Details

1.	Date of Collection / Notification of Death:	//
----	---	----

Cause of Death

2.	Cause of Death Status:	
	Cause of Death:	[]

Header Text: c4591001

Visit: Subject Status - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1013

Subject No: 10131176

Generated By: pfe.levisse

Form: SUBJECT STATUS

Form Status: Data Complete, Verified

Site Name: (1013) Clinical Neuroscience Solutions Inc.

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Subject Status

1.	Subject Status	FOLLOW-UP
2.	Subject Status Date	Nov/4/2020

Header Text: c4591001

Visit: Investigator Signature - Unscheduled

Form Version: 22-Apr-2020 21:04

Site No: 1013

Subject No: 10131176

Generated By: pfe.levisse

Form: CASEBOOK SIGNATURE FORM

Form Status: Data Complete, Signed, Verified

Site Name: (1013) Clinical Neuroscience Solutions Inc.

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Casebook Signature Form

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

Header Text: c4591001

Visit: Investigator Signature - Unscheduled

Form: CASEBOOK SIGNATURE FORM

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Signed, Verified

Site No: 1013

Site Name: (1013) Clinical Neuroscience Solutions Inc.

Subject No: 10131176

Subject Initials: ---

Generated By: pfe.levisse

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

[Audit Trail](#)

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

- CRF_Sign

Name	Signature Meaning	Date	Type	Action
Michael Dever	Approved	Mar-10-2021 10:45:53 (UTC-05:00) Eastern Time (US & Canada)	BOOK	Signed

Affidavit:

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

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

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

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 30-Jul-2020 21:29

Site No: 1013

Subject No: 10131176

Generated By: pfe.levissc

Form: INCLUSION/EXCLUSION CRITERIA - Comments

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1013) Clinical Neuroscience Solutions Inc.

Subject Initials: ---

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

[Back to Form](#)

Item	Date	User	Comment
Form	Aug-13-2020 16:03:14 (UTC-05:00) Eastern Time (US & Canada)	Matthew Stephens (pfe.mstephens)	Not Applicable

090177e196ae2f66\Final\Final On: 01-Apr-2021 03:42 (GMT)

Header Text: c4591001
Visit: POT_COVID_ILL 1
Form Version: 10-Oct-2020 16:02
Site No: 1013
Subject No: 10131176
Generated By: pfe.levissc

Form: SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - Comments
Form Status: Data Complete, Frozen, Not Complete
Site Name: (1013) Clinical Neuroscience Solutions Inc.
Subject Initials: ---
Generated Time (GMT): 29-Mar-2021 04:21

[Back to Form](#)

Item	Date	User	Comment
2	Nov-13-2020 08:23:02 (UTC-05:00) Eastern Time (US & Canada)	Matthew Stephens (pfe mstephens)	Not Applicable

Header Text: c4591001
Visit: POT_COVID_ILL 1
Form Version: 10-Oct-2020 16:02
Site No: 1013
Subject No: 10131176
Generated By: pfe.levissc

Form: SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - Comments
Form Status: Data Complete, Frozen, Not Complete
Site Name: (1013) Clinical Neuroscience Solutions Inc.
Subject Initials: ---
Generated Time (GMT): 29-Mar-2021 04:21

[Back to Form](#)

Item	Date	User	Comment
3	Nov-13-2020 08:23:13 (UTC-05:00) Eastern Time (US & Canada)	Matthew Stephens (pfe mstephens)	Not Applicable

090177e196ae2f66\Final\Final On: 01-Apr-2021 03:42 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on **Form:** MICROBIOLOGY SPECIMEN - Comments
Nov/09/2020

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen, Verified

Site No: 1013

Site Name: (1013) Clinical Neuroscience Solutions Inc.

Subject No: 10131176

Subject Initials: ---

Generated By: pfe.levissc

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

[Back to Form](#)

Item	Date	User	Comment
Form	Nov-09-2020 13:04:25 (UTC-05:00) Eastern Time (US & Canada)	Matthew Stephens (pfe.mstephens)	Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on **Form:** MICROBIOLOGY SPECIMEN - Comments
Nov/09/2020

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen, Verified

Site No: 1013

Site Name: (1013) Clinical Neuroscience Solutions Inc.

Subject No: 10131176

Subject Initials: ---

Generated By: pfe.levissc

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

[Back to Form](#)

Item	Date	User	Comment
1	Nov-09-2020 13:04:25 (UTC-05:00) Eastern Time (US & Canada)	Matthew Stephens (pfe mstephens)	Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on **Form:** MICROBIOLOGY SPECIMEN - Comments
Nov/09/2020

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen, Verified

Site No: 1013

Site Name: (1013) Clinical Neuroscience Solutions Inc.

Subject No: 10131176

Subject Initials: ---

Generated By: pfe.levissc

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

[Back to Form](#)

Item	Date	User	Comment
2	Nov-09-2020 13:04:25 (UTC-05:00) Eastern Time (US & Canada)	Matthew Stephens (pfe mstephens)	Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on **Form:** MICROBIOLOGY SPECIMEN - Comments
Nov/09/2020

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen, Verified

Site No: 1013

Site Name: (1013) Clinical Neuroscience Solutions Inc.

Subject No: 10131176

Subject Initials: ---

Generated By: pfe.levissc

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

[Back to Form](#)

Item	Date	User	Comment
3	Nov-09-2020 13:04:25 (UTC-05:00) Eastern Time (US & Canada)	Matthew Stephens (pfe mstephens)	Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on **Form:** MICROBIOLOGY SPECIMEN - Comments
Nov/09/2020

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen, Verified

Site No: 1013

Site Name: (1013) Clinical Neuroscience Solutions Inc.

Subject No: 10131176

Subject Initials: ---

Generated By: pfe.levissc

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

[Back to Form](#)

Item	Date	User	Comment
4	Nov-09-2020 13:04:25 (UTC-05:00) Eastern Time (US & Canada)	Matthew Stephens (pfe mstephens)	Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on **Form:** MICROBIOLOGY SPECIMEN - Comments
Nov/09/2020

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen, Verified

Site No: 1013

Site Name: (1013) Clinical Neuroscience Solutions Inc.

Subject No: 10131176

Subject Initials: ---

Generated By: pfe.levissc

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

[Back to Form](#)

Item	Date	User	Comment
5	Nov-09-2020 13:04:25 (UTC-05:00) Eastern Time (US & Canada)	Matthew Stephens (pfe mstephens)	Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on **Form:** MICROBIOLOGY SPECIMEN - Comments
Nov/09/2020

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen, Verified

Site No: 1013

Site Name: (1013) Clinical Neuroscience Solutions Inc.

Subject No: 10131176

Subject Initials: ---

Generated By: pfe.levissc

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

[Back to Form](#)

Item	Date	User	Comment
6	Nov-09-2020 13:04:25 (UTC-05:00) Eastern Time (US & Canada)	Matthew Stephens (pfe mstephens)	Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on **Form:** MICROBIOLOGY SPECIMEN - Comments
Nov/09/2020

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen, Verified

Site No: 1013

Site Name: (1013) Clinical Neuroscience Solutions Inc.

Subject No: 10131176

Subject Initials: ---

Generated By: pfe.levissc

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

[Back to Form](#)

Item	Date	User	Comment
7	Nov-09-2020 13:04:25 (UTC-05:00) Eastern Time (US & Canada)	Matthew Stephens (pfe mstephens)	Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on **Form:** MICROBIOLOGY SPECIMEN - Comments
Nov/09/2020

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen, Verified

Site No: 1013

Site Name: (1013) Clinical Neuroscience Solutions Inc.

Subject No: 10131176

Subject Initials: ---

Generated By: pfe.levissc

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

[Back to Form](#)

Item	Date	User	Comment
8	Nov-09-2020 13:04:25 (UTC-05:00) Eastern Time (US & Canada)	Matthew Stephens (pfe mstephens)	Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on **Form:** MICROBIOLOGY SPECIMEN - Comments
Nov/09/2020

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen, Verified

Site No: 1013

Site Name: (1013) Clinical Neuroscience Solutions Inc.

Subject No: 10131176

Subject Initials: ---

Generated By: pfe.levissc

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

[Back to Form](#)

Item	Date	User	Comment
9	Nov-09-2020 13:04:25 (UTC-05:00) Eastern Time (US & Canada)	Matthew Stephens (pfe mstephens)	Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on **Form:** HEALTH CARE UTILIZATION - Comments
Nov/09/2020

Form Version: 10-Oct-2020 15:59

Form Status: Data Complete, Frozen, Verified

Site No: 1013

Site Name: (1013) Clinical Neuroscience Solutions Inc.

Subject No: 10131176

Subject Initials: ---

Generated By: pfe.levissc

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

[Back to Form](#)

Item	Date	User	Comment
Form	Nov-10-2020 11:05:56 (UTC-05:00) Eastern Time (US & Canada)	Scott Salmon (pfe.ssalmon)	NO COVID ILLNESS VISIT PERFORMED.
Form	Nov-09-2020 13:06:13 (UTC-05:00) Eastern Time (US & Canada)	Matthew Stephens (pfe.mstephens)	NO COVID ILLNESS VISIT PERFORMED. <hr/> Not Done

Header Text: c4591001

Visit: POT_COVID_ILL 1

Form Version: 10-Oct-2020 15:59

Site No: 1013

Subject No: 10131176

Generated By: pfe.levissc

Form: HEALTH CARE UTILIZATION - Comments

Form Status: Data Complete, Frozen, Verified

Site Name: (1013) Clinical Neuroscience Solutions Inc.

Subject Initials: ---

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

[Back to Form](#)

Item	Date	User	Comment
1.a	Nov-10-2020 11:05:56 (UTC-05:00) Eastern Time (US & Canada)	Scott Salmon (pfe.ssalmon)	NO COVID ILLNESS VISIT PERFORMED.
1.a	Nov-09-2020 13:06:13 (UTC-05:00) Eastern Time (US & Canada)	Matthew Stephens (pfe.mstephens)	NO COVID ILLNESS VISIT PERFORMED. Not Done

Header Text: c4591001

Visit: POT_COVID_ILL 1

Form Version: 10-Oct-2020 15:59

Site No: 1013

Subject No: 10131176

Generated By: pfe.levissc

Form: HEALTH CARE UTILIZATION - Comments

Form Status: Data Complete, Frozen, Verified

Site Name: (1013) Clinical Neuroscience Solutions Inc.

Subject Initials: ---

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

[Back to Form](#)

Item	Date	User	Comment
1.b	Nov-10-2020 11:05:56 (UTC-05:00) Eastern Time (US & Canada)	Scott Salmon (pfe.ssalmon)	NO COVID ILLNESS VISIT PERFORMED.
1.b	Nov-09-2020 13:06:13 (UTC-05:00) Eastern Time (US & Canada)	Matthew Stephens (pfe.mstephens)	NO COVID ILLNESS VISIT PERFORMED. Not Done

Header Text: c4591001

Visit: POT_COVID_ILL 1

Form Version: 10-Oct-2020 15:59

Site No: 1013

Subject No: 10131176

Generated By: pfe.levissc

Form: HEALTH CARE UTILIZATION - Comments

Form Status: Data Complete, Frozen, Verified

Site Name: (1013) Clinical Neuroscience Solutions Inc.

Subject Initials: ---

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

[Back to Form](#)

Item	Date	User	Comment
1.c	Nov-10-2020 11:05:56 (UTC-05:00) Eastern Time (US & Canada)	Scott Salmon (pfe.ssalmon)	NO COVID ILLNESS VISIT PERFORMED.
1.c	Nov-09-2020 13:06:13 (UTC-05:00) Eastern Time (US & Canada)	Matthew Stephens (pfe.mstephens)	NO COVID ILLNESS VISIT PERFORMED. Not Done

Header Text: c4591001

Visit: POT_COVID_ILL 1

Form Version: 10-Oct-2020 15:59

Site No: 1013

Subject No: 10131176

Generated By: pfe.levissc

Form: HEALTH CARE UTILIZATION - Comments

Form Status: Data Complete, Frozen, Verified

Site Name: (1013) Clinical Neuroscience Solutions Inc.

Subject Initials: ---

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

[Back to Form](#)

Item	Date	User	Comment
1.d	Nov-10-2020 11:05:56 (UTC-05:00) Eastern Time (US & Canada)	Scott Salmon (pfe.ssalmon)	NO COVID ILLNESS VISIT PERFORMED.
1.d	Nov-09-2020 13:06:13 (UTC-05:00) Eastern Time (US & Canada)	Matthew Stephens (pfe.mstephens)	NO COVID ILLNESS VISIT PERFORMED. Not Done

Header Text: c4591001

Visit: POT_COVID_ILL 1

Form Version: 10-Oct-2020 15:59

Site No: 1013

Subject No: 10131176

Generated By: pfe.levissc

Form: HEALTH CARE UTILIZATION - Comments

Form Status: Data Complete, Frozen, Verified

Site Name: (1013) Clinical Neuroscience Solutions Inc.

Subject Initials: ---

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

[Back to Form](#)

Item	Date	User	Comment
1.e	Nov-10-2020 11:05:56 (UTC-05:00) Eastern Time (US & Canada)	Scott Salmon (pfe.ssalmon)	NO COVID ILLNESS VISIT PERFORMED.
1.e	Nov-09-2020 13:06:13 (UTC-05:00) Eastern Time (US & Canada)	Matthew Stephens (pfe.mstephens)	NO COVID ILLNESS VISIT PERFORMED. Not Done

Header Text: c4591001

Visit: POT_COVID_ILL 1

Form Version: 10-Oct-2020 15:59

Site No: 1013

Subject No: 10131176

Generated By: pfe.levissc

Form: HEALTH CARE UTILIZATION - Comments

Form Status: Data Complete, Frozen, Verified

Site Name: (1013) Clinical Neuroscience Solutions Inc.

Subject Initials: ---

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

[Back to Form](#)

Item	Date	User	Comment
1.f	Nov-10-2020 11:05:56 (UTC-05:00) Eastern Time (US & Canada)	Scott Salmon (pfe.ssalmon)	NO COVID ILLNESS VISIT PERFORMED.
1.f	Nov-09-2020 13:06:13 (UTC-05:00) Eastern Time (US & Canada)	Matthew Stephens (pfe.mstephens)	NO COVID ILLNESS VISIT PERFORMED. Not Done

Header Text: c4591001

Visit: POT_COVID_ILL 1

Form Version: 10-Oct-2020 15:59

Site No: 1013

Subject No: 10131176

Generated By: pfe.levissc

Form: HEALTH CARE UTILIZATION - Comments

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Site Name: (1013) Clinical Neuroscience Solutions Inc.

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

[Back to Form](#)

Item	Date	User	Comment
2	Nov-10-2020 11:05:56 (UTC-05:00) Eastern Time (US & Canada)	Scott Salmon (pfe.ssalmon)	NO COVID ILLNESS VISIT PERFORMED.
2	Nov-09-2020 13:06:13 (UTC-05:00) Eastern Time (US & Canada)	Matthew Stephens (pfe.mstephens)	NO COVID ILLNESS VISIT PERFORMED. Not Done

Header Text: c4591001

Visit: POT_COVID_ILL 1

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Subject No: 10131176

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

[Back to Form](#)

Item	Date	User	Comment
3	Nov-10-2020 11:05:56 (UTC-05:00) Eastern Time (US & Canada)	Scott Salmon (pfe.ssalmon)	NO COVID ILLNESS VISIT PERFORMED.
3	Nov-09-2020 13:06:13 (UTC-05:00) Eastern Time (US & Canada)	Matthew Stephens (pfe.mstephens)	NO COVID ILLNESS VISIT PERFORMED. Not Done

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on **Form:** RESPIRATORY TREATMENT - Comments
Nov/09/2020

Form Version: 06-Jul-2020 21:53

Form Status: Data Complete, Frozen, Verified

Site No: 1013

Site Name: (1013) Clinical Neuroscience Solutions Inc.

Subject No: 10131176

Subject Initials: ---

Generated By: pfe.levissc

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

[Back to Form](#)

Item	Date	User	Comment
Form	Nov-09-2020 13:06:31 (UTC-05:00) Eastern Time (US & Canada)	Matthew Stephens (pfe.mstephens)	Not Applicable

090177e196ae2f66\Final\Final On: 01-Apr-2021 03:42 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on **Form:** RESPIRATORY TREATMENT - Comments
Nov/09/2020

Form Version: 06-Jul-2020 21:53

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Site No: 1013

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

[Back to Form](#)

Item	Date	User	Comment
1	Nov-09-2020 13:06:31 (UTC-05:00) Eastern Time (US & Canada)	Matthew Stephens (pfe mstephens)	Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on **Form:** RESPIRATORY TREATMENT - Comments
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[Back to Form](#)

Item	Date	User	Comment
2	Nov-09-2020 13:06:31 (UTC-05:00) Eastern Time (US & Canada)	Matthew Stephens (pfe mstephens)	Not Applicable

Header Text: c4591001

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[Back to Form](#)

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[Back to Form](#)

Item	Date	User	Comment
4	Nov-09-2020 13:06:31 (UTC-05:00) Eastern Time (US & Canada)	Matthew Stephens (pfe mstephens)	Not Applicable

Header Text: c4591001

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

[Back to Form](#)

Item	Date	User	Comment
5	Nov-09-2020 13:06:31 (UTC-05:00) Eastern Time (US & Canada)	Matthew Stephens (pfe mstephens)	Not Applicable

Header Text: c4591001

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

[Back to Form](#)

Item	Date	User	Comment
6	Nov-09-2020 13:06:31 (UTC-05:00) Eastern Time (US & Canada)	Matthew Stephens (pfe mstephens)	Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on **Form:** ILLNESS DETAILS - SEVERE - Comments
Nov/09/2020

Form Version: 17-Jul-2020 21:55

Form Status: Data Complete, Frozen, Verified

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Subject No: 10131176

Subject Initials: ---

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

[Back to Form](#)

Item	Date	User	Comment
Form	Nov-09-2020 13:06:59 (UTC-05:00) Eastern Time (US & Canada)	Matthew Stephens (pfe.mstephens)	Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on **Form:** ILLNESS DETAILS - SEVERE - Comments
Nov/09/2020

Form Version: 17-Jul-2020 21:55

Form Status: Data Complete, Frozen, Verified

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

[Back to Form](#)

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Header Text: c4591001

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[Back to Form](#)

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[Back to Form](#)

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[Back to Form](#)

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Form Version: 30-Jul-2020 21:27

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[Back to Form](#)

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Form	Nov-09-2020 13:07:18 (UTC-05:00) Eastern Time (US & Canada)	Matthew Stephens (pfe.mstephens)	Not Applicable

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[Back to Form](#)

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[Back to Form](#)

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[Back to Form](#)

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[Back to Form](#)

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[Back to Form](#)

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[Back to Form](#)

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[Back to Form](#)

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[Back to Form](#)

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

[Back to Form](#)

Item	Date	User	Comment
5.b	Nov-09-2020 13:07:18 (UTC-05:00) Eastern Time (US & Canada)	Matthew Stephens (pfe mstephens)	Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/09/2020

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

[Back to Form](#)

Item	Date	User	Comment
5.b	Nov-09-2020 13:07:18 (UTC-05:00) Eastern Time (US & Canada)	Matthew Stephens (pfe mstephens)	Not Applicable

Header Text: c4591001

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[Back to Form](#)

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5.b	Nov-09-2020 13:07:18 (UTC-05:00) Eastern Time (US & Canada)	Matthew Stephens (pfe mstephens)	Not Applicable

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[Back to Form](#)

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[Back to Form](#)

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[Back to Form](#)

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[Back to Form](#)

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[Back to Form](#)

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[Back to Form](#)

Item	Date	User	Comment
5.d	Nov-09-2020 13:07:18 (UTC-05:00) Eastern Time (US & Canada)	Matthew Stephens (pfe mstephens)	Not Applicable

Header Text: c4591001

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[Back to Form](#)

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[Back to Form](#)

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[Back to Form](#)

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[Back to Form](#)

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[Back to Form](#)

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[Back to Form](#)

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[Back to Form](#)

Item	Date	User	Comment
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Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/09/2020 **Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY - Comments

Form Version: 30-Jul-2020 21:27

Form Status: Data Complete, Frozen, Verified

Site No: 1013

Site Name: (1013) Clinical Neuroscience Solutions Inc.

Subject No: 10131176

Subject Initials: ---

Generated By: pfe.levissc

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

[Back to Form](#)

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[Back to Form](#)

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[Back to Form](#)

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[Back to Form](#)

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[Back to Form](#)

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[Back to Form](#)

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[Back to Form](#)

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[Back to Form](#)

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

[Back to Form](#)

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

[Back to Form](#)

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Subject Initials: ---

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

[Back to Form](#)

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Subject No: 10131176

Subject Initials: ---

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

[Back to Form](#)

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

[Back to Form](#)

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

[Back to Form](#)

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[Back to Form](#)

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[Back to Form](#)

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[Back to Form](#)

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

[Back to Form](#)

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Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/09/2020 **Form:** LOCAL LABORATORY DATA - REPEATING Hematology - Comments

Form Version: 30-Jul-2020 21:28

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

[Back to Form](#)

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[Back to Form](#)

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[Back to Form](#)

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

[Back to Form](#)

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[Back to Form](#)

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[Back to Form](#)

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[Back to Form](#)

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Subject Initials: ---

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

[Back to Form](#)

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Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/09/2020 **Form:** LOCAL LABORATORY DATA - REPEATING Hematology - Comments

Form Version: 30-Jul-2020 21:28

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

[Back to Form](#)

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[Back to Form](#)

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[Back to Form](#)

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[Back to Form](#)

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[Back to Form](#)

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[Back to Form](#)

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Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/09/2020 **Form:** LOCAL LABORATORY DATA - REPEATING Hematology - Comments

Form Version: 30-Jul-2020 21:28

Form Status: Data Complete, Frozen, Verified

Site No: 1013

Site Name: (1013) Clinical Neuroscience Solutions Inc.

Subject No: 10131176

Subject Initials: ---

Generated By: pfe.levissc

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

[Back to Form](#)

Item	Date	User	Comment
5.g	Nov-09-2020 13:07:34 (UTC-05:00) Eastern Time (US & Canada)	Matthew Stephens (pfe mstephens)	Not Applicable

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[Back to Form](#)

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[Back to Form](#)

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[Back to Form](#)

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[Back to Form](#)

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[Back to Form](#)

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

[Back to Form](#)

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[Back to Form](#)

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[Back to Form](#)

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[Back to Form](#)

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[Back to Form](#)

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[Back to Form](#)

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[Back to Form](#)

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Visit: POT_COVID_ILL 1 - Unscheduled Visit on **Form:** VITAL SIGNS - COVID - Comments
Nov/09/2020

Form Version: 30-Jul-2020 21:27

Form Status: Data Complete, Frozen, Verified

Site No: 1013

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Subject No: 10131176

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

[Back to Form](#)

Item	Date	User	Comment
Form	Nov-09-2020 13:07:52 (UTC-05:00) Eastern Time (US & Canada)	Matthew Stephens (pfe.mstephens)	Not Applicable

Header Text: c4591001

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Nov/09/2020

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[Back to Form](#)

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Nov/09/2020

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[Back to Form](#)

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[Back to Form](#)

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[Back to Form](#)

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[Back to Form](#)

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Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on **Form:** VITAL SIGNS - PULSE OX ROOM AIR - Comments
Nov/09/2020

Form Version: 30-Jul-2020 21:28

Form Status: Data Complete, Frozen, Verified

Site No: 1013

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Subject Initials: ---

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

[Back to Form](#)

Item	Date	User	Comment
Form	Nov-09-2020 13:08:07 (UTC-05:00) Eastern Time (US & Canada)	Matthew Stephens (pfe.mstephens)	Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on **Form:** VITAL SIGNS - PULSE OX ROOM AIR - Comments
Nov/09/2020

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[Back to Form](#)

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Nov/09/2020

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

[Back to Form](#)

Item	Date	User	Comment
2.a	Nov-09-2020 13:08:07 (UTC-05:00) Eastern Time (US & Canada)	Matthew Stephens (pfe mstephens)	Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on **Form:** OXYGENATION PARAMETERS - Comments
Nov/09/2020

Form Version: 06-Jul-2020 21:52

Form Status: Data Complete, Frozen, Verified

Site No: 1013

Site Name: (1013) Clinical Neuroscience Solutions Inc.

Subject No: 10131176

Subject Initials: ---

Generated By: pfe.levissc

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

[Back to Form](#)

Item	Date	User	Comment
Form	Nov-09-2020 13:08:21 (UTC-05:00) Eastern Time (US & Canada)	Matthew Stephens (pfe.mstephens)	Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on **Form:** OXYGENATION PARAMETERS - Comments
Nov/09/2020

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

[Back to Form](#)

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1	Nov-09-2020 13:08:21 (UTC-05:00) Eastern Time (US & Canada)	Matthew Stephens (pfe mstephens)	Not Applicable

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[Back to Form](#)

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[Back to Form](#)

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3	Nov-09-2020 13:08:21 (UTC-05:00) Eastern Time (US & Canada)	Matthew Stephens (pfe mstephens)	Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on **Form:** CONCOMITANT MEDICATIONS - VASOPRESSORS - Comments
Nov/09/2020

Form Version: 06-Jul-2020 21:55

Form Status: Data Complete, Frozen, Verified

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

[Back to Form](#)

Item	Date	User	Comment
Form	Nov-09-2020 13:08:36 (UTC-05:00) Eastern Time (US & Canada)	Matthew Stephens (pfe.mstephens)	Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on **Form:** CONCOMITANT MEDICATIONS - VASOPRESSORS - Comments
Nov/09/2020

Form Version: 06-Jul-2020 21:55

Form Status: Data Complete, Frozen, Verified

Site No: 1013

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Subject Initials: ---

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

[Back to Form](#)

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1	Nov-09-2020 13:08:36 (UTC-05:00) Eastern Time (US & Canada)	Matthew Stephens (pfe mstephens)	Not Applicable

Header Text: c4591001

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Nov/09/2020

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[Back to Form](#)

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Header Text: c4591001

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Nov/09/2020

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[Back to Form](#)

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Nov/09/2020

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

[Back to Form](#)

Item	Date	User	Comment
4	Nov-09-2020 13:08:36 (UTC-05:00) Eastern Time (US & Canada)	Matthew Stephens (pfe mstephens)	Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on **Form:** CONCOMITANT MEDICATIONS - VASOPRESSORS - Comments
Nov/09/2020

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Subject Initials: ---

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

[Back to Form](#)

Item	Date	User	Comment
5	Nov-09-2020 13:08:36 (UTC-05:00) Eastern Time (US & Canada)	Matthew Stephens (pfe mstephens)	Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on **Form:** CONCOMITANT MEDICATIONS - VASOPRESSORS - Comments
Nov/09/2020

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

[Back to Form](#)

Item	Date	User	Comment
6	Nov-09-2020 13:08:36 (UTC-05:00) Eastern Time (US & Canada)	Matthew Stephens (pfe mstephens)	Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on **Form:** IMAGING - Comments
Nov/09/2020

Form Version: 06-Jul-2020 21:53

Form Status: Data Complete, Frozen, Verified

Site No: 1013

Site Name: (1013) Clinical Neuroscience Solutions Inc.

Subject No: 10131176

Subject Initials: ---

Generated By: pfe.levissc

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

[Back to Form](#)

Item	Date	User	Comment
Form	Nov-09-2020 13:08:52 (UTC-05:00) Eastern Time (US & Canada)	Matthew Stephens (pfe.mstephens)	Not Applicable

090177e196ae2f66\Final\Final On: 01-Apr-2021 03:42 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on **Form:** IMAGING - Comments
Nov/09/2020

Form Version: 06-Jul-2020 21:53

Form Status: Data Complete, Frozen, Verified

Site No: 1013

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[Back to Form](#)

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[Back to Form](#)

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[Back to Form](#)

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

[Back to Form](#)

Item	Date	User	Comment
4	Nov-09-2020 13:08:52 (UTC-05:00) Eastern Time (US & Canada)	Matthew Stephens (pfe mstephens)	Not Applicable

Header Text: c4591001

Visit: Investigator Signature - Unscheduled

Form: CASEBOOK SIGNATURE FORM - Signature History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Signed, Verified

Site No: 1013

Site Name: (1013) Clinical Neuroscience Solutions Inc.

Subject No: 10131176

Subject Initials: ---

Generated By: pfe.levissc

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

[Back to Form](#)

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

- CRF_Sign

Name	Signature Meaning	Date	Type	Action
Michael Dever	Approved	Mar-10-2021 10:45:53 (UTC-05:00) Eastern Time (US & Canada)	BOOK	Signed

Affidavit:

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

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

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

Scott Salmon	N/A	Mar-08-2021 15:23:29 (UTC-05:00) Eastern Time (US & Canada)		Edit - All signatures invalidated
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Affidavit:

N/A

Michael Dever	Approved	Mar-04-2021 07:08:34 (UTC-05:00) Eastern Time (US & Canada)	BOOK	Signed
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Affidavit:

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

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

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

Scott Salmon	N/A	Feb-25-2021 10:04:53 (UTC-05:00) Eastern Time (US & Canada)		Edit - All signatures invalidated
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Affidavit:

N/A

Michael Dever	Approved	Jan-20-2021 13:59:13 (UTC-05:00) Eastern Time (US & Canada)	BOOK	Signed
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090177e196ae2f66\Final\Final On: 01-Apr-2021 03:42 (GMT)

Header Text: c4591001

Visit: Investigator Signature - Unscheduled

Form: CASEBOOK SIGNATURE FORM - Signature History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Signed, Verified

Site No: 1013

Site Name: (1013) Clinical Neuroscience Solutions Inc.

Subject No: 10131176

Subject Initials: ---

Generated By: pfe.levissc

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	Dec-31-2020 11:56:05 (UTC-05:00) Eastern Time (US & Canada)		Edit - All signatures invalidated
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Affidavit:

N/A

Michael Dever	Approved	Nov-14-2020 09:40:08 (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.

Rebecca Klipper	N/A	Nov-07-2020 09:12:26 (UTC-05:00) Eastern Time (US & Canada)		Edit - All signatures invalidated
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Affidavit:

N/A

Michael Dever	Approved	Nov-06-2020 16:08:45 (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.

090177e196ae2f66\Final\Final On: 01-Apr-2021 03:42 (GMT)

Header Text: c4591001

Visit: Investigator Signature - Unscheduled

Form: CASEBOOK SIGNATURE FORM - Signature History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Signed, Verified

Site No: 1013

Site Name: (1013) Clinical Neuroscience Solutions Inc.

Subject No: 10131176

Subject Initials: ---

Generated By: pfe.levissc

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

Matthew Stephens	N/A	Oct-07-2020 16:11:39 (UTC-05:00) Eastern Time (US & Canada)		Edit - All signatures invalidated
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Affidavit:
N/A

Michael Dever	Approved	Oct-05-2020 12:41:35 (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.

Matthew Stephens	N/A	Sep-15-2020 08:30:10 (UTC-05:00) Eastern Time (US & Canada)		Edit - All signatures invalidated
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Affidavit:
N/A

Michael Dever	Approved	Sep-15-2020 06:28:55 (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.

090177e196ae2f66\Final\Final On: 01-Apr-2021 03:42 (GMT)

Header Text: c4591001

Visit: COHORT_SELECTION

Form Version: 30-Jul-2020 21:29

Site No: 1013

Subject No: 10131176

Generated By: pfe.levisse

Form: COHORT SELECTION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1013) Clinical Neuroscience Solutions Inc.

Subject Initials: ---

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

[Back to Form](#)

1. Select appropriate response - Protocol version

Date	Location	User	Value	Reason
Aug-13-2020 16:02:42 (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-13-2020 16:02:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe mstephens)	Data Entry: STAGE 3 COHORTS	Initial Entry

Header Text: c4591001

Visit: COHORT_SELECTION

Form Version: 22-Apr-2020 21:02

Site No: 1013

Subject No: 10131176

Generated By: pfe.levissc

Form: MAIN INFORMED CONSENT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1013) Clinical Neuroscience Solutions Inc.

Subject Initials: ---

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

[Back to Form](#)

I. Consent Was:

Date	Location	User	Value	Reason
Aug-13-2020 16:02:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe mstephens)	Data Entry: OBTAINED Date Written Consent Obtained Aug/13/2020	Initial Entry

Header Text: c4591001

Visit: COHORT_SELECTION

Form Version: 06-Jul-2020 21:55

Site No: 1013

Subject No: 10131176

Generated By: pfe.levissc

Form: DEMOGRAPHY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1013) Clinical Neuroscience Solutions Inc.

Subject Initials: ---

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

[Back to Form](#)

1. Subject ID

Date	Location	User	Value	Reason
Sep-03-2020 06:52:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Ricell Ann Piojo (pfe.quitor)	Query 1: Closed	event added in Inform
Sep-02-2020 08:52:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe.mstephens)	Query 1: Answered	Changed data per query
Sep-02-2020 08:14:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Ricell Ann Piojo (pfe.quitor)	Query 1: Opened	SAE RECON:AER#2020339639 Abdominal adhesions(onset date:29Aug2020)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.
Aug-13-2020 16:02:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 10131176	Item copied from previous form

2. Birth Date:

Date	Location	User	Value	Reason
Aug-13-2020 16:02:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: (b) (6) 1944	Enrollment Entry

3. Sex:

Date	Location	User	Value	Reason
Aug-13-2020 16:02:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe.mstephens)	Data Entry: MALE	Initial Entry

4. Ethnicity:

Date	Location	User	Value	Reason
Aug-13-2020 16:02:58 (UTC-05:00) Eastern	ACV0PFEINFP6000	Matthew Stephens	Data Entry: NOT HISPANIC OR LATINO(A)	Initial Entry

090177e196ae2f66\Final\Final On: 01-Apr-2021 03:42 (GMT)

Header Text: c4591001

Visit: COHORT_SELECTION

Form Version: 06-Jul-2020 21:55

Site No: 1013

Subject No: 10131176

Generated By: pfe.levissc

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

Time (US & Canada)		(pfe mstephens)	OR OF SPANISH ORIGIN	
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5. Race: (Check X all that apply):

Date	Location	User	Value	Reason
Aug-13-2020 16:02:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe mstephens)	Data Entry: WHITE	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:02

Site No: 1013

Subject No: 10131176

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

[Back to Form](#)

I. Date of Visit

Date	Location	User	Value	Reason
Oct-08-2020 03:19:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Teena Patra (pfe.patrat02)	Query 1: Closed	Response satisfies query
Oct-07-2020 08:02:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe.mstephens)	Query 1: Answered	SUBJECT RESCHEDULED AND WILL BE HERE TODAY 10/07/2020 FOR VISIT 2.
Oct-07-2020 04:54:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Sonal K (pfe.ks66)	Query 1: Reissued:Opened	DM 1: Thanks for the response, however the forms under visit 2 are not entered yet, please review and update.
Oct-06-2020 12:57:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe.mstephens)	Query 1: Answered	SUBJECT WILL BE HERE TODAY 10/06/2020 FOR V2.
Oct-06-2020 11:55:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Behnaz Yousefzadeh- Khiabani (pfe.youseb01)	Query 1: Reissued:Opened	Please response to the query once action has been taken.
Oct-06-2020 08:06:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe.mstephens)	Query 1: Answered	SUBJECT HAS NOT RETURNED FOR VISIT 2.
Oct-06-2020 02:55:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Rajashekhhar Reddy (pfe.reddy51)	Query 1: Opened	DM: Details on visit 'V2VX2L' are missing. Kindly consider to update or else clarify. Thank you.
Aug-13-2020 16:03:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe.mstephens)	Data Entry: Aug/13/2020	Initial Entry

090177e196ae2f66\Final\Final On: 01-Apr-2021 03:42 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1013

Subject No: 10131176

Generated By: pfe.levissc

Form: DISPOSITION - SCREENING - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1013) Clinical Neuroscience Solutions Inc.

Subject Initials: ---

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

[Back to Form](#)

1. Date of Completion/Discontinuation/Death

Date	Location	User	Value	Reason
Aug-13-2020 16:03:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe mstephens)	Data Entry: Aug/13/2020	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Aug-13-2020 16:03:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SCREENING	Initial Entry

3. Status:

Date	Location	User	Value	Reason
Aug-13-2020 16:03:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe mstephens)	Data Entry: COMPLETED	Initial Entry

090177e196ae2f66\Final\Final On: 01-Apr-2021 03:42 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1013

Subject No: 10131176

Generated By: pfe.levissc

Form: GENERAL MEDICAL HISTORY - 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](#)

I.a

Date	Location	User	Value	Reason
Aug-13-2020 16:03:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 1 Medical History Term: HYPERTENSION Start Date: UNK/UNK/2015 Ongoing: YES	Initial Entry

I.a Line/MH Number:

Date	Location	User	Value	Reason
Aug-13-2020 16:03:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 1	Initial Entry

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

Date	Location	User	Value	Reason
Aug-13-2020 16:03:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe mstephens)	Data Entry: HYPERTENSION	Initial Entry

I.a Start Date:

Date	Location	User	Value	Reason
Aug-13-2020 16:03:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe mstephens)	Data Entry: UNK/UNK/2015	Initial Entry

I.a Ongoing:

Date	Location	User	Value	Reason
Aug-13-2020 16:03:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe mstephens)	Data Entry: YES	Initial Entry

I.b

Date	Location	User	Value	Reason
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090177e196ae2f66\Final\Final On: 01-Apr-2021 03:42 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1013

Subject No: 10131176

Generated By: pfe.levissc

Form: GENERAL MEDICAL HISTORY - 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

Aug-13-2020 16:03:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Num 2 ber: Medical History Term: HYPERCHOLEST EROLEMIA Start Date: UNK/UNK/2014 Ongoing: YES	Initial Entry
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I.b Line/MH Number:

Date	Location	User	Value	Reason
Aug-13-2020 16:03:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 2	Initial Entry

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

Date	Location	User	Value	Reason
Aug-13-2020 16:03:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe mstephens)	Data Entry: HYPERCHOLESTEROLEMIA	Initial Entry

I.b Start Date:

Date	Location	User	Value	Reason
Aug-13-2020 16:03:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe mstephens)	Data Entry: UNK/UNK/2014	Initial Entry

I.b Ongoing:

Date	Location	User	Value	Reason
Aug-13-2020 16:03:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe mstephens)	Data Entry: YES	Initial Entry

I.c

Date	Location	User	Value	Reason
Aug-13-2020 16:04:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 3	Initial Entry

090177e196ae2f66\Final\Final On: 01-Apr-2021 03:42 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1013

Subject No: 10131176

Generated By: pfe.levissc

Form: GENERAL MEDICAL HISTORY - 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

			Medical History Term: GASTROESOPHAGEAL REFLUX DISEASE Start Date: UNK/UNK/2005 Ongoing: YES	
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I.c Line/MH Number:

Date	Location	User	Value	Reason
Aug-13-2020 16:04:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 3	Initial Entry

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

Date	Location	User	Value	Reason
Aug-13-2020 16:04:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe mstephens)	Data Entry: GASTROESOPHAGEAL REFLUX DISEASE	Initial Entry

I.c Start Date:

Date	Location	User	Value	Reason
Aug-13-2020 16:04:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe mstephens)	Data Entry: UNK/UNK/2005	Initial Entry

I.c Ongoing:

Date	Location	User	Value	Reason
Aug-13-2020 16:04:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe mstephens)	Data Entry: YES	Initial Entry

I.d

Date	Location	User	Value	Reason
Aug-13-2020 16:04:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 4 Medical History Term: CONSTIPATION Start Date: UNK/UNK/2018 Ongoing: YES	Initial Entry

090177e196ae2f66\Final\Final On: 01-Apr-2021 03:42 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1013

Subject No: 10131176

Generated By: pfe.levissc

Form: GENERAL MEDICAL HISTORY - 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

I.d Line/MH Number:

Date	Location	User	Value	Reason
Aug-13-2020 16:04:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 4	Initial Entry

I.d Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:

Date	Location	User	Value	Reason
Aug-13-2020 16:04:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe mstephens)	Data Entry: CONSTIPATION	Initial Entry

I.d Start Date:

Date	Location	User	Value	Reason
Aug-13-2020 16:04:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe mstephens)	Data Entry: UNK/UNK/2018	Initial Entry

I.d Ongoing:

Date	Location	User	Value	Reason
Aug-13-2020 16:04:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe mstephens)	Data Entry: YES	Initial Entry

I.e

Date	Location	User	Value	Reason
Aug-13-2020 16:04:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 5 Medical History Term: SMALL BOWEL RESECTION Start Date: UNK/UNK/2016 Ongoing: NO End Date: UNK/UNK/2016	Initial Entry

090177e196ae2f66\Final\Final On: 01-Apr-2021 03:42 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1013

Subject No: 10131176

Generated By: pfe.levissc

Form: GENERAL MEDICAL HISTORY - 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

I.e Line/MH Number:

Date	Location	User	Value	Reason
Aug-13-2020 16:04:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 5	Initial Entry

I.e Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:

Date	Location	User	Value	Reason
Aug-13-2020 16:04:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe mstephens)	Data Entry: SMALL BOWEL RESECTION	Initial Entry

I.e Start Date:

Date	Location	User	Value	Reason
Aug-13-2020 16:04:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe mstephens)	Data Entry: UNK/UNK/2016	Initial Entry

I.e Ongoing:

Date	Location	User	Value	Reason
Aug-13-2020 16:04:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe mstephens)	Data Entry: NO End Date: UNK/UNK/2016	Initial Entry

I.f

Date	Location	User	Value	Reason
Aug-13-2020 16:05:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Nu 6 mber: Medical Hist SMALL BOWEL PE ory Term: RFORATION Start Date: UNK/UNK/2016 Ongoing: NO End Date: UNK/UNK/2016	Initial Entry

090177e196ae2f66\Final\Final On: 01-Apr-2021 03:42 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1013

Subject No: 10131176

Generated By: pfe.levissc

Form: GENERAL MEDICAL HISTORY - 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

I.f Line/MH Number:

Date	Location	User	Value	Reason
Aug-13-2020 16:05:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 6	Initial Entry

I.f Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:

Date	Location	User	Value	Reason
Aug-13-2020 16:05:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe mstephens)	Data Entry: SMALL BOWEL PERFORATION	Initial Entry

I.f Start Date:

Date	Location	User	Value	Reason
Aug-13-2020 16:05:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe mstephens)	Data Entry: UNK/UNK/2016	Initial Entry

I.f Ongoing:

Date	Location	User	Value	Reason
Aug-13-2020 16:05:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe mstephens)	Data Entry: NO End Date: UNK/UNK/2016	Initial Entry

I.g

Date	Location	User	Value	Reason
Aug-13-2020 16:06:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 7 Medical History Term: HIATAL HER NIA Start Date: UNK/UNK/200 5 Ongoing: YES	Initial Entry

090177e196ae2f66\Final\Final On: 01-Apr-2021 03:42 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1013

Subject No: 10131176

Generated By: pfe.levissc

Form: GENERAL MEDICAL HISTORY - 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

I.g Line/MH Number:

Date	Location	User	Value	Reason
Aug-13-2020 16:06:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 7	Initial Entry

I.g Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:

Date	Location	User	Value	Reason
Aug-13-2020 16:06:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe mstephens)	Data Entry: HIATAL HERNIA	Initial Entry

I.g Start Date:

Date	Location	User	Value	Reason
Aug-13-2020 16:06:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe mstephens)	Data Entry: UNK/UNK/2005	Initial Entry

I.g Ongoing:

Date	Location	User	Value	Reason
Aug-13-2020 16:06:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe mstephens)	Data Entry: YES	Initial Entry

I.h

Date	Location	User	Value	Reason
Aug-13-2020 16:06:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 8 Medical History Term: INGUINAL HERNIA Start Date: UNK/UNK/2016 Ongoing: NO End Date: UNK/UNK/2017	Initial Entry

090177e196ae2f66\Final\Final On: 01-Apr-2021 03:42 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1013

Subject No: 10131176

Generated By: pfe.levissc

Form: GENERAL MEDICAL HISTORY - 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

I.h Line/MH Number:

Date	Location	User	Value	Reason
Aug-13-2020 16:06:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 8	Initial Entry

I.h Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:

Date	Location	User	Value	Reason
Aug-13-2020 16:06:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe mstephens)	Data Entry: INGUINAL HERNIA	Initial Entry

I.h Start Date:

Date	Location	User	Value	Reason
Aug-13-2020 16:06:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe mstephens)	Data Entry: UNK/UNK/2016	Initial Entry

I.h Ongoing:

Date	Location	User	Value	Reason
Aug-13-2020 16:06:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe mstephens)	Data Entry: NO End Date: UNK/UNK/2017	Initial Entry

I.i

Date	Location	User	Value	Reason
Aug-13-2020 16:07:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Num 9 ber: Medical Histo INGUINAL HERNI ry Term: A REPAIR Start Date: UNK/UNK/2017 Ongoing: NO End Date: UNK/UNK/2017	Initial Entry

090177e196ae2f66\Final\Final On: 01-Apr-2021 03:42 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1013

Subject No: 10131176

Generated By: pfe.levissc

Form: GENERAL MEDICAL HISTORY - 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

I.i Line/MH Number:

Date	Location	User	Value	Reason
Aug-13-2020 16:07:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 9	Initial Entry

I.i Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:

Date	Location	User	Value	Reason
Aug-13-2020 16:07:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe mstephens)	Data Entry: INGUINAL HERNIA REPAIR	Initial Entry

I.i Start Date:

Date	Location	User	Value	Reason
Aug-13-2020 16:07:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe mstephens)	Data Entry: UNK/UNK/2017	Initial Entry

I.i Ongoing:

Date	Location	User	Value	Reason
Aug-13-2020 16:07:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe mstephens)	Data Entry: NO End Date: UNK/UNK/2017	Initial Entry

I.j

Date	Location	User	Value	Reason
Aug-13-2020 16:07:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Nu 10 mber: Medical Histo RIGHT KNEE REPL ry Term: ACEMENT Start Date: UNK/UNK/2009 Ongoing: NO End Date: UNK/UNK/2009	Initial Entry

090177e196ae2f66\Final\Final On: 01-Apr-2021 03:42 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1013

Subject No: 10131176

Generated By: pfe.levissc

Form: GENERAL MEDICAL HISTORY - 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

I.j Line/MH Number:

Date	Location	User	Value	Reason
Aug-13-2020 16:07:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 10	Initial Entry

I.j Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:

Date	Location	User	Value	Reason
Aug-13-2020 16:07:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe mstephens)	Data Entry: RIGHT KNEE REPLACEMENT	Initial Entry

I.j Start Date:

Date	Location	User	Value	Reason
Aug-13-2020 16:07:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe mstephens)	Data Entry: UNK/UNK/2009	Initial Entry

I.j Ongoing:

Date	Location	User	Value	Reason
Aug-13-2020 16:07:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe mstephens)	Data Entry: NO End Date: UNK/UNK/2009	Initial Entry

090177e196ae2f66\Final\Final On: 01-Apr-2021 03:42 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1013

Subject No: 10131176

Generated By: pfe.lewissc

Form: GENERAL MEDICAL HISTORY - 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](#)

<i>I.k</i>				
Date	Location	User	Value	Reason
Aug-13-2020 16:07:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 11 Medical History Term: LEFT KNEE REPLACEMENT Start Date: UNK/UNK/2000 Ongoing: NO End Date: UNK/UNK/2000	Initial Entry

<i>I.k Line/MH Number:</i>				
Date	Location	User	Value	Reason
Aug-13-2020 16:07:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 11	Initial Entry

<i>I.k Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:</i>				
Date	Location	User	Value	Reason
Aug-13-2020 16:07:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe.mstephens)	Data Entry: LEFT KNEE REPLACEMENT	Initial Entry

<i>I.k Start Date:</i>				
Date	Location	User	Value	Reason
Aug-13-2020 16:07:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe.mstephens)	Data Entry: UNK/UNK/2000	Initial Entry

<i>I.k Ongoing:</i>				
Date	Location	User	Value	Reason
Aug-13-2020 16:07:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe.mstephens)	Data Entry: NO End Date: UNK/UNK/2000	Initial Entry

090177e196ae2f66\Final\Final On: 01-Apr-2021 03:42 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1013

Subject No: 10131176

Generated By: pfe.levissc

Form: GENERAL MEDICAL HISTORY - 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

1.1				
Date	Location	User	Value	Reason
Aug-13-2020 16:07:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 12 Medical History Term: RIGHT KNEE OSTEOARTHRITIS Start Date: UNK/UNK/1990 Ongoing: NO End Date: UNK/UNK/2009	Initial Entry

1.1 Line/MH Number:				
Date	Location	User	Value	Reason
Aug-13-2020 16:07:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 12	Initial Entry

1.1 Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:				
Date	Location	User	Value	Reason
Aug-13-2020 16:07:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe.mstephens)	Data Entry: RIGHT KNEE OSTEOARTHRITIS	Initial Entry

1.1 Start Date:				
Date	Location	User	Value	Reason
Aug-13-2020 16:07:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe.mstephens)	Data Entry: UNK/UNK/1990	Initial Entry

1.1 Ongoing:				
Date	Location	User	Value	Reason
Aug-13-2020 16:07:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe.mstephens)	Data Entry: NO End Date: UNK/UNK/2009	Initial Entry

090177e196ae2f66\Final\Final On: 01-Apr-2021 03:42 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1013

Subject No: 10131176

Generated By: pfe.levissc

Form: GENERAL MEDICAL HISTORY - 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

<i>I.m</i>				
Date	Location	User	Value	Reason
Aug-13-2020 16:08:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 13 Medical History Term: LEFT KNEE OSTEOARTHRITIS Start Date: UNK/UNK/1990 Ongoing: NO End Date: UNK/UNK/2000	Initial Entry

<i>I.m Line/MH Number:</i>				
Date	Location	User	Value	Reason
Aug-13-2020 16:08:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 13	Initial Entry

<i>I.m Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:</i>				
Date	Location	User	Value	Reason
Aug-13-2020 16:08:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe.mstephens)	Data Entry: LEFT KNEE OSTEOARTHRITIS	Initial Entry

<i>I.m Start Date:</i>				
Date	Location	User	Value	Reason
Aug-13-2020 16:08:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe.mstephens)	Data Entry: UNK/UNK/1990	Initial Entry

<i>I.m Ongoing:</i>				
Date	Location	User	Value	Reason
Aug-13-2020 16:08:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe.mstephens)	Data Entry: NO End Date: UNK/UNK/2000	Initial Entry

090177e196ae2f66\Final\Final On: 01-Apr-2021 03:42 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 30-Jul-2020 21:28

Site No: 1013

Subject No: 10131176

Generated By: pfe.levissc

Form: VITAL SIGNS - BASELINE - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1013) Clinical Neuroscience Solutions Inc.

Subject Initials: ---

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

[Back to Form](#)

1. Date:

Date	Location	User	Value	Reason
Aug-13-2020 16:08:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe mstephens)	Data Entry: Aug/13/2020	Initial Entry

2. Weight:

Date	Location	User	Value	Reason
Aug-13-2020 16:08:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe mstephens)	Data Entry: 72.2	Initial Entry

3. Unit:

Date	Location	User	Value	Reason
Aug-13-2020 16:08:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe mstephens)	Data Entry: kg	Initial Entry

4. Height:

Date	Location	User	Value	Reason
Aug-13-2020 16:08:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe mstephens)	Data Entry: 174.9	Initial Entry

5. Unit:

Date	Location	User	Value	Reason
Aug-13-2020 16:08:49 (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-13-2020 16:08:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 23.6	Initial Entry

090177e196ae2f66\Final\Final On: 01-Apr-2021 03:42 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 30-Jul-2020 21:28

Site No: 1013

Subject No: 10131176

Generated By: pfe.levissc

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

7.a

Date	Location	User	Value	Reason
Aug-13-2020 16:08:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe mstephens)	Data Entry: Record Identifier:: 1 Temperature: 36.5 Temperature Unit: C Temperature Locat ORAL CAVI ion:: TY	Initial Entry

7.a Record Identifier:

Date	Location	User	Value	Reason
Aug-13-2020 16:08:49 (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-13-2020 16:08:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe mstephens)	Data Entry: 36.5	Initial Entry

7.a Unit:

Date	Location	User	Value	Reason
Aug-13-2020 16:08:49 (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-13-2020 16:08:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe mstephens)	Data Entry: ORAL CAVITY	Initial Entry

090177e196ae2f66\Final\Final On: 01-Apr-2021 03:42 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1013

Subject No: 10131176

Generated By: pfe.levissc

Form: RANDOMIZATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1013) Clinical Neuroscience Solutions Inc.

Subject Initials: ---

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

[Back to Form](#)

1. Randomization Date :

Date	Location	User	Value	Reason
Aug-13-2020 16:09:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe mstephens)	Data Entry: Aug/13/2020	Initial Entry

2. Randomization Number:

Date	Location	User	Value	Reason
Aug-13-2020 16:09:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe mstephens)	Data Entry: 227629	Initial Entry

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: 10131176

Subject Initials: ---

Generated By: pfe.levissc

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

[Back to Form](#)

1. Data Origin

Date	Location	User	Value	Reason
Aug-13-2020 16:09:14 (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-13-2020 16:09:14 (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-13-2020 17:51:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Aug-13-2020 16:09:14 (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.
Aug-13-2020 16:09:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe mstephens)	Data Entry: YES Date of Collection: Aug/13/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Aug-13-2020 17:51:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe mstephens)	Data Entry: Sample ID: BPYWBS	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
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090177e196ae2f66\Final\Final On: 01-Apr-2021 03:42 (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: 10131176

Subject Initials: ---

Generated By: pfe.levisse

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

Aug-13-2020 17:51:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe mstephens)	Data Entry: BPYWBS	Initial Entry
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5.b

Date	Location	User	Value	Reason
Aug-13-2020 17:51:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe mstephens)	Data Entry: Sample ID: BPYWBT	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Aug-13-2020 17:51:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe mstephens)	Data Entry: BPYWBT	Initial Entry

5.c

Date	Location	User	Value	Reason
Aug-13-2020 17:52:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe mstephens)	Data Entry: Sample ID: BPYWBV	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Aug-13-2020 17:52:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe mstephens)	Data Entry: BPYWBV	Initial Entry

5.d

Date	Location	User	Value	Reason
Aug-13-2020 17:52:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe mstephens)	Data Entry: Sample ID: BNWHH0	Initial Entry

090177e196ae2f66\Final\Final On: 01-Apr-2021 03:42 (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: 10131176

Subject Initials: ---

Generated By: pfe.levissc

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

5.d Sample ID

Date	Location	User	Value	Reason
Aug-13-2020 17:52:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe mstephens)	Data Entry: BNWHH0	Initial Entry

5.e

Date	Location	User	Value	Reason
Aug-13-2020 17:52:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe mstephens)	Data Entry: Sample ID: BNWHH1	Initial Entry

5.e Sample ID

Date	Location	User	Value	Reason
Aug-13-2020 17:52:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe mstephens)	Data Entry: BNWHH1	Initial Entry

090177e196ae2f66\Final\Final On: 01-Apr-2021 03:42 (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: 10131176

Subject Initials: ---

Generated By: pfe.levissc

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

[Back to Form](#)

1. Data Origin

Date	Location	User	Value	Reason
Aug-13-2020 16:09:21 (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-13-2020 16:09:21 (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-13-2020 17:52:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Aug-13-2020 16:09:21 (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.
Aug-13-2020 16:09:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe mstephens)	Data Entry: YES Date of Collection: Aug/13/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Aug-13-2020 17:52:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe mstephens)	Data Entry: Sample ID: BM8S47	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
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090177e196ae2f66\Final\Final On: 01-Apr-2021 03:42 (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: 10131176

Subject Initials: ---

Generated By: pfe.levissc

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

Aug-13-2020 17:52:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe mstephens)	Data Entry: BM8S47	Initial Entry
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Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:04

Site No: 1013

Subject No: 10131176

Generated By: pfe.levissc

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1013) Clinical Neuroscience Solutions Inc.

Subject Initials: ---

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

[Back to Form](#)

1. Was there a temporary delay of vaccination?

Date	Location	User	Value	Reason
Aug-13-2020 16:09:33 (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-13-2020 16:09:33 (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-13-2020 16:09:33 (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
Aug-13-2020 16:09:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe mstephens)	Data Entry: Aug/13/2020 12:35	Initial Entry

5. Anatomical Location:

Date	Location	User	Value	Reason
Aug-13-2020 16:09:33 (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-13-2020 16:09:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe mstephens)	Data Entry: LEFT	Initial Entry

090177e196ae2f66\Final\Final On: 01-Apr-2021 03:42 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:04

Site No: 1013

Subject No: 10131176

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

7. Route:

Date	Location	User	Value	Reason
Aug-13-2020 16:09:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INTRAMUSCULAR	Initial Entry

10. Timeframe Subject Was Observed

Date	Location	User	Value	Reason
Aug-13-2020 16:09:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: THE PROTOCOL SPECIFIED OBS ERVATION 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-13-2020 16:09:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe mstephens)	Data Entry: YES	Initial Entry

090177e196ae2f66\Final\Final On: 01-Apr-2021 03:42 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 06-Jul-2020 21:53

Site No: 1013

Subject No: 10131176

Generated By: pfe.levissc

Form: REACTOGENICITY DIARY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1013) Clinical Neuroscience Solutions Inc.

Subject Initials: ---

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

[Back to Form](#)

1. Select appropriate response - Reactogenicity diary collection

Date	Location	User	Value	Reason
Aug-13-2020 16:09:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe mstephens)	Data Entry: YES - REACTOGENICITY E-DI ARY COLLECTED FOR THIS S UBJECT	Initial Entry

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 1013

Subject No: 10131176

Generated By: pfe.levissc

Form: DATE OF VISIT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1013) Clinical Neuroscience Solutions Inc.

Subject Initials: ---

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

[Back to Form](#)

I. Date of Visit

Date	Location	User	Value	Reason
Oct-08-2020 08:47:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Pankaj Bhoir (pfe.bhoirp02)	Query 1: Closed	Response satisfies query
Oct-08-2020 07:56:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe.mstephens)	Query 1: Answered	CORRECT AS RECORDED. SUBJECT CAME IN YESTERDAY FOR VISIT 2 VACCINATION.
Oct-08-2020 02:48:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	PFE SDQ PROD (pfe.PFESDQ_PROD)	Query 1: Opened	PDQ: Date of visit at V2_VAX2_L is out of window for 32 days from V1_DAY1_VAX1_L Dose Date. Please verify and update. Else, confirm in query response appropriately. "[Iv04 SDQ=15923]"
Oct-07-2020 16:15:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe.mstephens)	Data Entry: Oct/7/202 0	Initial Entry

090177e196ae2f66\Final\Final On: 01-Apr-2021 03:42 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1013

Site Name: (1013) Clinical Neuroscience Solutions Inc.

Subject No: 10131176

Subject Initials: ---

Generated By: pfe.levissc

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

[Back to Form](#)

I. Were medications to treat fever/pain given on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Oct-26-2020 05:22:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Pramod Margaj (pfe margap03)	Query 1: Closed	Response satisfies query
Oct-13-2020 08:24:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Pramod Margaj (pfe margap03)	Query 1: Reissued:Candidate	Email to be sent for CRA Follow up
Oct-12-2020 08:26:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe mstephens)	Query 1: Answered	CRC IS AWARE AND WILL COMPLETE.
Oct-09-2020 14:09:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Cody Wei (pfe.weic20)	Query 1: Reissued:Opened	eDiary RQ2: Thanks for your response. Please consider raising DCF to correct the eDiary data. Thanks.
Oct-09-2020 09:32:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe mstephens)	Query 1: Answered	PER CRC SUBJECT DID NOT PHYSICALLY TAKE ANY MEDICATION. TREATMENT FOR FEVER/PAIN WAS ENTERED IN ERROR AS SUBJECT DID NOT HAVE ANY PAIN FOR FEVER LAST DAY OF E DIARY ENTRY.
Oct-09-2020 05:21:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Pramod Margaj (pfe margap03)	Query 1: Reissued:Opened	eDiary RQ1: Thanks for your response. Per diary records, FEVER/PAIN MED present on Last day 19-Aug-2020, however inform entered with 'No' for the same. Please

090177e196ae2f66\Final\Final On: 01-Apr-2021 03:42 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1013

Site Name: (1013) Clinical Neuroscience Solutions Inc.

Subject No: 10131176

Subject Initials: ---

Generated By: pfe.levissc

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

				consider entering 'Yes' in inform for the same with stop date as last date of diary.
Oct-08-2020 10:11:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe mstephens)	Query 1: Answered	PER CRC SUBJECT DID NOT TAKE ANY MEDICATION AND CANNOT DOCUMENT IF SUBJECT DID NOT TAKE ANY MEDICATION.
Oct-08-2020 05:10:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Pramod Margaj (pfe margap03)	Query 1: Opened	eDiary: Per diary records, FEVER/PAIN MED present on Last day however inform entered with 'No' for the same. Please verify and update. If diary entered in error, please enter stop date as last date of diary. Thanks.
Oct-07-2020 16:15:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe mstephens)	Data Entry: NO	Initial Entry

2.a

Date	Location	User	Value	Reason
Oct-07-2020 16:15:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe mstephens)	Data Entry: Symptom:: FE VE R Were fever or systemic symptoms present on the last day the Subject Diary was completed?: N O	Initial Entry

2.a Symptom:

Date	Location	User	Value	Reason
Oct-07-2020 16:15:29	ACV0PFEINFP6000	Matthew	Data Entry:	Initial Entry

Header Text: c4591001

Visit: V2_VAX2_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED
DATES - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1013

Site Name: (1013) Clinical Neuroscience Solutions Inc.

Subject No: 10131176

Subject Initials: ---

Generated By: pfe.lewissc

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

(UTC-05:00) Eastern Time (US & Canada)		Stephens (pfe mstephens)	FEVER	
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2.a Were fever or systemic symptoms present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Oct-07-2020 16:15:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe mstephens)	Data Entry: NO	Initial Entry

2.b

Date	Location	User	Value	Reason
Oct-07-2020 16:15:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe mstephens)	Data Entry: Symptom:: FA TIG UE Were fever or systemic symptoms present on the last day the Subject Diary was completed?: NO	Initial Entry

2.b Symptom:

Date	Location	User	Value	Reason
Oct-07-2020 16:15:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe mstephens)	Data Entry: FATIGUE	Initial Entry

2.b Were fever or systemic symptoms present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Oct-07-2020 16:15:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe mstephens)	Data Entry: NO	Initial Entry

2.c

Date	Location	User	Value	Reason
Oct-07-2020 16:15:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe mstephens)	Data Entry: Symptom:: HE AD AC HE	Initial Entry

090177e196ae2f66\Final\Final On: 01-Apr-2021 03:42 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1013

Site Name: (1013) Clinical Neuroscience Solutions Inc.

Subject No: 10131176

Subject Initials: ---

Generated By: pfe.levissc

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

			Were fever or systemic symptoms present on the last day the Subject Diary was completed?:	
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2.c Symptom:

Date	Location	User	Value	Reason
Oct-07-2020 16:15:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe mstephens)	Data Entry: HEADACHE	Initial Entry

2.c Were fever or systemic symptoms present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Oct-07-2020 16:15:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe mstephens)	Data Entry: NO	Initial Entry

2.d

Date	Location	User	Value	Reason
Oct-07-2020 16:15:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe mstephens)	Data Entry: Symptom:: CH IL LS Were fever or systemic symptoms present on the last day the Subject Diary was completed?: NO	Initial Entry

2.d Symptom:

Date	Location	User	Value	Reason
Oct-07-2020 16:15:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe mstephens)	Data Entry: CHILLS	Initial Entry

2.d Were fever or systemic symptoms present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Oct-07-2020 16:15:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe mstephens)	Data Entry: NO	Initial Entry

090177e196ae2f66\Final\Final On: 01-Apr-2021 03:42 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED
DATES - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1013

Site Name: (1013) Clinical Neuroscience Solutions Inc.

Subject No: 10131176

Subject Initials: ---

Generated By: pfe.levissc

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

2.e

Date	Location	User	Value	Reason
Oct-07-2020 16:15:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe mstephens)	Data Entry: Symptom:: VO MIT ING Were fever or systemic sy mptoms present on the last day the Subject Diary was completed?: NO	Initial Entry

2.e Symptom:

Date	Location	User	Value	Reason
Oct-07-2020 16:15:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe mstephens)	Data Entry: VOMITING	Initial Entry

2.e Were fever or systemic symptoms present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Oct-07-2020 16:15:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe mstephens)	Data Entry: NO	Initial Entry

2.f

Date	Location	User	Value	Reason
Oct-07-2020 16:15:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe mstephens)	Data Entry: Symptom:: DIA RR HE A Were fever or systemic sy mptoms present on the last day the Subject Diary was completed?: NO	Initial Entry

090177e196ae2f66\Final\Final On: 01-Apr-2021 03:42 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED
DATES - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1013

Site Name: (1013) Clinical Neuroscience Solutions Inc.

Subject No: 10131176

Subject Initials: ---

Generated By: pfe.levissc

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

2.f Symptom:

Date	Location	User	Value	Reason
Oct-07-2020 16:15:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe mstephens)	Data Entry: DIARRHEA	Initial Entry

2.f Were fever or systemic symptoms present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Oct-07-2020 16:15:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe mstephens)	Data Entry: NO	Initial Entry

2.g

Date	Location	User	Value	Reason
Oct-07-2020 16:15:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe mstephens)	Data Entry: Symptom:: NEW OR WORSE NED MUS CLE PAI N Were fever or systemi c symptoms present o n the last day the Sub ject Diary was compl eted?: NO	Initial Entry

2.g Symptom:

Date	Location	User	Value	Reason
Oct-07-2020 16:15:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe mstephens)	Data Entry: NEW OR WORSE NED MUSCLE PAIN	Initial Entry

2.g Were fever or systemic symptoms present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Oct-07-2020 16:15:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe mstephens)	Data Entry: NO	Initial Entry

2.h

090177e196ae2f66\Final\Final On: 01-Apr-2021 03:42 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1013

Site Name: (1013) Clinical Neuroscience Solutions Inc.

Subject No: 10131176

Subject Initials: ---

Generated By: pfe.levissc

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

Date	Location	User	Value	Reason
Oct-07-2020 16:15:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe mstephens)	Data Entry: Symptom:: NEW OR WORSE NED JOINT PAIN Were fever or systemic symptoms present on the last day the Subject Diary was completed?: NO	Initial Entry

2.h Symptom:

Date	Location	User	Value	Reason
Oct-07-2020 16:15:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe mstephens)	Data Entry: NEW OR WORSENEED JOINT PAIN	Initial Entry

2.h Were fever or systemic symptoms present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Oct-07-2020 16:15:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe mstephens)	Data Entry: NO	Initial Entry

3. Injection Site Location:

Date	Location	User	Value	Reason
Oct-07-2020 16:15:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: DELTOID MUSCLE	Initial Entry

4. Injection Site Body Side:

Date	Location	User	Value	Reason
Oct-07-2020 16:15:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe mstephens)	Data Entry: LEFT	Initial Entry

5.a

Date	Location	User	Value	Reason
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090177e196ae2f66\Final\Final On: 01-Apr-2021 03:42 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED
DATES - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1013

Site Name: (1013) Clinical Neuroscience Solutions Inc.

Subject No: 10131176

Subject Initials: ---

Generated By: pfe.levissc

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

Oct-07-2020 16:15:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe mstephens)	Data Entry: Injection Site Reaction:: RE DN ESS Were injection site reaction NO s present on the last day th e Subject Diary was comple ted?:	Initial Entry
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5.a Injection Site Reaction:

Date	Location	User	Value	Reason
Oct-07-2020 16:15:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe mstephens)	Data Entry: REDNESS	Initial Entry

5.a Were injection site reactions present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Oct-07-2020 16:15:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe mstephens)	Data Entry: NO	Initial Entry

5.b

Date	Location	User	Value	Reason
Oct-07-2020 16:15:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe mstephens)	Data Entry: Injection Site Reaction:: SWE LLI NG Were injection site reactio ns present on the last day t he Subject Diary was com pleted?: NO	Initial Entry

090177e196ae2f66\Final\Final On: 01-Apr-2021 03:42 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED
DATES - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1013

Site Name: (1013) Clinical Neuroscience Solutions Inc.

Subject No: 10131176

Subject Initials: ---

Generated By: pfe.levisse

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

5.b Injection Site Reaction:

Date	Location	User	Value	Reason
Oct-07-2020 16:15:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe mstephens)	Data Entry: SWELLING	Initial Entry

5.b Were injection site reactions present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Oct-07-2020 16:15:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe mstephens)	Data Entry: NO	Initial Entry

5.c

Date	Location	User	Value	Reason
Oct-07-2020 16:15:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe mstephens)	Data Entry: Injection Site Reaction: PAIN AT INJECTION SITE Were injection site reactions present on the last day the Subject Diary was completed?: NO	Initial Entry

5.c Injection Site Reaction:

Date	Location	User	Value	Reason
Oct-07-2020 16:15:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe mstephens)	Data Entry: PAIN AT INJECTION SITE	Initial Entry

5.c Were injection site reactions present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Oct-07-2020 16:15:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe mstephens)	Data Entry: NO	Initial Entry

090177e196ae2f66\Final\Final On: 01-Apr-2021 03:42 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 15-Sep-2020 21:54

Site No: 1013

Subject No: 10131176

Generated By: pfe.levissc

Form: VITAL SIGNS - TEMP - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1013) Clinical Neuroscience Solutions Inc.

Subject Initials: ---

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

[Back to Form](#)

1. Date:

Date	Location	User	Value	Reason
Oct-07-2020 16:15:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe mstephens)	Data Entry: Oct/7/2020	Initial Entry

2.a

Date	Location	User	Value	Reason
Oct-07-2020 16:15:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe mstephens)	Data Entry: Record Identifier:: 1 Temperature: 36.8 Temperature Unit: C Temperature Locat ORAL CAVI ion:: TY	Initial Entry

2.a Record Identifier:

Date	Location	User	Value	Reason
Oct-07-2020 16:15:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe mstephens)	Data Entry: 1	Initial Entry

2.a Temperature:

Date	Location	User	Value	Reason
Oct-07-2020 16:15:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe mstephens)	Data Entry: 36.8	Initial Entry

2.a Unit:

Date	Location	User	Value	Reason
Oct-07-2020 16:15:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe mstephens)	Data Entry: C	Initial Entry

2.a Temperature Location:

Date	Location	User	Value	Reason
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090177e196ae2f66\Final\Final On: 01-Apr-2021 03:42 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 15-Sep-2020 21:54

Site No: 1013

Subject No: 10131176

Generated By: pfe.levissc

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

Oct-07-2020 16:15:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe mstephens)	Data Entry: ORAL CAVITY	Initial Entry
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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: 10131176

Subject Initials: ---

Generated By: pfe.levissc

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

[Back to Form](#)

1. Data Origin

Date	Location	User	Value	Reason
Oct-07-2020 16:11:39 (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-07-2020 16:11:39 (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
Oct-07-2020 16:11:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Oct-07-2020 16:11:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Oct-07-2020 16:11:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe mstephens)	Data Entry: YES Date of Collection: Oct/7/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Oct-07-2020 16:11:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe mstephens)	Data Entry: Sample ID: BRG2V7	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
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090177e196ae2f66\Final\Final On: 01-Apr-2021 03:42 (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: 10131176

Subject Initials: ---

Generated By: pfe.levissc

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

Oct-07-2020 16:11:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe mstephens)	Data Entry: BRG2V7	Initial Entry
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Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1013

Subject No: 10131176

Generated By: pfe.levissc

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1013) Clinical Neuroscience Solutions Inc.

Subject Initials: ---

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

[Back to Form](#)

1. Was there a temporary delay of vaccination?

Date	Location	User	Value	Reason
Oct-07-2020 16:16:07 (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
Oct-07-2020 16:16:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: BLINDED THERAPY	Initial Entry

3. Formulation:

Date	Location	User	Value	Reason
Oct-07-2020 16:16:07 (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
Oct-07-2020 16:16:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe mstephens)	Data Entry: Oct/7/2020 15:10	Initial Entry

5. Anatomical Location:

Date	Location	User	Value	Reason
Oct-07-2020 16:16:07 (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
Oct-07-2020 16:16:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe mstephens)	Data Entry: LEFT	Initial Entry

090177e196ae2f66\Final\Final On: 01-Apr-2021 03:42 (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: 10131176

Subject Initials: ---

Generated By: pfe.levissc

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

7. Route:

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

10. Timeframe Subject Was Observed

Date	Location	User	Value	Reason
Oct-07-2020 16:16:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: THE PROTOCOL SPECIFIED OBS ERVATION PERIOD	Initial Entry

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

Date	Location	User	Value	Reason
Oct-07-2020 16:16:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe mstephens)	Data Entry: YES	Initial Entry

090177e196ae2f66\Final\Final On: 01-Apr-2021 03:42 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 1013

Subject No: 10131176

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

[Back to Form](#)

I. Date of Visit

Date	Location	User	Value	Reason
Nov-07-2020 12:35:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Gladys Noi (pfe noig)	Query 1: Closed	re-queried on symptoms resolved CRF
Nov-07-2020 09:18:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Rebecca Klipper (pfe rklipper)	Query 1: Answered	Subject inadvertently marked as yes
Nov-06-2020 03:40:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Pavan Prakash Naik (pfe naikp09)	Query 1: Opened	eDiary: Per eDiary Records, subject took Fever/Pain medication on the Last day (Day 7), however Inform CRF data is indicated 'No'. Please verify and update the data as appropriate. Else clarify. SDQ
Nov-04-2020 17:12:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Scott Salmon (pfe.ssalmon)	Data Entry: Nov/4/2020	Initial Entry

090177e196ae2f66\Final\Final On: 01-Apr-2021 03:42 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1013

Site Name: (1013) Clinical Neuroscience Solutions Inc.

Subject No: 10131176

Subject Initials: ---

Generated By: pfe.levissc

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

[Back to Form](#)

I. Were medications to treat fever/pain given on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Nov-09-2020 16:18:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Pamela Benne prod (pfe.bennep07)	Query 1: Closed	Response satisfies query
Nov-09-2020 13:14:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe.mstephens)	Query 1: Answered	CRC WILL COMPLETE DCF.
Nov-07-2020 12:35:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Gladys Noi (pfe.noig)	Query 1: Reissued:Opened	eDiary RQ: Thanks for response. Per CCG, If 'FEVER/PAIN MEDICATION in e-diary was entered in error on the last day, please consider updating 'Yes' in inform with stop date as last date of e-diary or consider raising DCF to correct eDiary data. Thanks
Nov-07-2020 09:19:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Rebecca Klipper (pfe.rklipper)	Query 1: Answered	Subject inadvertently marked as yes
Nov-06-2020 03:52:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Pramod Margaj (pfe.margap03)	Query 1: Opened	eDiary: Per diary records, FEVER/PAIN MED present on Last day however inform entered with 'No' for the same. Please verify and update. If diary entered in error, please enter stop date as last date of diary. Thanks.
Nov-04-2020 17:13:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Scott Salmon (pfe.ssalmon)	Data Entry: NO	Initial Entry

090177e196ae2f66\Final\Final On: 01-Apr-2021 03:42 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1013

Site Name: (1013) Clinical Neuroscience Solutions Inc.

Subject No: 10131176

Subject Initials: ---

Generated By: pfe.levisse

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

2.a

Date	Location	User	Value	Reason
Nov-04-2020 17:13:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Scott Salmon (pfe.ssalmon)	Data Entry: Symptom:: FE VE R Were fever or systemic symptoms present on the last day the Subject Diary was completed?: NO	Initial Entry

2.a Symptom:

Date	Location	User	Value	Reason
Nov-04-2020 17:13:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Scott Salmon (pfe.ssalmon)	Data Entry: FEVER	Initial Entry

2.a Were fever or systemic symptoms present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Nov-04-2020 17:13:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Scott Salmon (pfe.ssalmon)	Data Entry: NO	Initial Entry

2.b

Date	Location	User	Value	Reason
Nov-04-2020 17:13:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Scott Salmon (pfe.ssalmon)	Data Entry: Symptom:: FAT IG UE Were fever or systemic symptoms present on the last day the Subject Diary was completed?: NO	Initial Entry

090177e196ae2f66\Final\Final On: 01-Apr-2021 03:42 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1013

Site Name: (1013) Clinical Neuroscience Solutions Inc.

Subject No: 10131176

Subject Initials: ---

Generated By: pfe.levissc

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

2.b Symptom:

Date	Location	User	Value	Reason
Nov-04-2020 17:13:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Scott Salmon (pfe.ssalmon)	Data Entry: FATIGUE	Initial Entry

2.b Were fever or systemic symptoms present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Nov-04-2020 17:13:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Scott Salmon (pfe.ssalmon)	Data Entry: NO	Initial Entry

2.c

Date	Location	User	Value	Reason
Nov-04-2020 17:13:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Scott Salmon (pfe.ssalmon)	Data Entry: Symptom:: HEA DA CHE Were fever or systemic sym NO ptoms present on the last da y the Subject Diary was co mpleted?:	Initial Entry

2.c Symptom:

Date	Location	User	Value	Reason
Nov-04-2020 17:13:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Scott Salmon (pfe.ssalmon)	Data Entry: HEADACHE	Initial Entry

2.c Were fever or systemic symptoms present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Nov-04-2020 17:13:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Scott Salmon (pfe.ssalmon)	Data Entry: NO	Initial Entry

2.d

Date	Location	User	Value	Reason
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090177e196ae2f66\Final\Final On: 01-Apr-2021 03:42 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1013

Site Name: (1013) Clinical Neuroscience Solutions Inc.

Subject No: 10131176

Subject Initials: ---

Generated By: pfe.levissc

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

Nov-04-2020 17:13:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Scott Salmon (pfe.ssalmon)	Data Entry: Symptom:: CH ILL S Were fever or systemic symptoms present on the last day the Subject Diary was completed?: NO	Initial Entry
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2.d Symptom:

Date	Location	User	Value	Reason
Nov-04-2020 17:13:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Scott Salmon (pfe.ssalmon)	Data Entry: CHILLS	Initial Entry

2.d Were fever or systemic symptoms present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Nov-04-2020 17:13:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Scott Salmon (pfe.ssalmon)	Data Entry: NO	Initial Entry

2.e

Date	Location	User	Value	Reason
Nov-04-2020 17:13:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Scott Salmon (pfe.ssalmon)	Data Entry: Symptom:: VO MIT ING Were fever or systemic symptoms present on the last day the Subject Diary was completed?: NO	Initial Entry

090177e196ae2f66\Final\Final On: 01-Apr-2021 03:42 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1013

Site Name: (1013) Clinical Neuroscience Solutions Inc.

Subject No: 10131176

Subject Initials: ---

Generated By: pfe.levisse

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

2.e Symptom:

Date	Location	User	Value	Reason
Nov-04-2020 17:13:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Scott Salmon (pfe.ssalmon)	Data Entry: VOMITING	Initial Entry

2.e Were fever or systemic symptoms present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Nov-04-2020 17:13:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Scott Salmon (pfe.ssalmon)	Data Entry: NO	Initial Entry

2.f

Date	Location	User	Value	Reason
Nov-04-2020 17:13:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Scott Salmon (pfe.ssalmon)	Data Entry: Symptom:: DIA RR HE A Were fever or systemic symptoms present on the last day the Subject Diary was completed?: NO	Initial Entry

2.f Symptom:

Date	Location	User	Value	Reason
Nov-04-2020 17:13:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Scott Salmon (pfe.ssalmon)	Data Entry: DIARRHEA	Initial Entry

2.f Were fever or systemic symptoms present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Nov-04-2020 17:13:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Scott Salmon (pfe.ssalmon)	Data Entry: NO	Initial Entry

2.g

Date	Location	User	Value	Reason
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090177e196ae2f66\Final\Final On: 01-Apr-2021 03:42 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1013

Site Name: (1013) Clinical Neuroscience Solutions Inc.

Subject No: 10131176

Subject Initials: ---

Generated By: pfe.levisse

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

Nov-04-2020 17:13:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Scott Salmon (pfe.ssalmon)	Data Entry: Symptom:: NEW OR WORSE ED MUSC LE PAIN Were fever or systemi NO c symptoms present o n the last day the Subj ect Diary was complet ed?:	Initial Entry
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2.g Symptom:

Date	Location	User	Value	Reason
Nov-04-2020 17:13:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Scott Salmon (pfe.ssalmon)	Data Entry: NEW OR WORSE NED MUSCLE P AIN	Initial Entry

2.g Were fever or systemic symptoms present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Nov-04-2020 17:13:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Scott Salmon (pfe.ssalmon)	Data Entry: NO	Initial Entry

2.h

Date	Location	User	Value	Reason
Nov-04-2020 17:13:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Scott Salmon (pfe.ssalmon)	Data Entry: Symptom:: NEW OR WORSE NED JOIN T PAIN Were fever or systemic NO symptoms present on t he last day the Subject Diary was completed?:	Initial Entry

090177e196ae2f66\Final\Final On: 01-Apr-2021 03:42 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED
DATES - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1013

Site Name: (1013) Clinical Neuroscience Solutions Inc.

Subject No: 10131176

Subject Initials: ---

Generated By: pfe.levissc

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

2.h Symptom:

Date	Location	User	Value	Reason
Nov-04-2020 17:13:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Scott Salmon (pfe.ssalmon)	Data Entry: NEW OR WORSENE D JOINT PAI N	Initial Entry

2.h Were fever or systemic symptoms present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Nov-04-2020 17:13:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Scott Salmon (pfe.ssalmon)	Data Entry: NO	Initial Entry

3. Injection Site Location:

Date	Location	User	Value	Reason
Nov-04-2020 17:13:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: DELTOID MUSCLE	Initial Entry

4. Injection Site Body Side:

Date	Location	User	Value	Reason
Nov-04-2020 17:13:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Scott Salmon (pfe.ssalmon)	Data Entry: LEFT	Initial Entry

5.a

Date	Location	User	Value	Reason
Nov-04-2020 17:13:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Scott Salmon (pfe.ssalmon)	Data Entry: Injection Site Reaction:: RE DN ESS Were injection site reactions NO present on the last day the S ubject Diary was completed ?:	Initial Entry

5.a Injection Site Reaction:

Date	Location	User	Value	Reason
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090177e196ae2f66\Final\Final On: 01-Apr-2021 03:42 (GMT)

Header Text: c4591001**Visit:** V3_MONTH1_POSTVAX2_L**Form:** VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History**Form Version:** 30-Jul-2020 21:30**Form Status:** Data Complete, Locked, Frozen, Verified**Site No:** 1013**Site Name:** (1013) Clinical Neuroscience Solutions Inc.**Subject No:** 10131176**Subject Initials:** ---**Generated By:** pfe.levissc**Generated Time (GMT):** 29-Mar-2021 04:21

Nov-04-2020 17:13:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Scott Salmon (pfe.ssalmon)	Data Entry: REDNESS	Initial Entry
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5.a Were injection site reactions present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Nov-04-2020 17:13:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Scott Salmon (pfe.ssalmon)	Data Entry: NO	Initial Entry

5.b

Date	Location	User	Value	Reason
Nov-04-2020 17:13:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Scott Salmon (pfe.ssalmon)	Data Entry: Injection Site Reaction:: SWE LLI NG Were injection site reaction NO s present on the last day the Subject Diary was complete d?:	Initial Entry

5.b Injection Site Reaction:

Date	Location	User	Value	Reason
Nov-04-2020 17:13:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Scott Salmon (pfe.ssalmon)	Data Entry: SWELLING	Initial Entry

5.b Were injection site reactions present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Nov-04-2020 17:13:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Scott Salmon (pfe.ssalmon)	Data Entry: NO	Initial Entry

5.c

Date	Location	User	Value	Reason
Nov-04-2020 17:13:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Scott Salmon (pfe.ssalmon)	Data Entry: Injection Site Reaction:: PAIN A T INJE CTION	Initial Entry

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1013

Site Name: (1013) Clinical Neuroscience Solutions Inc.

Subject No: 10131176

Subject Initials: ---

Generated By: pfe.lewissc

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

			SITE	
			Were injection site reactions present on the last day the Subject Diary was completed?:	NO

5.c Injection Site Reaction:

Date	Location	User	Value	Reason
Nov-04-2020 17:13:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Scott Salmon (pfe.ssalmon)	Data Entry: PAIN AT INJECTION SITE	Initial Entry

5.c Were injection site reactions present on the last day the Subject Diary was completed?:

Date	Location	User	Value	Reason
Nov-04-2020 17:13:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Scott Salmon (pfe.ssalmon)	Data Entry: NO	Initial Entry

090177e196ae2f66\Final\Final On: 01-Apr-2021 03:42 (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: 10131176

Subject Initials: ---

Generated By: pfe.levissc

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

[Back to Form](#)

1. Data Origin

Date	Location	User	Value	Reason
Nov-04-2020 17:13:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Nov-04-2020 17:13:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SERUM	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Nov-04-2020 17:19:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Nov-04-2020 17:13:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Nov-04-2020 17:13:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Scott Salmon (pfe.ssalmon)	Data Entry: YES Date of Collection: Nov/4/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Nov-04-2020 17:19:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe.mstephens)	Data Entry: Sample ID: BS0J7D	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
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090177e196ae2f66\Final\Final On: 01-Apr-2021 03:42 (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: 10131176

Subject Initials: ---

Generated By: pfe.levisse

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

Nov-04-2020 17:19:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe mstephens)	Data Entry: BS0J7D	Initial Entry
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5.b

Date	Location	User	Value	Reason
Nov-04-2020 17:19:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe mstephens)	Data Entry: Sample ID: BS0J7F	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Nov-04-2020 17:19:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe mstephens)	Data Entry: BS0J7F	Initial Entry

5.c

Date	Location	User	Value	Reason
Nov-04-2020 17:19:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe mstephens)	Data Entry: Sample ID: BRHVB9	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Nov-04-2020 17:19:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe mstephens)	Data Entry: BRHVB9	Initial Entry

5.d

Date	Location	User	Value	Reason
Nov-04-2020 17:20:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe mstephens)	Data Entry: Sample ID: BRHVBB	Initial Entry

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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: 10131176

Subject Initials: ---

Generated By: pfe.levissc

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

5.d Sample ID

Date	Location	User	Value	Reason
Nov-04-2020 17:20:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe mstephens)	Data Entry: BRHVBB	Initial Entry

5.e

Date	Location	User	Value	Reason
Nov-04-2020 17:20:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe mstephens)	Data Entry: Sample ID: BRHVBC	Initial Entry

5.e Sample ID

Date	Location	User	Value	Reason
Nov-04-2020 17:20:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe mstephens)	Data Entry: BRHVBC	Initial Entry

090177e196ae2f66\Final\Final On: 01-Apr-2021 03:42 (GMT)

Header Text: c4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit on **Form:** DATE OF VISIT - ILLNESS ONSET - eCRF Audit Trail History
Nov/09/2020**Form Version:** 22-Apr-2020 21:03**Form Status:** Data Complete, Frozen, Verified**Site No:** 1013**Site Name:** (1013) Clinical Neuroscience Solutions Inc.**Subject No:** 10131176**Subject Initials:** ---**Generated By:** pfe.levisse**Generated Time (GMT):** 29-Mar-2021 04:21[Back to Form](#)**I. Date of Visit**

Date	Location	User	Value	Reason
Nov-10-2020 00:47:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Annam Sireesha (pfe.sireea)	Query 1: Deleted	Deleted as per comment on SWAB forms,updated PD tracker
Nov-09-2020 13:02:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Deleted	Close Auto Query
Nov-09-2020 13:02:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Candidate	Date of Visit is completed but Date of Assessment in the Signs and Symptoms form is missing. Please review and update as appropriate.
Nov-09-2020 13:02:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	Date of Visit is completed but Date of Collection in both Nasal Swab Self and Nasal Swab are missing. Please review and update as appropriate.
Nov-09-2020 13:02:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe.mstephens)	Data Entry: Nov/9/2020	Initial Entry

3. COVID-19 Illness Visit:

Date	Location	User	Value	Reason
Nov-09-2020 13:02:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: COVID_A	Initial Entry

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/09/2020 **Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF Audit Trail History

Form Version: 10-Oct-2020 16:02

Form Status: Data Complete, Frozen, Not Complete

Site No: 1013

Site Name: (1013) Clinical Neuroscience Solutions Inc.

Subject No: 10131176

Subject Initials: ---

Generated By: pfe.levissc

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

[Back to Form](#)

I. Date of Assessment:

Date	Location	User	Value	Reason
Nov-13-2020 12:32:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Pamela Benne prod (pfe.bennep07)	Query 4: Closed	Response satisfies query
Nov-13-2020 08:23:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe.mstephens)	Query 4: Answered	page updated. per crc no symptoms to report.
Nov-13-2020 08:22:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 4: Opened	All symptoms are reported as Not Present and there is no Other Symptom reported. Please review and update as appropriate.
Nov-13-2020 08:22:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 3: Closed	Close Auto Query
Nov-13-2020 08:22:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 3: Opened	All symptoms are reported as Not Present and there is no Other Symptom reported. Please review and update as appropriate.
Nov-09-2020 13:04:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Closed	Close Auto Query
Nov-09-2020 13:04:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe.mstephens)	Data Entry: Nov/9/2020	Transcription Error
Nov-09-2020 13:03:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Nov-09-2020 13:02:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Opened	Date of assessment is not same as Date Visit. Please check and correct.

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Header Text: c4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit on
Nov/09/2020**Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF
Audit Trail History**Form Version:** 10-Oct-2020 16:02**Form Status:** Data Complete, Frozen, Not Complete**Site No:** 1013**Site Name:** (1013) Clinical Neuroscience Solutions Inc.**Subject No:** 10131176**Subject Initials:** ---**Generated By:** pfe.levissc**Generated Time (GMT):** 29-Mar-2021 04:21

Nov-09-2020 13:02:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	All symptoms are reported as Not Present and there is no Other Symptom reported. Please review and update as appropriate.
Nov-09-2020 13:02:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe.mstephens)	Data Entry: Sep/9/2020	Initial Entry

2. Date of First Symptom Started:

Date	Location	User	Value	Reason
Nov-13-2020 14:53:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Salim Bouguermouh (pfe.bogus)	Query 1: Closed	Response satisfies query
Nov-13-2020 13:43:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe.mstephens)	Query 1: Answered	PER CRC SUBJECT DID NOT HAVE SYMPTOMS.
Nov-13-2020 13:36:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Salim Bouguermouh (pfe.bogus)	Query 1: Reissued:Opened	Clin: Please could you confirm that the subject did not experience shortness of breath, fever, or cough.
Nov-13-2020 08:23:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe.mstephens)	Data Entry: Not Applicable	Initial Entry
Nov-13-2020 08:22:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Transcription Error
Nov-13-2020 08:22:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe.mstephens)	Data Entry:	Transcription Error
Nov-12-2020 18:39:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Salim Bouguermouh (pfe.bogus)	Query 1: Opened	Clin: Please any symptoms associated with "Aspiration Pneumonia" should be recorded on the SIGNS AND SYMPTOMS OF

Header Text: c4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit on Nov/09/2020 **Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF Audit Trail History**Form Version:** 10-Oct-2020 16:02**Form Status:** Data Complete, Frozen, Not Complete**Site No:** 1013**Site Name:** (1013) Clinical Neuroscience Solutions Inc.**Subject No:** 10131176**Subject Initials:** ---**Generated By:** pfe.levissc**Generated Time (GMT):** 29-Mar-2021 04:21

				POTENTIAL COVID-19 CRF form (i.e. shortness of breath, fever, cough...)
Nov-09-2020 13:02:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe.mstephens)	Data Entry: Aug/30/2020	Initial Entry

3. Symptoms Ongoing?

Date	Location	User	Value	Reason
Nov-13-2020 08:23:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe.mstephens)	Data Entry: Not Applicable	Initial Entry
Nov-13-2020 08:22:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe.mstephens)	Data Entry:	Transcription Error
Nov-09-2020 13:02:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe.mstephens)	Data Entry: NO Date of Last Symptom Resolved: Sep/5/2020	Initial Entry

4.a

Date	Location	User	Value	Reason
Nov-09-2020 13:02:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe.mstephens)	Data Entry: Symptoms: FEVER Symptom Present: NO	Initial Entry

4.a Symptoms:

Date	Location	User	Value	Reason
Nov-09-2020 13:02:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe.mstephens)	Data Entry: FEVER	Initial Entry

4.a Was symptom present?

Date	Location	User	Value	Reason
Nov-09-2020 13:02:50 (UTC-05:00) Eastern	ACV0PFEINFP6000	Matthew Stephens	Data Entry: NO	Initial Entry

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/09/2020 Form: SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF Audit Trail History

Form Version: 10-Oct-2020 16:02

Form Status: Data Complete, Frozen, Not Complete

Site No: 1013

Site Name: (1013) Clinical Neuroscience Solutions Inc.

Subject No: 10131176

Subject Initials: ---

Generated By: pfe.levisse

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

Time (US & Canada)		(pfe mstephens)	
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4.b

Date	Location	User	Value	Reason
Nov-09-2020 13:02:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe mstephens)	Data Entry: Symptoms: NEW OR INCREASED COUGH Symptom Present: NO	Initial Entry

4.b Symptoms:

Date	Location	User	Value	Reason
Nov-09-2020 13:02:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe mstephens)	Data Entry: NEW OR INCREASED COUGH	Initial Entry

4.b Was symptom present?

Date	Location	User	Value	Reason
Nov-09-2020 13:02:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe mstephens)	Data Entry: NO	Initial Entry

4.c

Date	Location	User	Value	Reason
Nov-09-2020 13:02:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe mstephens)	Data Entry: Symptom Present: NEW OR INCREASED SHORTNESS OF BREATH Symptom Present: NO	Initial Entry

090177e196ae2f66\Final\Final On: 01-Apr-2021 03:42 (GMT)

Header Text: c4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit on Nov/09/2020 **Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF Audit Trail History**Form Version:** 10-Oct-2020 16:02**Form Status:** Data Complete, Frozen, Not Complete**Site No:** 1013**Site Name:** (1013) Clinical Neuroscience Solutions Inc.**Subject No:** 10131176**Subject Initials:** ---**Generated By:** pfe.levissc**Generated Time (GMT):** 29-Mar-2021 04:21**4.c Symptoms:**

Date	Location	User	Value	Reason
Nov-09-2020 13:02:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe mstephens)	Data Entry: NEW OR INCREASED SHORTN ESS OF BREATH	Initial Entry

4.c Was symptom present?

Date	Location	User	Value	Reason
Nov-09-2020 13:02:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe mstephens)	Data Entry: NO	Initial Entry

4.d

Date	Location	User	Value	Reason
Nov-09-2020 13:02:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe mstephens)	Data Entry: Symptoms: CHILLS Symptom Present: NO	Initial Entry

4.d Symptoms:

Date	Location	User	Value	Reason
Nov-09-2020 13:02:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe mstephens)	Data Entry: CHILLS	Initial Entry

4.d Was symptom present?

Date	Location	User	Value	Reason
Nov-09-2020 13:02:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe mstephens)	Data Entry: NO	Initial Entry

4.e

Date	Location	User	Value	Reason
Nov-09-2020 13:02:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe mstephens)	Data Entry: Symptoms NEW OR INCREASE : D MUSCLE PAIN Symptom NO Present:	Initial Entry

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/09/2020

Form: SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF Audit Trail History

Form Version: 10-Oct-2020 16:02

Form Status: Data Complete, Frozen, Not Complete

Site No: 1013

Site Name: (1013) Clinical Neuroscience Solutions Inc.

Subject No: 10131176

Subject Initials: ---

Generated By: pfe.levissc

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

4.e Symptoms:

Date	Location	User	Value	Reason
Nov-09-2020 13:02:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe mstephens)	Data Entry: NEW OR INCREASED MUSCLE PAIN	Initial Entry

4.e Was symptom present?

Date	Location	User	Value	Reason
Nov-09-2020 13:02:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe mstephens)	Data Entry: NO	Initial Entry

4.f

Date	Location	User	Value	Reason
Nov-09-2020 13:02:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe mstephens)	Data Entry: Symptoms NEW LOSS OF TASTE OR SMELL Symptom Present: NO	Initial Entry

4.f Symptoms:

Date	Location	User	Value	Reason
Nov-09-2020 13:02:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe mstephens)	Data Entry: NEW LOSS OF TASTE OR SMELL	Initial Entry

4.f Was symptom present?

Date	Location	User	Value	Reason
Nov-09-2020 13:02:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe mstephens)	Data Entry: NO	Initial Entry

4.g

Date	Location	User	Value	Reason
Nov-09-2020 13:02:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe mstephens)	Data Entry: Symptoms: NEW OR INCREASED SORE THROAT	Initial Entry

090177e196ae2f66\Final\Final On: 01-Apr-2021 03:42 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/09/2020 Form: SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF Audit Trail History

Form Version: 10-Oct-2020 16:02

Form Status: Data Complete, Frozen, Not Complete

Site No: 1013

Site Name: (1013) Clinical Neuroscience Solutions Inc.

Subject No: 10131176

Subject Initials: ---

Generated By: pfe.levisse

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

			Symptom NO Present:	
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4.g Symptoms:

Date	Location	User	Value	Reason
Nov-09-2020 13:02:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe mstephens)	<u>Data Entry:</u> NEW OR INCREASED SORE TH ROAT	Initial Entry

4.g Was symptom present?

Date	Location	User	Value	Reason
Nov-09-2020 13:02:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe mstephens)	<u>Data Entry:</u> NO	Initial Entry

4.h

Date	Location	User	Value	Reason
Nov-09-2020 13:02:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe mstephens)	<u>Data Entry:</u> Symptoms: DIARRHEA Symptom Present: NO	Initial Entry

4.h Symptoms:

Date	Location	User	Value	Reason
Nov-09-2020 13:02:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe mstephens)	<u>Data Entry:</u> DIARRHEA	Initial Entry

4.h Was symptom present?

Date	Location	User	Value	Reason
Nov-09-2020 13:02:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe mstephens)	<u>Data Entry:</u> NO	Initial Entry

4.i

Date	Location	User	Value	Reason
Nov-09-2020 13:02:50 (UTC-05:00) Eastern	ACV0PFEINFP6000	Matthew Stephens	<u>Data Entry:</u> Symptoms: VOMITING	Initial Entry

090177e196ae2f66\Final\Final On: 01-Apr-2021 03:42 (GMT)

Header Text: c4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit on Nov/09/2020 **Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF Audit Trail History**Form Version:** 10-Oct-2020 16:02**Form Status:** Data Complete, Frozen, Not Complete**Site No:** 1013**Site Name:** (1013) Clinical Neuroscience Solutions Inc.**Subject No:** 10131176**Subject Initials:** ---**Generated By:** pfe.levissc**Generated Time (GMT):** 29-Mar-2021 04:21

Time (US & Canada)		(pfe mstephens)	Symptom Present: NO	
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4.i Symptoms:

Date	Location	User	Value	Reason
Nov-09-2020 13:02:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe mstephens)	Data Entry: VOMITING	Initial Entry

4.i Was symptom present?

Date	Location	User	Value	Reason
Nov-09-2020 13:02:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe mstephens)	Data Entry: NO	Initial Entry

5.a

Date	Location	User	Value	Reason
Nov-13-2020 08:22:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe mstephens)	Data Entry: Symptoms - Other:	Transcription Error (DELETED)
Nov-13-2020 08:22:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe mstephens)	Data Entry: Symptoms - Other:	Transcription Error
Nov-12-2020 14:28:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe mstephens)	Data Entry: Symptoms - ASPIRATION PN Other: UMONIA	Changed Information
Nov-09-2020 13:03:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe mstephens)	Data Entry: Symptoms - Other: INTUBATIO r: N	Initial Entry

5.a Symptoms - Other Text:

Date	Location	User	Value	Reason
Nov-13-2020 13:36:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Vrunda Parikh (pfe.parikv06)	Query 1: Closed	Response satisfies query
Nov-13-2020 08:22:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe.mstephens)	Data Entry:	Transcription Error (DELETED)

Header Text: c4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit on
Nov/09/2020**Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF
Audit Trail History**Form Version:** 10-Oct-2020 16:02**Form Status:** Data Complete, Frozen, Not Complete**Site No:** 1013**Site Name:** (1013) Clinical Neuroscience Solutions Inc.**Subject No:** 10131176**Subject Initials:** ---**Generated By:** pfe.levisse**Generated Time (GMT):** 29-Mar-2021 04:21

Nov-13-2020 08:22:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Transcription Error
Nov-13-2020 08:22:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe.mstephens)	Data Entry:	Transcription Error
Nov-12-2020 18:40:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Salim Bouguermouh (pfe.bogus)	Query 1: Reissued:Opened	Clin: Please should not be recorded on the SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 CRF form, already captured as a diagnosis.
Nov-12-2020 14:28:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Changed Information
Nov-12-2020 14:28:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe.mstephens)	Data Entry: ASPIRATION PNUMONIA	Changed Information
Nov-10-2020 18:36:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Vrunda Parikh (pfe.parikv06)	Query 1: Opened	CLINQUERY: Only signs and symptoms of potential COVID-19 are captured on this SOD CRF. Please review 'intubation' as such and update CRF as appropriate to reflect all the symptoms that the participant reported throughout illness. Reference preprinted Sx.
Nov-09-2020 13:03:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe.mstephens)	Data Entry: INTUBATION	Initial Entry

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on **Form:** MICROBIOLOGY SPECIMEN - eCRF Audit Trail History
Nov/09/2020

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen, Verified

Site No: 1013

Site Name: (1013) Clinical Neuroscience Solutions Inc.

Subject No: 10131176

Subject Initials: ---

Generated By: pfe.levissc

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

[Back to Form](#)

1. Actual Date of Collection:

Date	Location	User	Value	Reason
Nov-09-2020 13:04:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe mstephens)	Data Entry: Not Applicable	Initial Entry

2. Specimen Type:

Date	Location	User	Value	Reason
Nov-09-2020 13:04:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe mstephens)	Data Entry: Not Applicable	Initial Entry

3. Specimen Collection Location:

Date	Location	User	Value	Reason
Nov-09-2020 13:04:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe mstephens)	Data Entry: Not Applicable	Initial Entry

4. Assay Code and Description:

Date	Location	User	Value	Reason
Nov-09-2020 13:04:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe mstephens)	Data Entry: Not Applicable	Initial Entry

5. Device Type:

Date	Location	User	Value	Reason
Nov-09-2020 13:04:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe mstephens)	Data Entry: Not Applicable	Initial Entry

6. Trade Name:

Date	Location	User	Value	Reason
Nov-09-2020 13:04:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe mstephens)	Data Entry: Not Applicable	Initial Entry

090177e196ae2f66\Final\Final On: 01-Apr-2021 03:42 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on **Form:** MICROBIOLOGY SPECIMEN - eCRF Audit Trail History
Nov/09/2020

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen, Verified

Site No: 1013

Site Name: (1013) Clinical Neuroscience Solutions Inc.

Subject No: 10131176

Subject Initials: ---

Generated By: pfe.lewissc

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

7. Test Result:

Date	Location	User	Value	Reason
Nov-09-2020 13:04:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe mstephens)	Data Entry: Not Applicable	Initial Entry

8. Comments/Findings/Details:

Date	Location	User	Value	Reason
Nov-09-2020 13:04:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe mstephens)	Data Entry: Not Applicable	Initial Entry

9. Trade Name Other, Specify:

Date	Location	User	Value	Reason
Nov-09-2020 13:04:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe mstephens)	Data Entry: Not Applicable	Initial Entry

090177e196ae2f66\Final\Final On: 01-Apr-2021 03:42 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/09/2020 **Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB SELF - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1013

Site Name: (1013) Clinical Neuroscience Solutions Inc.

Subject No: 10131176

Subject Initials: ---

Generated By: pfe.levissc

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

[Back to Form](#)

1. Data Origin

Date	Location	User	Value	Reason
Nov-09-2020 13:04:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Nov-09-2020 13:04:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: NASAL_SWAB_SELF	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Nov-09-2020 13:04:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe mstephens)	Data Entry: NO	Initial Entry

4. If no sample was collected or sample was not collected according to protocol, please provide reason:

Date	Location	User	Value	Reason
Nov-09-2020 13:04:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe mstephens)	Data Entry: NO SWAB COLLECTED. NO VI SIT WAS COMPLETED FOR CO VID ILLNESS.	Initial Entry

090177e196ae2f66\Final\Final On: 01-Apr-2021 03:42 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/09/2020 **Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1013

Site Name: (1013) Clinical Neuroscience Solutions Inc.

Subject No: 10131176

Subject Initials: ---

Generated By: pfe.levissc

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

[Back to Form](#)

1. Data Origin

Date	Location	User	Value	Reason
Nov-09-2020 13:05:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Nov-09-2020 13:05:43 (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
Nov-09-2020 13:05:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe mstephens)	Data Entry: NO	Initial Entry

4. If no sample was collected or sample was not collected according to protocol, please provide reason:

Date	Location	User	Value	Reason
Nov-09-2020 13:05:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe mstephens)	Data Entry: NO SWAB COLLECTED AS TH EIR WAS NO COVID ILLNESS VISIT.	Initial Entry

090177e196ae2f66\Final\Final On: 01-Apr-2021 03:42 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/09/2020 Form: HEALTH CARE UTILIZATION - eCRF Audit Trail History

Form Version: 10-Oct-2020 15:59

Form Status: Data Complete, Frozen, Verified

Site No: 1013

Site Name: (1013) Clinical Neuroscience Solutions Inc.

Subject No: 10131176

Subject Initials: ---

Generated By: pfe.levissc

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

[Back to Form](#)

I.a

Date	Location	User	Value	Reason
Nov-10-2020 11:06:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Scott Salmon (pfe.ssalmon)	Data Entry: Type of Practitioner: Not Done Occurrence of Visits or Contacts: NO	Initial Entry
Nov-10-2020 11:05:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Scott Salmon (pfe.ssalmon)	Data Entry: Type of Practitioner: Not Done Occurrence of Visits or Contacts:	Initial Entry
Nov-09-2020 13:06:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe.mstephens)	Data Entry: Type of Practitioner: Not Done Occurrence of Visits or Contacts: Not Done	Initial Entry

I.a Physician or Healthcare Professional:

Date	Location	User	Value	Reason
Nov-09-2020 13:06:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe.mstephens)	Data Entry: Not Done	Initial Entry

I.a Occurrence of Visits or Contacts:

Date	Location	User	Value	Reason
Nov-10-2020 11:50:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Gbenga Akinkunmi (pfe.akinkg)	Query 1: Closed	Response satisfies query
Nov-10-2020 11:06:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Scott Salmon (pfe.ssalmon)	Data Entry: NO	Initial Entry

090177e196ae2f66\Final\Final On: 01-Apr-2021 03:42 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on **Form:** HEALTH CARE UTILIZATION - eCRF Audit Trail History
Nov/09/2020

Form Version: 10-Oct-2020 15:59

Form Status: Data Complete, Frozen, Verified

Site No: 1013

Site Name: (1013) Clinical Neuroscience Solutions Inc.

Subject No: 10131176

Subject Initials: ---

Generated By: pfe.levissc

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

Canada)				
Nov-10-2020 11:05:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Scott Salmon (pfe.ssalmon)	Data Entry:	Initial Entry
Nov-10-2020 10:58:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Scott Salmon (pfe.ssalmon)	Query 1: Ans wered	Changed data per query
Nov-10-2020 08:58:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Behnaz Yousefzadeh- Khiabani (pfe.youseb01)	Query 1: Reis sued:O pened	DM: Per CCG 8.35, this is a required CRF. If subject didn't utilize any of the listed healthcare services, complete the form with answering as "No". Provide appropriate answers to each question asked even if subject didn't utilize healthcare services.
Nov-10-2020 07:46:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe.mstephens)	Query 1: Ans wered	SOD CRF FORM WAS COMPLETED PER SPONSOR. NO OTHER FORMS TO COMPLETE AS THIS WAS NOT A COVID ILLNESS VISIT.
Nov-10-2020 01:44:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (pfe.DMW_QUERY)	Query 1: Ope ned	DMW5328712;Occurrence of Visits or Contacts is not expected to be Not Done or Not Applicable or Unknown. Please review and update appropriately or clarify
Nov-09-2020 13:06:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe.mstephens)	Data Entry: Not D one	Initial Entry

I.b

090177e196ae2f66\Final\Final On: 01-Apr-2021 03:42 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on **Form:** HEALTH CARE UTILIZATION - eCRF Audit Trail History
Nov/09/2020

Form Version: 10-Oct-2020 15:59

Form Status: Data Complete, Frozen, Verified

Site No: 1013

Site Name: (1013) Clinical Neuroscience Solutions Inc.

Subject No: 10131176

Subject Initials: ---

Generated By: pfe.levissc

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

Date	Location	User	Value	Reason
Nov-10-2020 11:11:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Scott Salmon (pfe.ssalmon)	Data Entry: Type of Practitioner: Not Done Occurrence of Visits or Contacts: YES <i>Number of Visits or Contacts</i> : 1	Transcription Error
Nov-10-2020 11:06:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Scott Salmon (pfe.ssalmon)	Data Entry: Type of Practitioner: Not Done Occurrence of Visits or Contacts: NO	Initial Entry
Nov-10-2020 11:05:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Scott Salmon (pfe.ssalmon)	Data Entry: Type of Practitioner: Not Done Occurrence of Visits or Contacts:	Initial Entry
Nov-09-2020 13:06:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe.mstephens)	Data Entry: Type of Practitioner: Not Done Occurrence of Visits or Contacts: Not Done	Initial Entry

090177e196ae2f66\Final\Final On: 01-Apr-2021 03:42 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Form: HEALTH CARE UTILIZATION - eCRF Audit Trail History
Nov/09/2020

Form Version: 10-Oct-2020 15:59

Form Status: Data Complete, Frozen, Verified

Site No: 1013

Site Name: (1013) Clinical Neuroscience Solutions Inc.

Subject No: 10131176

Subject Initials: ---

Generated By: pfe.levissc

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

1.b Physician or Healthcare Professional:

Date	Location	User	Value	Reason
Nov-09-2020 13:06:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe.mstephens)	Data Entry: Not Done	Initial Entry

1.b Occurrence of Visits or Contacts:

Date	Location	User	Value	Reason
Nov-10-2020 11:50:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Gbenga Akinkunmi (pfe.akinkg)	Query 1: Closed	Response satisfies query
Nov-10-2020 11:11:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Scott Salmon (pfe.ssalmon)	Data Entry: YES <i>Number of Visits or Contacts:</i> 1	Transcription Error
Nov-10-2020 11:06:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Scott Salmon (pfe.ssalmon)	Data Entry: NO	Initial Entry
Nov-10-2020 11:05:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Scott Salmon (pfe.ssalmon)	Data Entry:	Initial Entry
Nov-10-2020 10:59:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Scott Salmon (pfe.ssalmon)	Query 1: Answered	Changed data per query

090177e196ae2f66\Final\Final On: 01-Apr-2021 03:42 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on **Form:** HEALTH CARE UTILIZATION - eCRF Audit Trail History
Nov/09/2020

Form Version: 10-Oct-2020 15:59

Form Status: Data Complete, Frozen, Verified

Site No: 1013

Site Name: (1013) Clinical Neuroscience Solutions Inc.

Subject No: 10131176

Subject Initials: ---

Generated By: pfe.levissc

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

Canada)				
Nov-10-2020 08:59:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Behnaz Yousefzadeh- Khiabani (pfe.youseb01)	Query 1: Reis sued:O pened	DM: Per CCG 8.35, this is a required CRF. If subject didn't utilize any of the listed healthcare services, complete the form with answering as "No". Provide appropriate answers to each question asked even if subject didn't utilize healthcare services.
Nov-10-2020 07:46:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe mstephens)	Query 1: Ans wered	PER SPONSOR SOD FORM WAS COMPLETED. THIS WAS NOT A COVID ILLNESS VISIT, SO NO OTHER FORMS TO COMPLETE.
Nov-10-2020 01:44:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (pfe.DMW_QUERY)	Query 1: Ope ned	DMW5328714;Occurrence of Visits or Contacts is not expected to be Not Done or Not Applicable or Unknown. Please review and update appropriately or clarify
Nov-09-2020 13:06:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe mstephens)	Data Entry: Not D one	Initial Entry

I.c

Date	Location	User	Value	Reason
Nov-10-2020 11:06:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Scott Salmon (pfe.ssalmon)	Data Entry: Type of Practitioner: Not Done Occurrence of Visits or Contacts: NO	Initial Entry
Nov-10-2020 11:05:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Scott Salmon (pfe.ssalmon)	Data Entry: Type of Practitioner: Not Done	Initial Entry

090177e196ae2f66\Final\Final On: 01-Apr-2021 03:42 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on **Form:** HEALTH CARE UTILIZATION - eCRF Audit Trail History
Nov/09/2020

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Site No: 1013

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Subject Initials: ---

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

			Occurrence of Visits or Contacts:	
Nov-09-2020 13:06:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe mstephens)	Data Entry: Type of Practitioner: Not Done Occurrence of Visits or Contacts: Not Done	Initial Entry

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on **Form:** HEALTH CARE UTILIZATION - eCRF Audit Trail History
Nov/09/2020

Form Version: 10-Oct-2020 15:59

Form Status: Data Complete, Frozen, Verified

Site No: 1013

Site Name: (1013) Clinical Neuroscience Solutions Inc.

Subject No: 10131176

Subject Initials: ---

Generated By: pfe.levisse

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

I.c Physician or Healthcare Professional:

Date	Location	User	Value	Reason
Nov-09-2020 13:06:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe.mstephens)	Data Entry: Not Done	Initial Entry

I.c Occurrence of Visits or Contacts:

Date	Location	User	Value	Reason
Nov-10-2020 11:50:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Gbenga Akinkunmi (pfe.akinkg)	Query 1: Clos ed	Response satisfies query
Nov-10-2020 11:06:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Scott Salmon (pfe.ssalmon)	Data Entry: NO	Initial Entry
Nov-10-2020 11:05:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Scott Salmon (pfe.ssalmon)	Data Entry:	Initial Entry
Nov-10-2020 10:59:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Scott Salmon (pfe.ssalmon)	Query 1: Ans wered	Changed data per query
Nov-10-2020 08:59:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Behnaz Yousefzadeh- Khiabani (pfe.youseb01)	Query 1: Reis sued:O pened	DM: Per CCG 8.35, this is a required CRF. If subject didn't utilize any of the listed healthcare services, complete the form with answering as "No". Provide appropriate answers to each question asked even if subject didn't utilize healthcare services.

090177e196ae2f66\Final\Final On: 01-Apr-2021 03:42 (GMT)

Header Text: c4591001

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Nov/09/2020

Form Version: 10-Oct-2020 15:59

Form Status: Data Complete, Frozen, Verified

Site No: 1013

Site Name: (1013) Clinical Neuroscience Solutions Inc.

Subject No: 10131176

Subject Initials: ---

Generated By: pfe.levissc

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

Nov-10-2020 07:46:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe.mstephens)	Query 1: Ans wered	PER SPONSOR SOD FORM WAS COMPLETED. THIS WAS NOT A COVID ILLNESS VISIT, SO NO OTHER FORMS TO COMPLETE.
Nov-10-2020 01:44:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (pfe.DMW_QUERY)	Query 1: Ope ned	DMW5328716;Occurrence of Visits or Contacts is not expected to be Not Done or Not Applicable or Unknown. Please review and update appropriately or clarify
Nov-09-2020 13:06:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe.mstephens)	Data Entry: Not D one	Initial Entry

I.d

Date	Location	User	Value	Reason
Nov-10-2020 11:06:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Scott Salmon (pfe.ssalmon)	Data Entry: Type of Practitioner: Not Do ne Occurrence of Visits or Contacts: NO	Initial Entry
Nov-10-2020 11:05:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Scott Salmon (pfe.ssalmon)	Data Entry: Type of Practitioner: Not Do ne Occurrence of Visits or Contacts:	Initial Entry
Nov-09-2020 13:06:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe.mstephens)	Data Entry: Type of Practitioner: Not Do ne Occurrence of Visits or Contacts: Not Do ne	Initial Entry

090177e196ae2f66\Final\Final On: 01-Apr-2021 03:42 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on **Form:** HEALTH CARE UTILIZATION - eCRF Audit Trail History
Nov/09/2020

Form Version: 10-Oct-2020 15:59

Form Status: Data Complete, Frozen, Verified

Site No: 1013

Site Name: (1013) Clinical Neuroscience Solutions Inc.

Subject No: 10131176

Subject Initials: ---

Generated By: pfe.levissc

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

1.d Physician or Healthcare Professional:

Date	Location	User	Value	Reason
Nov-09-2020 13:06:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe.mstephens)	Data Entry: Not Done	Initial Entry

1.d Occurrence of Visits or Contacts:

Date	Location	User	Value	Reason
Nov-10-2020 11:06:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Scott Salmon (pfe.ssalmon)	Data Entry: NO	Initial Entry
Nov-10-2020 11:05:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Scott Salmon (pfe.ssalmon)	Data Entry:	Initial Entry
Nov-10-2020 08:59:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Behnaz Yousefzadeh- Khiabani (pfe.youseb01)	Query 1: Clos ed	Response satisfies query
Nov-10-2020 07:46:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe.mstephens)	Query 1: Ans wered	PER SPONSOR SOD FORM WAS COMPLETED. THIS WAS NOT A COVID ILLNESS VISIT, SO NO OTHER FORMS TO COMPLETE.
Nov-10-2020 01:44:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (pfe.DMW_QUERY)	Query 1: Ope ned	DMW5328717;Occurrence of Visits or Contacts is not expected to be Not Done or Not Applicable or Unknown. Please review and update appropriately or clarify
Nov-09-2020	ACV0PFEINFP6000	Matthew Stephens	Data	Initial Entry

090177e196ae2f66\Final\Final On: 01-Apr-2021 03:42 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on **Form:** HEALTH CARE UTILIZATION - eCRF Audit Trail History
Nov/09/2020

Form Version: 10-Oct-2020 15:59

Form Status: Data Complete, Frozen, Verified

Site No: 1013

Site Name: (1013) Clinical Neuroscience Solutions Inc.

Subject No: 10131176

Subject Initials: ---

Generated By: pfe.levissc

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

13:06:13 (UTC-05:00) Eastern Time (US & Canada)		(pfe.mstephens)	Entry: Not D one	
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I.e

Date	Location	User	Value	Reason
Nov-10-2020 11:06:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Scott Salmon (pfe.ssalmon)	Data Entry: Type of Practitioner: Not Do ne Occurrence of Visits or C NO ontacts:	Initial Entry
Nov-10-2020 11:05:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Scott Salmon (pfe.ssalmon)	Data Entry: Type of Practitioner: Not Do ne Occurrence of Visits or C ontacts:	Initial Entry

090177e196ae2f66\Final\Final On: 01-Apr-2021 03:42 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on **Form:** HEALTH CARE UTILIZATION - eCRF Audit Trail History
Nov/09/2020

Form Version: 10-Oct-2020 15:59

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Site No: 1013

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

[Back to Form](#)

<i>I.e</i>				
Date	Location	User	Value	Reason
Nov-09-2020 13:06:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe.mstephens)	Data Entry: Type of Practitioner: Not Do ne Occurrence of Visits or Contacts: Not Do ne	Initial Entry

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Form: HEALTH CARE UTILIZATION - eCRF Audit Trail History
Nov/09/2020

Form Version: 10-Oct-2020 15:59

Form Status: Data Complete, Frozen, Verified

Site No: 1013

Site Name: (1013) Clinical Neuroscience Solutions Inc.

Subject No: 10131176

Subject Initials: ---

Generated By: pfe.levissc

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

1.e Physician or Healthcare Professional:

Date	Location	User	Value	Reason
Nov-09-2020 13:06:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe.mstephens)	Data Entry: Not Done	Initial Entry

1.e Occurrence of Visits or Contacts:

Date	Location	User	Value	Reason
Nov-10-2020 11:06:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Scott Salmon (pfe.ssalmon)	Data Entry : NO	Initial Entry
Nov-10-2020 11:05:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Scott Salmon (pfe.ssalmon)	Data Entry :	Initial Entry
Nov-10-2020 08:59:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Behnaz Yousefzadeh- Khiabani (pfe.youseb01)	Query 1: Clo sed	Response satisfies query
Nov-10-2020 07:46:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe mstephens)	Query 1: Ans wered	PER SPONSOR SOD FORM WAS COMPLETED. THIS WAS NOT A COVID ILLNESS VISIT, SO NO OTHER FORMS TO COMPLETE.
Nov-10-2020 01:44:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (pfe.DMW_QUERY)	Query 1: Op ened	DMW5328718;Occurrence of Visits or Contacts is not expected to be Not Done or Not Applicable or Unknown. Please review and update appropriately or clarify
Nov-09-2020	ACV0PFEINFP6000	Matthew Stephens	Data	Initial Entry

090177e196ae2f66\Final\Final On: 01-Apr-2021 03:42 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Form: HEALTH CARE UTILIZATION - eCRF Audit Trail History
Nov/09/2020

Form Version: 10-Oct-2020 15:59

Form Status: Data Complete, Frozen, Verified

Site No: 1013

Site Name: (1013) Clinical Neuroscience Solutions Inc.

Subject No: 10131176

Subject Initials: ---

Generated By: pfe.levissc

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

13:06:13 (UTC-05:00) Eastern Time (US & Canada)	(pfe mstephens)	Entry : Not Done
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<i>If</i>				
Date	Location	User	Value	Reason
Nov-11-2020 10:00:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe mstephens)	Data Entry: Type of Practitioner: Not Done Occurrence of Visits or Contacts: YES Number of Visits or Contacts: 1	Transcription Error
Nov-10-2020 11:06:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Scott Salmon (pfe.ssalmon)	Data Entry: Type of Practitioner: Not Done Occurrence of Visits or Contacts: NO	Initial Entry
Nov-10-2020 11:05:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Scott Salmon (pfe.ssalmon)	Data Entry: Type of Practitioner: Not Done Occurrence of Visits or Contacts:	Initial Entry
Nov-09-2020 13:06:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe mstephens)	Data Entry: Type of Practitioner: Not Done Occurrence of Visits or Contacts: Not Done	Initial Entry

090177e196ae2f66\Final\Final On: 01-Apr-2021 03:42 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Form: HEALTH CARE UTILIZATION - eCRF Audit Trail History
Nov/09/2020

Form Version: 10-Oct-2020 15:59

Form Status: Data Complete, Frozen, Verified

Site No: 1013

Site Name: (1013) Clinical Neuroscience Solutions Inc.

Subject No: 10131176

Subject Initials: ---

Generated By: pfe.levissc

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

If Physician or Healthcare Professional:

Date	Location	User	Value	Reason
Nov-09-2020 13:06:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe.mstephens)	Data Entry: Not Done	Initial Entry

If Occurrence of Visits or Contacts:

Date	Location	User	Value	Reason
Nov-11-2020 10:00:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe.mstephens)	Data Entry : YES <i>Num ber of Vi sits or C onta cts:</i> 1	Transcription Error
Nov-10-2020 11:06:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Scott Salmon (pfe.ssalmon)	Data Entry : NO	Initial Entry
Nov-10-2020 11:05:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Scott Salmon (pfe.ssalmon)	Data Entry :	Initial Entry
Nov-10-2020 08:59:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Behnaz Yousefzadeh- Khiabani (pfe.youseb01)	Query 1: Clo sed	Response satisfies query
Nov-10-2020 07:47:06 (UTC-05:00)	ACV0PFEINFP6000	Matthew Stephens (pfe.mstephens)	Query 1: Ans wered	PER SPONSOR SOD FORM WAS COMPLETED. THIS

090177e196ae2f66\Final\Final On: 01-Apr-2021 03:42 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Form: HEALTH CARE UTILIZATION - eCRF Audit Trail History
Nov/09/2020

Form Version: 10-Oct-2020 15:59

Form Status: Data Complete, Frozen, Verified

Site No: 1013

Site Name: (1013) Clinical Neuroscience Solutions Inc.

Subject No: 10131176

Subject Initials: ---

Generated By: pfe.levisss

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

Eastern Time (US & Canada)				WAS NOT A COVID ILLNESS VISIT, SO NO OTHER FORMS TO COMPLETE.
Nov-10-2020 01:44:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (pfe.DMW_QUERY)	Query 1: Opened	DMW5328719;Occurrence of Visits or Contacts is not expected to be Not Done or Not Applicable or Unknown. Please review and update appropriately or clarify
Nov-09-2020 13:06:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe.mstephens)	Data Entry : Not Done	Initial Entry

2. Other Type of Practitioner Specify:

Date	Location	User	Value	Reason
Nov-10-2020 19:11:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Vrunda Parikh (pfe.parikv06)	Query 1: Closed	Response satisfies query
Nov-10-2020 18:33:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Vrunda Parikh (pfe.parikv06)	Query 1: Opened	CLINQUERY: Please clarify whether the subject was hospitalized? Response to this question is noted as NO, but subject is noted to have had an Emergency Room visit as well as Intensive Care Unit. Please update or else clarify.
Nov-10-2020 11:11:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Scott Salmon (pfe.ssalmon)	Data Entry: INTENSIVE CARE UNIT	Initial Entry
Nov-10-2020 11:05:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Scott Salmon (pfe.ssalmon)	Data Entry:	Initial Entry

090177e196ae2f66\Final\Final On: 01-Apr-2021 03:42 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Form: HEALTH CARE UTILIZATION - eCRF Audit Trail History
Nov/09/2020

Form Version: 10-Oct-2020 15:59

Form Status: Data Complete, Frozen, Verified

Site No: 1013

Site Name: (1013) Clinical Neuroscience Solutions Inc.

Subject No: 10131176

Subject Initials: ---

Generated By: pfe.levissc

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

Nov-09-2020 13:06:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe.mstephens)	Data Entry: Not Done	Initial Entry
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3. Has the subject been hospitalized due to potential COVID-19 illness?

Date	Location	User	Value	Reason
Nov-12-2020 20:55:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Vrunda Parikh (pfe.parikv06)	Query 2: Clos ed	Response satisfies query
Nov-12-2020 13:16:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Erik Sundgaard (pfe.sundgaardea)	Query 3: Clos ed	Response satisfies query
Nov-11-2020 14:50:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Ans wered	Transcription Error
Nov-11-2020 14:50:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe.mstephens)	Data E ntry: NO	Transcription Error
Nov-11-2020 13:41:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Vrunda Parikh (pfe.parikv06)	Query 2: Reis sued:O pened	CLINQUERY:Thank you.Subject had COVID-19 illness and was hospitalized. Please enter on the relevant CRF form any available information (vital signs, pulse oxymet, respiratory treatment, lab results, imaging...). Please make every effort to obtain this info.

090177e196ae2f66\Final\Final On: 01-Apr-2021 03:42 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Form: HEALTH CARE UTILIZATION - eCRF Audit Trail History
Nov/09/2020

Form Version: 10-Oct-2020 15:59

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Subject Initials: ---

Generated By: pfe.levissc

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

Nov-11-2020 13:33:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Ans wered	Transcription Error
Nov-11-2020 13:33:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe.mstephens)	Data Entry: YES Has the subject been in intensive care due to potential COVID-19 illness? YES	Transcription Error
Nov-11-2020 13:20:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Vrunda Parikh (pfe.parikv06)	Query 2: Reissued: Opened	CLINQUERY: Question 'Has the subject been in intensive care due to potential COVID-19 illness?' is noted as NO. Please review and update data as free field text indicates 'Intensive Care Unit'. Please clarify?
Nov-11-2020 10:00:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 3: Ans wered	Transcription Error
Nov-11-2020 10:00:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Ans wered	Transcription Error

090177e196ae2f66\Final\Final On: 01-Apr-2021 03:42 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on **Form:** HEALTH CARE UTILIZATION - eCRF Audit Trail History
Nov/09/2020

Form Version: 10-Oct-2020 15:59

Form Status: Data Complete, Frozen, Verified

Site No: 1013

Site Name: (1013) Clinical Neuroscience Solutions Inc.

Subject No: 10131176

Subject Initials: ---

Generated By: pfe.levissc

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

Nov-11-2020 10:00:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe.mstephens)	Data Entry: YES Has the subject been in intensive care due to potential COVID-19 illness? NO	Transcription Error
Nov-11-2020 02:59:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Teena Patra (pfe.patrat02)	Query 3: Opened	DM: Please confirm if Comment entered needs to be recorded in appropriate data point. Please confirm and correct else clarify, thank you.
Nov-10-2020 19:11:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Vrunda Parikh (pfe.parikv06)	Query 2: Opened	CLINQUERY: Please clarify whether the subject was hospitalized? Response to this question is noted as NO, but subject is noted to have had an 'Emergency Room' visit as well as 'Intensive Care Unit' service. Please update or else clarify.
Nov-10-2020 11:48:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Gbenga Akinkunmi (pfe.akinkg)	Query 1: Closed	Response satisfies query
Nov-10-2020 11:06:21 (UTC-05:00)	ACV0PFEINFP6000	Scott Salmon (pfe.ssalmon)	Data Entry: NO	Initial Entry

090177e196ae2f66\Final\Final On: 01-Apr-2021 03:42 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Form: HEALTH CARE UTILIZATION - eCRF Audit Trail History
Nov/09/2020

Form Version: 10-Oct-2020 15:59

Form Status: Data Complete, Frozen, Verified

Site No: 1013

Site Name: (1013) Clinical Neuroscience Solutions Inc.

Subject No: 10131176

Subject Initials: ---

Generated By: pfe.levissc

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

Eastern Time (US & Canada)				
Nov-10-2020 11:05:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Scott Salmon (pfe.ssalmon)	Data Entry:	Initial Entry
Nov-10-2020 10:59:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Scott Salmon (pfe.ssalmon)	Query 1: Answered	Changed data per query
Nov-10-2020 09:00:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Behnaz Yousefzadeh-Khiabani (pfe.youseb01)	Query 1: Reissued: Opened	DM: Per CCG 8.35, this is a required CRF. If subject didn't utilize any of the listed healthcare services, complete the form with answering as "No". Provide appropriate answers to each question asked even if subject didn't utilize healthcare services.
Nov-10-2020 07:45:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe.mstephens)	Query 1: Answered	SOD CRF FORM WAS COMPLETED PER SPONSOR. NO OTHER FORMS TO COMPLETE.
Nov-10-2020 01:44:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (pfe.DMW_QUERY)	Query 1: Opened	DMW5328689;Response to 'Has the subject been hospitalized due to potential COVID-19 illness?' is not expected to be Not Done or Not Applicable or Unknown. Please review and update appropriately or clarify
Nov-09-2020 13:06:13 (UTC-05:00)	ACV0PFEINFP6000	Matthew Stephens (pfe.mstephens)	Data Entry: Not Do	Initial Entry

090177e196ae2f66\Final\Final On: 01-Apr-2021 03:42 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on **Form:** HEALTH CARE UTILIZATION - eCRF Audit Trail History
Nov/09/2020

Form Version: 10-Oct-2020 15:59

Form Status: Data Complete, Frozen, Verified

Site No: 1013

Site Name: (1013) Clinical Neuroscience Solutions Inc.

Subject No: 10131176

Subject Initials: ---

Generated By: pfe.levissc

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

Eastern Time (US & Canada)			ne	
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090177e196ae2f66\Final\Final On: 01-Apr-2021 03:42 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/09/2020 Form: RESPIRATORY TREATMENT - eCRF Audit Trail History

Form Version: 06-Jul-2020 21:53

Form Status: Data Complete, Frozen, Verified

Site No: 1013

Site Name: (1013) Clinical Neuroscience Solutions Inc.

Subject No: 10131176

Subject Initials: ---

Generated By: pfe.levissc

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

[Back to Form](#)

1. What is the treatment Identifier?

Date	Location	User	Value	Reason
Nov-09-2020 13:06:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe mstephens)	Data Entry: Not Applicable	Initial Entry

2. Concomitant Non-drug Treatment Pre-specified:

Date	Location	User	Value	Reason
Nov-09-2020 13:06:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe mstephens)	Data Entry: Not Applicable	Initial Entry

3. Treatment:

Date	Location	User	Value	Reason
Nov-09-2020 13:06:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe mstephens)	Data Entry: Not Applicable	Initial Entry

4. Treatment:

Date	Location	User	Value	Reason
Nov-09-2020 13:06:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe mstephens)	Data Entry: Not Applicable	Initial Entry

5. Start Date:

Date	Location	User	Value	Reason
Nov-09-2020 13:06:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe mstephens)	Data Entry: Not Applicable	Initial Entry

6. Ongoing?

Date	Location	User	Value	Reason
Nov-09-2020 13:06:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe mstephens)	Data Entry: Not Applicable	Initial Entry

090177e196ae2f66\Final\Final On: 01-Apr-2021 03:42 (GMT)

Header Text: c4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit on **Form:** ILLNESS DETAILS - eCRF Audit Trail History
Nov/09/2020**Form Version:** 06-Jul-2020 21:52**Form Status:** Data Complete, Frozen, Verified**Site No:** 1013**Site Name:** (1013) Clinical Neuroscience Solutions Inc.**Subject No:** 10131176**Subject Initials:** ---**Generated By:** pfe.levissc**Generated Time (GMT):** 29-Mar-2021 04:21[Back to Form](#)**1. Category of Clinical Event:**

Date	Location	User	Value	Reason
Nov-09-2020 13:06:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: POTENTIAL COVID-19 ILLNESS	Initial Entry

2. Was a diagnosis obtained for Potential COVID-19 Illness?

Date	Location	User	Value	Reason
Nov-12-2020 18:50:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Salim Bouguermouh (pfe.bogus)	Query 1: Closed	Response satisfies query
Nov-12-2020 14:29:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe.mstephens)	Data Entry: YES <i>Respiratory Illness Diagnosis:</i> ASPIRATION PNEUMONIA Date of Diagnosis: Aug/30/2020	Changed Information
Nov-11-2020 13:07:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe.mstephens)	Query 1: Answered	Original value is correct
Nov-10-2020 23:59:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Salim Bouguermouh (pfe.bogus)	Query 1: Opened	Clin: Please consider in response to "Was a diagnosis obtained for Potential COVID-19 Illness" entering ASPIRATION PNEUMONIA.
Nov-09-2020 13:06:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe.mstephens)	Data Entry: NO	Initial Entry

3. Toxicity Grade:

Date	Location	User	Value	Reason
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Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on **Form:** ILLNESS DETAILS - eCRF Audit Trail History
Nov/09/2020

Form Version: 06-Jul-2020 21:52

Form Status: Data Complete, Frozen, Verified

Site No: 1013

Site Name: (1013) Clinical Neuroscience Solutions Inc.

Subject No: 10131176

Subject Initials: ---

Generated By: pfe.levissc

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

Nov-09-2020 13:06:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe mstephens)	Data Entry: 3	Initial Entry
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Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on **Form:** ILLNESS DETAILS - SEVERE - eCRF Audit Trail History
Nov/09/2020

Form Version: 17-Jul-2020 21:55

Form Status: Data Complete, Frozen, Verified

Site No: 1013

Site Name: (1013) Clinical Neuroscience Solutions Inc.

Subject No: 10131176

Subject Initials: ---

Generated By: pfe.levissc

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

[Back to Form](#)

1. Category of Clinical Event:

Date	Location	User	Value	Reason
Nov-09-2020 13:06:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe mstephens)	Data Entry: Not Applicable	Initial Entry

2. Subcategory of Clinical Event:

Date	Location	User	Value	Reason
Nov-09-2020 13:06:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe mstephens)	Data Entry: Not Applicable	Initial Entry

3. Was a diagnosis obtained?

Date	Location	User	Value	Reason
Nov-09-2020 13:06:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe mstephens)	Data Entry: Not Applicable	Initial Entry

4. Toxicity Grade:

Date	Location	User	Value	Reason
Nov-09-2020 13:06:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe mstephens)	Data Entry: Not Applicable	Initial Entry

090177e196ae2f66\Final\Final On: 01-Apr-2021 03:42 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/09/2020 Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:27

Form Status: Data Complete, Frozen, Verified

Site No: 1013

Site Name: (1013) Clinical Neuroscience Solutions Inc.

Subject No: 10131176

Subject Initials: ---

Generated By: pfe.levissc

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

[Back to Form](#)

1. Lab Panel:

Date	Location	User	Value	Reason
Nov-09-2020 13:07:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe mstephens)	Data Entry: Not Applicable	Initial Entry

2. Laboratory Name and Address

Date	Location	User	Value	Reason
Nov-09-2020 13:07:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe mstephens)	Data Entry: Not Applicable	Initial Entry

3. Collection Date:

Date	Location	User	Value	Reason
Nov-09-2020 13:07:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe mstephens)	Data Entry: Not Applicable	Initial Entry

4. Specimen Type:

Date	Location	User	Value	Reason
Nov-09-2020 13:07:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe mstephens)	Data Entry: Not Applicable	Initial Entry

5.a

Date	Location	User	Value	Reason
Nov-09-2020 13:07:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe mstephens)	Data Entry: Sponsor-Defined Identifier: Not Applicable Test:: Not Applicable Result:: Not Applicable Not Done:: Not Applicable	Initial Entry

090177e196ae2f66\Final\Final On: 01-Apr-2021 03:42 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/09/2020 Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:27

Form Status: Data Complete, Frozen, Verified

Site No: 1013

Site Name: (1013) Clinical Neuroscience Solutions Inc.

Subject No: 10131176

Subject Initials: ---

Generated By: pfe.levissc

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

			Lab Normal Range: Not Applicable	
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5.a Sponsor ID:

Date	Location	User	Value	Reason
Nov-09-2020 13:07:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe mstephens)	Data Entry: Not Applicable	Initial Entry

5.a Test:

Date	Location	User	Value	Reason
Nov-09-2020 13:07:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe mstephens)	Data Entry: Not Applicable	Initial Entry

5.a Result:

Date	Location	User	Value	Reason
Nov-09-2020 13:07:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe mstephens)	Data Entry: Not Applicable	Initial Entry

5.a Not Done:

Date	Location	User	Value	Reason
Nov-09-2020 13:07:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe mstephens)	Data Entry: Not Applicable	Initial Entry

5.a LNMT

Date	Location	User	Value	Reason
Nov-09-2020 13:07:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe mstephens)	Data Entry: Not Applicable	Initial Entry

5.b

Date	Location	User	Value	Reason
Nov-09-2020 13:07:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe mstephens)	Data Entry: Sponsor-Defined Identifier: Not Applicable	Initial Entry

090177e196ae2f66\Final\Final On: 01-Apr-2021 03:42 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/09/2020 **Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:27

Form Status: Data Complete, Frozen, Verified

Site No: 1013

Site Name: (1013) Clinical Neuroscience Solutions Inc.

Subject No: 10131176

Subject Initials: ---

Generated By: pfe.levissc

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

			Test:: Not Applicable	
			Result:: Not Applicable	
			Not Done:: Not Applicable	
			Lab Normal Range: Not Applicable	

5.b Sponsor ID:

Date	Location	User	Value	Reason
Nov-09-2020 13:07:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe mstephens)	Data Entry: Not Applicable	Initial Entry

5.b Test:

Date	Location	User	Value	Reason
Nov-09-2020 13:07:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe mstephens)	Data Entry: Not Applicable	Initial Entry

5.b Result:

Date	Location	User	Value	Reason
Nov-09-2020 13:07:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe mstephens)	Data Entry: Not Applicable	Initial Entry

5.b Not Done:

Date	Location	User	Value	Reason
Nov-09-2020 13:07:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe mstephens)	Data Entry: Not Applicable	Initial Entry

5.b LNMT

Date	Location	User	Value	Reason
Nov-09-2020 13:07:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe mstephens)	Data Entry: Not Applicable	Initial Entry

090177e196ae2f66\Final\Final On: 01-Apr-2021 03:42 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/09/2020 **Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History

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Subject Initials: ---

Generated By: pfe.levissc

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

5.c

Date	Location	User	Value	Reason
Nov-09-2020 13:07:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe mstephens)	Data Entry: Sponsor-Defined Identifier: Not Applicable Test:: Not Applicable Result:: Not Applicable Not Done:: Not Applicable Lab Normal Range: Not Applicable	Initial Entry

090177e196ae2f66\Final\Final On: 01-Apr-2021 03:42 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/09/2020 Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:27

Form Status: Data Complete, Frozen, Verified

Site No: 1013

Site Name: (1013) Clinical Neuroscience Solutions Inc.

Subject No: 10131176

Subject Initials: ---

Generated By: pfe.levissc

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

5.c Sponsor ID:

Date	Location	User	Value	Reason
Nov-09-2020 13:07:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe mstephens)	Data Entry: Not Applicable	Initial Entry

5.c Test:

Date	Location	User	Value	Reason
Nov-09-2020 13:07:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe mstephens)	Data Entry: Not Applicable	Initial Entry

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Date	Location	User	Value	Reason
Nov-09-2020 13:07:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe mstephens)	Data Entry: Not Applicable	Initial Entry

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Date	Location	User	Value	Reason
Nov-09-2020 13:07:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe mstephens)	Data Entry: Sponsor-Defined Identifier: Not Applicable Test:: Not Applicable	Initial Entry

090177e196ae2f66\Final\Final On: 01-Apr-2021 03:42 (GMT)

Header Text: c4591001

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			Result:: Not Applicable	
			Not Done:: Not Applicable	
			Lab Normal Range: Not Applicable	

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5.e

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Date	Location	User	Value	Reason
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Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/09/2020 Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

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Subject No: 10131176

Subject Initials: ---

Generated By: pfe.levissc

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[Back to Form](#)

1. Lab Panel:

Date	Location	User	Value	Reason
Nov-09-2020 13:07:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe mstephens)	Data Entry: Not Applicable	Initial Entry

2. Laboratory Name and Address

Date	Location	User	Value	Reason
Nov-09-2020 13:07:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe mstephens)	Data Entry: Not Applicable	Initial Entry

3. Collection Date:

Date	Location	User	Value	Reason
Nov-09-2020 13:07:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe mstephens)	Data Entry: Not Applicable	Initial Entry

4. Specimen Type:

Date	Location	User	Value	Reason
Nov-09-2020 13:07:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe mstephens)	Data Entry: Not Applicable	Initial Entry

5.a

Date	Location	User	Value	Reason
Nov-09-2020 13:07:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe mstephens)	Data Entry: Sponsor-Defined Identifier: Not Applicable Test:: Not Applicable Result:: Not Applicable Not Done:: Not Applicable	Initial Entry

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			Lab Normal Range: Not Applicable	
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5.a Sponsor ID:

Date	Location	User	Value	Reason
Nov-09-2020 13:07:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe mstephens)	Data Entry: Not Applicable	Initial Entry

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Date	Location	User	Value	Reason
Nov-09-2020 13:07:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe mstephens)	Data Entry: Not Applicable	Initial Entry

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Nov-09-2020 13:07:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe mstephens)	Data Entry: Not Applicable	Initial Entry

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Date	Location	User	Value	Reason
Nov-09-2020 13:07:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe mstephens)	Data Entry: Not Applicable	Initial Entry

5.a LNMT

Date	Location	User	Value	Reason
Nov-09-2020 13:07:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe mstephens)	Data Entry: Not Applicable	Initial Entry

5.b

Date	Location	User	Value	Reason
Nov-09-2020 13:07:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe mstephens)	Data Entry: Sponsor-Defined Identifier: Not Applicable	Initial Entry

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5.b Sponsor ID:

Date	Location	User	Value	Reason
Nov-09-2020 13:07:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe mstephens)	Data Entry: Not Applicable	Initial Entry

5.b Test:

Date	Location	User	Value	Reason
Nov-09-2020 13:07:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe mstephens)	Data Entry: Not Applicable	Initial Entry

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Date	Location	User	Value	Reason
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Date	Location	User	Value	Reason
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Date	Location	User	Value	Reason
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5.f LNMT

Date	Location	User	Value	Reason
Nov-09-2020 13:07:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe mstephens)	Data Entry: Not Applicable	Initial Entry

5.g

090177e196ae2f66\Final\Final On: 01-Apr-2021 03:42 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/09/2020 **Form:** LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:28

Form Status: Data Complete, Frozen, Verified

Site No: 1013

Site Name: (1013) Clinical Neuroscience Solutions Inc.

Subject No: 10131176

Subject Initials: ---

Generated By: pfe.levissc

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

Date	Location	User	Value	Reason
Nov-09-2020 13:07:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe mstephens)	Data Entry: Sponsor-Defined Identifier: Not Applicable Test:: Not Applicable Result:: Not Applicable Not Done:: Not Applicable Lab Normal Range: Not Applicable	Initial Entry

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/09/2020 **Form:** LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:28

Form Status: Data Complete, Frozen, Verified

Site No: 1013

Site Name: (1013) Clinical Neuroscience Solutions Inc.

Subject No: 10131176

Subject Initials: ---

Generated By: pfe.levissc

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

5.g Sponsor ID:

Date	Location	User	Value	Reason
Nov-09-2020 13:07:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe mstephens)	Data Entry: Not Applicable	Initial Entry

5.g Test:

Date	Location	User	Value	Reason
Nov-09-2020 13:07:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe mstephens)	Data Entry: Not Applicable	Initial Entry

5.g Result:

Date	Location	User	Value	Reason
Nov-09-2020 13:07:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe mstephens)	Data Entry: Not Applicable	Initial Entry

5.g Not Done:

Date	Location	User	Value	Reason
Nov-09-2020 13:07:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe mstephens)	Data Entry: Not Applicable	Initial Entry

5.g LNMT

Date	Location	User	Value	Reason
Nov-09-2020 13:07:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe mstephens)	Data Entry: Not Applicable	Initial Entry

5.h

Date	Location	User	Value	Reason
Nov-09-2020 13:07:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe mstephens)	Data Entry: Sponsor-Defined Identifier: Not Applicable Test:: Not Applicable	Initial Entry

090177e196ae2f66\Final\Final On: 01-Apr-2021 03:42 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/09/2020

Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:28

Form Status: Data Complete, Frozen, Verified

Site No: 1013

Site Name: (1013) Clinical Neuroscience Solutions Inc.

Subject No: 10131176

Subject Initials: ---

Generated By: pfe.lewissc

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

			Result:: Not Applicable Not Done:: Not Applicable Lab Normal Range: Not Applicable	
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5.h Sponsor ID:

Date	Location	User	Value	Reason
Nov-09-2020 13:07:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe mstephens)	Data Entry: Not Applicable	Initial Entry

5.h Test:

Date	Location	User	Value	Reason
Nov-09-2020 13:07:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe mstephens)	Data Entry: Not Applicable	Initial Entry

5.h Result:

Date	Location	User	Value	Reason
Nov-09-2020 13:07:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe mstephens)	Data Entry: Not Applicable	Initial Entry

5.h Not Done:

Date	Location	User	Value	Reason
Nov-09-2020 13:07:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe mstephens)	Data Entry: Not Applicable	Initial Entry

5.h LNMT

Date	Location	User	Value	Reason
Nov-09-2020 13:07:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe mstephens)	Data Entry: Not Applicable	Initial Entry

5.i

090177e196ae2f66\Final\Final On: 01-Apr-2021 03:42 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/09/2020 **Form:** LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:28

Form Status: Data Complete, Frozen, Verified

Site No: 1013

Site Name: (1013) Clinical Neuroscience Solutions Inc.

Subject No: 10131176

Subject Initials: ---

Generated By: pfe.levissc

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

Date	Location	User	Value	Reason
Nov-09-2020 13:07:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe mstephens)	Data Entry: Sponsor-Defined Identifier: Not Applicable Test:: Not Applicable Result:: Not Applicable Not Done:: Not Applicable Lab Normal Range: Not Applicable	Initial Entry

090177e196ae2f66\Final\Final On: 01-Apr-2021 03:42 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/09/2020

Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:28

Form Status: Data Complete, Frozen, Verified

Site No: 1013

Site Name: (1013) Clinical Neuroscience Solutions Inc.

Subject No: 10131176

Subject Initials: ---

Generated By: pfe.levissc

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

[Back to Form](#)

5.i Sponsor ID:

Date	Location	User	Value	Reason
Nov-09-2020 13:07:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe mstephens)	Data Entry: Not Applicable	Initial Entry

5.i Test:

Date	Location	User	Value	Reason
Nov-09-2020 13:07:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe mstephens)	Data Entry: Not Applicable	Initial Entry

5.i Result:

Date	Location	User	Value	Reason
Nov-09-2020 13:07:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe mstephens)	Data Entry: Not Applicable	Initial Entry

5.i Not Done:

Date	Location	User	Value	Reason
Nov-09-2020 13:07:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe mstephens)	Data Entry: Not Applicable	Initial Entry

5.i LNMT

Date	Location	User	Value	Reason
Nov-09-2020 13:07:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe mstephens)	Data Entry: Not Applicable	Initial Entry

5.j

Date	Location	User	Value	Reason
Nov-09-2020 13:07:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe mstephens)	Data Entry: Sponsor-Defined Identifier: Not Applicable	Initial Entry

090177e196ae2f66\Final\Final On: 01-Apr-2021 03:42 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/09/2020

Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:28

Form Status: Data Complete, Frozen, Verified

Site No: 1013

Site Name: (1013) Clinical Neuroscience Solutions Inc.

Subject No: 10131176

Subject Initials: ---

Generated By: pfe.levissc

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

			Test:: Not Applicable Result:: Not Applicable Not Done:: Not Applicable Lab Normal Range: Not Applicable	
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5.j Sponsor ID:

Date	Location	User	Value	Reason
Nov-09-2020 13:07:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe mstephens)	Data Entry: Not Applicable	Initial Entry

5.j Test:

Date	Location	User	Value	Reason
Nov-09-2020 13:07:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe mstephens)	Data Entry: Not Applicable	Initial Entry

5.j Result:

Date	Location	User	Value	Reason
Nov-09-2020 13:07:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe mstephens)	Data Entry: Not Applicable	Initial Entry

5.j Not Done:

Date	Location	User	Value	Reason
Nov-09-2020 13:07:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe mstephens)	Data Entry: Not Applicable	Initial Entry

5.j LNMT

Date	Location	User	Value	Reason
Nov-09-2020 13:07:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe mstephens)	Data Entry: Not Applicable	Initial Entry

090177e196ae2f66\Final\Final On: 01-Apr-2021 03:42 (GMT)

Header Text: c4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit on **Form:** VITAL SIGNS - COVID - eCRF Audit Trail History
Nov/09/2020**Form Version:** 30-Jul-2020 21:27**Form Status:** Data Complete, Frozen, Verified**Site No:** 1013**Site Name:** (1013) Clinical Neuroscience Solutions Inc.**Subject No:** 10131176**Subject Initials:** ---**Generated By:** pfe.levissc**Generated Time (GMT):** 29-Mar-2021 04:21[Back to Form](#)**1. Date:**

Date	Location	User	Value	Reason
Nov-09-2020 13:07:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe mstephens)	Data Entry: Not Applicable	Initial Entry

2.a

Date	Location	User	Value	Reason
Nov-09-2020 13:07:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe mstephens)	Data Entry: Record Identifier:: Not Applicable Systolic:: Not Applicable Diastolic:: Not Applicable Respiratory Rate in re spirations/minute: Not Applicable Heart Rate in beats/mi nute: Not Applicable	Initial Entry

2.a Record Identifier:

Date	Location	User	Value	Reason
Nov-09-2020 13:07:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe mstephens)	Data Entry: Not Applicable	Initial Entry

2.a Systolic:

Date	Location	User	Value	Reason
Nov-09-2020 13:07:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe mstephens)	Data Entry: Not Applicable	Initial Entry

2.a Diastolic:

Date	Location	User	Value	Reason
Nov-09-2020 13:07:52 (UTC-05:00) Eastern	ACV0PFEINFP6000	Matthew Stephens	Data Entry: Not Applicable	Initial Entry

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on **Form:** VITAL SIGNS - COVID - eCRF Audit Trail History
Nov/09/2020

Form Version: 30-Jul-2020 21:27

Form Status: Data Complete, Frozen, Verified

Site No: 1013

Site Name: (1013) Clinical Neuroscience Solutions Inc.

Subject No: 10131176

Subject Initials: ---

Generated By: pfe.levissc

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

Time (US & Canada)		(pfe mstephens)		
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2.a Respiratory Rate in respirations/minute:

Date	Location	User	Value	Reason
Nov-09-2020 13:07:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe mstephens)	Data Entry: Not Applicable	Initial Entry

2.a Heart Rate in beats/minute:

Date	Location	User	Value	Reason
Nov-09-2020 13:07:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe mstephens)	Data Entry: Not Applicable	Initial Entry

090177e196ae2f66\Final\Final On: 01-Apr-2021 03:42 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on **Form:** VITAL SIGNS - PULSE OX ROOM AIR - eCRF Audit Trail History
Nov/09/2020

Form Version: 30-Jul-2020 21:28

Form Status: Data Complete, Frozen, Verified

Site No: 1013

Site Name: (1013) Clinical Neuroscience Solutions Inc.

Subject No: 10131176

Subject Initials: ---

Generated By: pfe.levissc

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

[Back to Form](#)

I. Date:

Date	Location	User	Value	Reason
Nov-09-2020 13:08:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe mstephens)	Data Entry: Not Applicable	Initial Entry

2.a

Date	Location	User	Value	Reason
Nov-09-2020 13:08:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe mstephens)	Data Entry: Record Identifier: Not Applicabl : e Oxygen Saturatio Not Applicabl n: e	Initial Entry

2.a Record Identifier:

Date	Location	User	Value	Reason
Nov-09-2020 13:08:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe mstephens)	Data Entry: Not Applicable	Initial Entry

2.a SPO2 Pulse Oximetry %

Date	Location	User	Value	Reason
Nov-09-2020 13:08:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe mstephens)	Data Entry: Not Applicable	Initial Entry

090177e196ae2f66\Final\Final On: 01-Apr-2021 03:42 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on **Form:** OXYGENATION PARAMETERS - eCRF Audit Trail History
Nov/09/2020

Form Version: 06-Jul-2020 21:52

Form Status: Data Complete, Frozen, Verified

Site No: 1013

Site Name: (1013) Clinical Neuroscience Solutions Inc.

Subject No: 10131176

Subject Initials: ---

Generated By: pfe.levissc

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

[Back to Form](#)

1. Date Time of Assessment:

Date	Location	User	Value	Reason
Nov-09-2020 13:08:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe mstephens)	Data Entry: Not Applicable	Initial Entry

2. Arterial Blood Gases PaO2 (mmHg):

Date	Location	User	Value	Reason
Nov-09-2020 13:08:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe mstephens)	Data Entry: Not Applicable	Initial Entry

3. FiO2 (Fraction of Inhaled Oxygen):

Date	Location	User	Value	Reason
Nov-09-2020 13:08:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe mstephens)	Data Entry: Not Applicable	Initial Entry

090177e196ae2f66\Final\Final On: 01-Apr-2021 03:42 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/09/2020 Form: CONCOMITANT MEDICATIONS - VASOPRESSORS - eCRF Audit Trail History

Form Version: 06-Jul-2020 21:55

Form Status: Data Complete, Frozen, Verified

Site No: 1013

Site Name: (1013) Clinical Neuroscience Solutions Inc.

Subject No: 10131176

Subject Initials: ---

Generated By: pfe.levissc

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

[Back to Form](#)

1. What is the medication identifier?

Date	Location	User	Value	Reason
Nov-09-2020 13:08:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe mstephens)	Data Entry: Not Applicable	Initial Entry

2. Category:

Date	Location	User	Value	Reason
Nov-09-2020 13:08:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe mstephens)	Data Entry: Not Applicable	Initial Entry

3. Concomitant Medications Pre-specified:

Date	Location	User	Value	Reason
Nov-09-2020 13:08:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe mstephens)	Data Entry: Not Applicable	Initial Entry

4. Medication:

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

Date	Location	User	Value	Reason
Nov-09-2020 13:08:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe mstephens)	Data Entry: Not Applicable	Initial Entry

5. Start Date:

Date	Location	User	Value	Reason
Nov-09-2020 13:08:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe mstephens)	Data Entry: Not Applicable	Initial Entry

6. Ongoing?

Date	Location	User	Value	Reason
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090177e196ae2f66\Final\Final On: 01-Apr-2021 03:42 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on
Nov/09/2020

Form: CONCOMITANT MEDICATIONS - VASOPRESSORS - eCRF
Audit Trail History

Form Version: 06-Jul-2020 21:55

Form Status: Data Complete, Frozen, Verified

Site No: 1013

Site Name: (1013) Clinical Neuroscience Solutions Inc.

Subject No: 10131176

Subject Initials: ---

Generated By: pfe.levissc

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

Nov-09-2020 13:08:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe mstephens)	Data Entry: Not Applicable	Initial Entry
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090177e196ae2f66\Final\Final On: 01-Apr-2021 03:42 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on **Form:** IMAGING - eCRF Audit Trail History
Nov/09/2020

Form Version: 06-Jul-2020 21:53

Form Status: Data Complete, Frozen, Verified

Site No: 1013

Site Name: (1013) Clinical Neuroscience Solutions Inc.

Subject No: 10131176

Subject Initials: ---

Generated By: pfe.levissc

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

[Back to Form](#)

1. Date of Assessment:

Date	Location	User	Value	Reason
Nov-09-2020 13:08:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe mstephens)	Data Entry: Not Applicable	Initial Entry

2. Location of Assessment:

Date	Location	User	Value	Reason
Nov-09-2020 13:08:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe mstephens)	Data Entry: Not Applicable	Initial Entry

3. Type of Imaging Exam:

Date	Location	User	Value	Reason
Nov-09-2020 13:08:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe mstephens)	Data Entry: Not Applicable	Initial Entry

4. Assessment:

Date	Location	User	Value	Reason
Nov-09-2020 13:08:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe mstephens)	Data Entry: Not Applicable	Initial Entry

090177e196ae2f66\Final\Final On: 01-Apr-2021 03:42 (GMT)

Header Text: c4591001

Visit: End of Treatment - Unscheduled

Form Version: 15-Sep-2020 21:55

Site No: 1013

Subject No: 10131176

Generated By: pfe.levisse

Form: DISPOSITION - TREATMENT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1013) Clinical Neuroscience Solutions Inc.

Subject Initials: ---

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

[Back to Form](#)

1. Date of Completion/Discontinuation/Death :

Date	Location	User	Value	Reason
Nov-04-2020 17:13:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Scott Salmon (pfe.ssalmon)	Data Entry: Nov/4/2020	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Nov-04-2020 17:13:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: VACCINATION	Initial Entry

3. Status:

Date	Location	User	Value	Reason
Nov-04-2020 17:13:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Scott Salmon (pfe.ssalmon)	Data Entry: COMPLETED	Initial Entry

090177e196ae2f66\Final\Final On: 01-Apr-2021 03:42 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1013

Subject No: 10131176

Generated By: pfe.levissc

Form: ADVERSE EVENT REPORT - Audit Trail

Form Status:

Site Name: (1013) Clinical Neuroscience Solutions Inc.

Subject Initials: ---

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

[Back to Form](#)

Date	Location	User	Value	Reason
Sep-02-2020 08:54:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe mstephens)	Form Created	

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1013

Subject No: 10131176

Generated By: pfe.levissc

Form: ADVERSE EVENT REPORT - Audit Trail

Form Status:

Site Name: (1013) Clinical Neuroscience Solutions Inc.

Subject Initials: ---

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

[Back to Form](#)

Date	Location	User	Value	Reason
Sep-16-2020 17:22:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Monica Cooper (pfe mcooper)	Form Created	

090177e196ae2f66\Final\Final On: 01-Apr-2021 03:42 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1013

Subject No: 10131176

Generated By: pfe.levissc

Form: ADVERSE EVENT REPORT - Audit Trail

Form Status:

Site Name: (1013) Clinical Neuroscience Solutions Inc.

Subject Initials: ---

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

[Back to Form](#)

Date	Location	User	Value	Reason
Sep-16-2020 17:23:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Monica Cooper (pfe mcooper)	Form Created	

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1013

Subject No: 10131176

Generated By: pfe.levissc

Form: ADVERSE EVENT REPORT - Audit Trail

Form Status:

Site Name: (1013) Clinical Neuroscience Solutions Inc.

Subject Initials: ---

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

[Back to Form](#)

Date	Location	User	Value	Reason
Sep-16-2020 17:24:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Monica Cooper (pfe mcooper)	Form Created	

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1013

Subject No: 10131176

Generated By: pfe.levissc

Form: ADVERSE EVENT REPORT - Audit Trail

Form Status:

Site Name: (1013) Clinical Neuroscience Solutions Inc.

Subject Initials: ---

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

[Back to Form](#)

Date	Location	User	Value	Reason
Sep-16-2020 17:25:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Monica Cooper (pfe mcooper)	Form Created	

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1013

Subject No: 10131176

Generated By: pfe.levissc

Form: ADVERSE EVENT REPORT - Audit Trail

Form Status:

Site Name: (1013) Clinical Neuroscience Solutions Inc.

Subject Initials: ---

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

[Back to Form](#)

Date	Location	User	Value	Reason
Sep-16-2020 17:26:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Monica Cooper (pfe mcooper)	Form Created	

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1013

Subject No: 10131176

Generated By: pfe.levissc

Form: ADVERSE EVENT REPORT - Audit Trail

Form Status:

Site Name: (1013) Clinical Neuroscience Solutions Inc.

Subject Initials: ---

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

[Back to Form](#)

Date	Location	User	Value	Reason
Sep-16-2020 17:27:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Monica Cooper (pfe mcooper)	Form Created	

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1013

Subject No: 10131176

Generated By: pfe.levissc

Form: ADVERSE EVENT REPORT - Audit Trail

Form Status:

Site Name: (1013) Clinical Neuroscience Solutions Inc.

Subject Initials: ---

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

[Back to Form](#)

Date	Location	User	Value	Reason
Sep-16-2020 17:28:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Monica Cooper (pfe mcooper)	Form Created	

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1013

Subject No: 10131176

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Form: ADVERSE EVENT REPORT - Audit Trail

Form Status:

Site Name: (1013) Clinical Neuroscience Solutions Inc.

Subject Initials: ---

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

[Back to Form](#)

Date	Location	User	Value	Reason
Oct-28-2020 14:48:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe mstephens)	Form Created	

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1013

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Form: ADVERSE EVENT REPORT - Audit Trail

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Site Name: (1013) Clinical Neuroscience Solutions Inc.

Subject Initials: ---

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

[Back to Form](#)

Date	Location	User	Value	Reason
Oct-28-2020 14:49:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe mstephens)	Form Created	

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Form Version: 22-Apr-2020 21:02

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Form: ADVERSE EVENT REPORT - Audit Trail

Form Status:

Site Name: (1013) Clinical Neuroscience Solutions Inc.

Subject Initials: ---

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

[Back to Form](#)

Date	Location	User	Value	Reason
Oct-28-2020 14:50:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe mstephens)	Form Created	

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1013

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Form: ADVERSE EVENT REPORT - Audit Trail

Form Status:

Site Name: (1013) Clinical Neuroscience Solutions Inc.

Subject Initials: ---

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

[Back to Form](#)

Date	Location	User	Value	Reason
Oct-28-2020 14:51:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe mstephens)	Form Created	

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1013

Subject No: 10131176

Generated By: pfe.levissc

Form: ADVERSE EVENT REPORT - Audit Trail

Form Status:

Site Name: (1013) Clinical Neuroscience Solutions Inc.

Subject Initials: ---

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

[Back to Form](#)

Date	Location	User	Value	Reason
Nov-11-2020 10:04:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Scott Salmon (pfe.ssalmon)	Form Created	

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1013

Subject No: 10131176

Generated By: pfe.levissc

Form: ADVERSE EVENT REPORT - Audit Trail

Form Status:

Site Name: (1013) Clinical Neuroscience Solutions Inc.

Subject Initials: ---

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

[Back to Form](#)

Date	Location	User	Value	Reason
Mar-08-2021 15:23:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Scott Salmon (pfe.ssalmon)	Form Created	

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1013

Subject No: 10131176

Generated By: pfe.levissc

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen

Site Name: (1013) Clinical Neuroscience Solutions Inc.

Subject Initials: ---

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

[Back to Form](#)

1. Category:

Date	Location	User	Value	Reason
Sep-02-2020 08:54:45 (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
Sep-02-2020 08:54:45 (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
Sep-22-2020 15:03:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 4: Closed	Response satisfies query
Sep-22-2020 09:44:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 5: Closed	moving query about 'chronic' to new AE for chronic CHF (not in past med hx)
Sep-17-2020 19:30:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Charu Sabharwal (pfe.sabhac)	Query 3: Closed	Clinical_will close query as it was communicated that an SAE fu was submitted to update the term in the safety database to from "lysis of adhesions" to "abdominal adhesions".
Sep-16-2020 17:17:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 5: Answered	New Information
Sep-16-2020 17:17:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 4: Answered	New Information
Sep-16-2020 17:17:27	ACV0PFEINFP6000	auto query	Query 3: Answered	New Information

090177e196ae2f66\Final\Final On: 01-Apr-2021 03:42 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1013

Subject No: 10131176

Generated By: pfe.levissc

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen

Site Name: (1013) Clinical Neuroscience Solutions Inc.

Subject Initials: ---

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

(UTC-05:00) Eastern Time (US & Canada)		(autoquery)		
Sep-16-2020 17:17:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Monica Cooper (pfe.mcooper)	Data Entry: abdominal adhesions	New Information
Sep-16-2020 13:08:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 5: Opened	CLINICAL SAE report includes chronic congestive heart failure (CHF). Medical History does not include CHF; please review and update if CHF is chronic.
Sep-16-2020 12:47:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 4: Opened	Clinical Please report the underlying diagnosis that led to the surgical treatment. Reported in the SAE narrative, the subject had a small bowel obstruction – if this is the underlying diagnosis, please update accordingly
Sep-16-2020 12:47:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 1: Closed	update of query language
Sep-16-2020 09:54:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 1: Reissued:Opened	CLINICAL - to avoid use of a surgical treatment (lysis) consider SAE event term as high grade small bowel obstruction (treated by lysis of adhesions) as reported in SAE followup
Sep-16-2020 09:52:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 2: Closed	Response satisfies query
Sep-15-2020 13:31:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Charu Sabharwal (pfe.sabhac)	Query 3: Opened	Clinical following terms were submitted as SERIOUS to safety db - acute hypoxic

090177e196ae2f66\Final\Final On: 01-Apr-2021 03:42 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1013

Subject No: 10131176

Generated By: pfe.levissc

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen

Site Name: (1013) Clinical Neuroscience Solutions Inc.

Subject Initials: ---

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

				respiratory failure post extubation, anemia, hypokalemia, chronic CHF, altered mental status. 1) Update AE log according. 2) Submit fu SAE with details of clinical course
Sep-15-2020 08:30:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Answered	New Information
Sep-15-2020 08:30:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	New Information
Sep-15-2020 08:30:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe.mstephens)	Data Entry: LYSIS OF ADHESION	New Information
Sep-13-2020 23:53:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 2: Opened	CLINICAL Please clarify the medical issue caused by Abd Adhesions that required hospitalization, e.g. pain, ileus, bowel obstruction or other clinical complaint
Sep-13-2020 23:51:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 1: Opened	CLINICAL Abd Adhesions are not reported on Med Hx; are Abd Adhesions a previously known complication of prior Sm. bowel perforation/resection? If so please add to Medical Hx. If not previously known, include workup in SAE which diagnosed Abd Adhesions.
Sep-02-2020 08:54:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe.mstephens)	Data Entry: ABDOMINAL ADHESIONS	Initial Entry

090177e196ae2f66\Final\Final On: 01-Apr-2021 03:42 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1013

Subject No: 10131176

Generated By: pfe.levissc

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen

Site Name: (1013) Clinical Neuroscience Solutions Inc.

Subject Initials: ---

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

4. Start Date Time:

Date	Location	User	Value	Reason
Sep-02-2020 08:54:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe mstephens)	Data Entry: Aug/29/2020 UNK:UNK	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Oct-05-2020 11:40:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 1: Closed	Response satisfies query
Oct-05-2020 08:56:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Scott Salmon (pfe.ssalmon)	Query 1: Answered	Correct as recorded.
Oct-02-2020 13:40:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 1: Opened	CLINICAL Upon review of the SAE report, stop date for this event was 16 Sept 2020; however this does not match with the AE stop date. Please review, and update accordingly.
Sep-16-2020 17:18:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Monica Cooper (pfe mcooper)	Data Entry: NO End Date Time: Aug/30/2020 UNK:UNK	New Information
Sep-02-2020 08:54:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe mstephens)	Data Entry: YES	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
Sep-02-2020 08:54:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe mstephens)	Data Entry: 3	Initial Entry

7. Is the adverse event serious?

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090177e196ae2f66\Final\Final On: 01-Apr-2021 03:42 (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, Locked, Frozen

Site No: 1013

Site Name: (1013) Clinical Neuroscience Solutions Inc.

Subject No: 10131176

Subject Initials: ---

Generated By: pfe.levissc

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

If Yes, NOTIFY PFIZER IMMEDIATELY.

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

Date	Location	User	Value	Reason
Nov-11-2020 08:56:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 4: Closed	information received
Nov-10-2020 22:49:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 4: Opened	CLINICAL - No update in recent SAE 09Nov20 for COVID test status in Hosp (Yes/No/no info available; if Yes then date/result); this is a request from independent Data Monitoring Committee; please submit to SAE.
Nov-05-2020 14:27:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 3: Closed	Query closed; will follow for SAE update with the requested COVID test info
Nov-03-2020 13:36:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe.mstephens)	Query 3: Answered	CRC WILL FOLLOW UP.
Nov-03-2020 13:26:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Erik Sundgaard (pfe.sundgaardea)	Query 3: Opened	Clinical Followup - COVID testing has not been reported [by CRC] in the SAE submitted to safety. Please submit a follow-up SAE form [#2020339639] to provide whether COVID testing was performed (yes/no) and if yes, the results.
Nov-03-2020 09:36:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 3: Candidate	Clinical Followup - COVID testing has not been reported [by

090177e196ae2f66\Final\Final On: 01-Apr-2021 03:42 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1013

Subject No: 10131176

Generated By: pfe.levissc

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen

Site Name: (1013) Clinical Neuroscience Solutions Inc.

Subject Initials: ---

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

				CRC] in the SAE submitted to safety. Please submit a follow-up SAE form [#2020339639] to provide whether COVID testing was performed (yes/no) and if yes, the results.
Oct-28-2020 00:32:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 2: Closed	Query closed; will follow for SAE update with requested COVID test info
Oct-27-2020 08:02:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe.mstephens)	Query 2: Answered	CRC WILL UPDATE.
Oct-22-2020 22:15:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 2: Opened	Clinical - COVID testing has not been reported in the SAE submitted to safety. Please submit a follow-up SAE form [#2020339639] to provide whether COVID testing was performed (yes/no) and if yes, the results.
Sep-03-2020 06:37:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Sep-02-2020 08:54:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	For AE ABDOMINAL ADHESIONS: Response to "Is the adverse event serious?" is 'Yes' but "Serious Adverse Event Number" is blank.
Sep-02-2020 08:54:45 (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?	Initial Entry

090177e196ae2f66\Final\Final On: 01-Apr-2021 03:42 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1013

Subject No: 10131176

Generated By: pfe.levisss

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen

Site Name: (1013) Clinical Neuroscience Solutions Inc.

Subject Initials: ---

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

Date	Location	User	Value	Reason
Sep-02-2020 08:54:45 (UTC-05:00) Eastern Time (US & Canada)	ACVOPFEINFP6000	Matthew Stephens (pfe mstephens)	Data Entry: NO	Initial Entry

9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Sep-02-2020 09:01:37 (UTC-05:00) Eastern Time (US & Canada)	ACVOPFEINFP6000	Matthew Stephens (pfe mstephens)	Data Entry: NOT RELATED If Not Related to study treatment (s), this event is due to: OTHER If Other, specify:	Transcription Error

090177e196ae2f66\Final\Final On: 01-Apr-2021 03:42 (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, Locked, Frozen

Site No: 1013

Site Name: (1013) Clinical Neuroscience Solutions Inc.

Subject No: 10131176

Subject Initials: ---

Generated By: pfe.lewissc

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

PREVIOUS SURGERY				
Sep-02-2020 08:54:45 (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: OTHER <i>If Other, specify:</i> ABDOMINAL ADHESION S	Initial Entry

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Sep-02-2020 08:54:45 (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
Sep-02-2020 08:54:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe mstephens)	Data Entry: YES	Initial Entry

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Oct-13-2020 18:32:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 1: Closed	Response satisfies query
Oct-13-2020 08:21:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe mstephens)	Query 1: Answered	PER SOURCE PER AE OF ABDOMINAL ADHESIONS NO OTHER NO DRUG TREATMENT REQUIRED.
Oct-12-2020 12:10:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 1: Reissued:Opened	CLINICAL: The query is not about medications; but about non-Drug

090177e196ae2f66\Final\Final On: 01-Apr-2021 03:42 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1013

Subject No: 10131176

Generated By: pfe.levissc

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen

Site Name: (1013) Clinical Neuroscience Solutions Inc.

Subject Initials: ---

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

				treatment including surgery; please review surgery for lysis of adhesions, and update as appropriate.
Oct-12-2020 08:48:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe.mstephens)	Query 1: Answered	PER SOURCE SUBJECT ONLY TOOK CONMEDS FOR AE.
Oct-09-2020 17:58:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 1: Reissued:Opened	Clinical AE unlocked / For this AE, non-drug treatment is answered 'no'; however, subject had surgery for lysis of adhesions. Please review, and update as appropriate

090177e196ae2f66\Final\Final On: 01-Apr-2021 03:42 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1013

Subject No: 10131176

Generated By: pfe.levissc

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen

Site Name: (1013) Clinical Neuroscience Solutions Inc.

Subject Initials: ---

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

[Back to Form](#)

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Oct-09-2020 08:37:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe.mstephens)	Query 1: Answered	PLEASE UNLOCK AE SO DATA CAN BE UPDATED.
Oct-09-2020 07:42:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 1: Opened	CLINICAL For this AE, non-drug treatment is answered 'no'; however, subject had surgery for lysis of adhesions. Please review, and update as appropriate
Sep-02-2020 08:54:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe.mstephens)	Data Entry: NO	Initial Entry

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

Date	Location	User	Value	Reason
Sep-22-2020 06:50:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Ricell Ann Piojo (pfe.quotior)	Query 6: Closed	Response satisfies query
Sep-21-2020 07:58:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe.mstephens)	Query 6: Answered	Changed data per query
Sep-21-2020 06:53:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Ricell Ann Piojo (pfe.quotior)	Query 6: Opened	SAE RECON:AER# 2020339639 ,outcome was recorded as RECOVERING/RESOLVING in Safety DB. Per previous query response RECOVERED/RESOLVED is the correct outcome. Please submit a follow up AEM form to update SDB outcome.
Sep-19-2020 01:47:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Vijay Venugopal (pfe.venugv04)	Query 5: Closed	Response satisfies query

090177e196ae2f66\Final\Final On: 01-Apr-2021 03:42 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1013

Subject No: 10131176

Generated By: pfe.levissc

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen

Site Name: (1013) Clinical Neuroscience Solutions Inc.

Subject Initials: ---

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

Sep-18-2020 10:15:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe mstephens)	Query 5: Answered	CORRECT AS RECORDED.
Sep-18-2020 05:30:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Ricell Ann Piojo (pfe.quitor)	Query 5: Opened	SAE RECON:AER# 2020339639 ,outcome was recorded as RECOVERING/RESOLVING in Safety DB however,updated to RECOVERED/RESOLVED on AE CRF. Please confirm correct outcome.If safety update is required, please submit a follow-up for
Sep-16-2020 17:18:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 4: Closed	Close Auto Query
Sep-16-2020 17:17:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 4: Opened	For AE abdominal adhesions: Response to "What was the outcome of this adverse event?" is 3 but End Date/Time is missing.
Sep-16-2020 17:17:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Monica Cooper (pfe mcooper)	Data Entry: RECOVERED/RESOLVE D	Transcription Error
Sep-15-2020 06:50:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Ricell Ann Piojo (pfe.quitor)	Query 3: Closed	resolved
Sep-14-2020 07:57:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 3: Answered	updated in error.
Sep-14-2020 07:57:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe mstephens)	Data Entry: RECOVERING/RESOLV ING	updated in error.
Sep-14-2020 05:17:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Ricell Ann Piojo (pfe.quitor)	Query 3: Opened	SAE RECON:AER# 2020339639 ,outcome was updated to RECOVERING/RESOLVING in Safety DB however, recorded as NOT RECOVERED/NOT RESOLVED on AE CRF. Please confirm correct

090177e196ae2f66\Final\Final On: 01-Apr-2021 03:42 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1013

Subject No: 10131176

Generated By: pfe.levissc

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen

Site Name: (1013) Clinical Neuroscience Solutions Inc.

Subject Initials: ---

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

				outcome.If safety update is required, please submit a follow-up form
Sep-09-2020 07:33:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Ricell Ann Piojo (pfe.quitor)	Query 1: Closed	data updated. issue resolved
Sep-08-2020 07:57:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Transcription Error
Sep-08-2020 07:57:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe.mstephens)	Data Entry: NOT RECOVERED/NOT RESOLVED	Transcription Error
Sep-07-2020 05:04:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Ricell Ann Piojo (pfe.quitor)	Query 1: Reissued:Opened	SAE RECON 1: Per latest SAE listing,the outcome was updated to NOT RECOVERED/NOT RESOLVED. Please confirm correct outcome for the event. If safety update is required, please submit a follow-up form.
Sep-03-2020 11:32:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Erik Sundgaard (pfe.sundgaardea)	Query 2: Closed	Response satisfies query
Sep-03-2020 07:55:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe.mstephens)	Query 2: Answered	Changed data per query
Sep-03-2020 07:54:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Opened	For AE ABDOMINAL ADHESIONS: Response to "What was the outcome of this adverse event?" is 'Unknown' but End Date/Time is provided or "Is the adverse event still ongoing?" is marked "Yes".
Sep-03-2020 07:54:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Transcription Error
Sep-03-2020 07:54:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe.mstephens)	Data Entry: UNKNOWN	Transcription Error

090177e196ae2f66\Final\Final On: 01-Apr-2021 03:42 (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, Locked, Frozen

Site No: 1013

Site Name: (1013) Clinical Neuroscience Solutions Inc.

Subject No: 10131176

Subject Initials: ---

Generated By: pfe.levissc

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

Sep-03-2020 06:50:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Ricell Ann Piojo (pfe.quitor)	Query 1: Opened	SAE RECON:AER# 2020319554 ,outcome was reported as UNKNOWN in SAE form however, recorded as RECOVERING/RESOLVING on AE CRF. Please confirm correct outcome. If safety update is required, please submit a follow-up form.
Sep-02-2020 08:54:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe.mstephens)	Data Entry: RECOVERING/RESOLV ING	Initial Entry

14. Did the adverse event cause the subject to be discontinued from the study?				
Date	Location	User	Value	Reason
Sep-21-2020 20:50:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lingyan Zuo (pfe.zuol02)	Query 2: Closed	Response satisfies query
Sep-18-2020 10:14:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Answered	Transcription Error
Sep-18-2020 10:14:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Sep-18-2020 10:14:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe.mstephens)	Data Entry: NO	Transcription Error
Sep-17-2020 19:43:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lingyan Zuo (pfe.zuol02)	Query 2: Opened	ClinQuery: abdominal adhesions: 'Did the AE cause study discontinuation' marked as yes, however, EOT and FUP are blank. Please review/update. Thanks
Sep-16-2020 17:18:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Did the adverse event cause the subject to be discontinued from the study?' is Yes but neither

090177e196ae2f66\Final\Final On: 01-Apr-2021 03:42 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1013

Subject No: 10131176

Generated By: pfe.lewissc

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen

Site Name: (1013) Clinical Neuroscience Solutions Inc.

Subject Initials: ---

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

				DISPOSITION - TREATMENT form nor DISPOSITION - FOLLOW-UP has Status as "ADVERSE EVENT". Please review and update as appropriate.
Sep-16-2020 17:18:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Monica Cooper (pfe.mcooper)	Data Entry: YES	New Information
Sep-02-2020 08:54:45 (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
Sep-03-2020 06:37:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Ricell Ann Piojo (pfe.quoter)	Data Entry: 2020339639	Initial Entry

090177e196ae2f66\Final\Final On: 01-Apr-2021 03:42 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1013

Subject No: 10131176

Generated By: pfe.levisse

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen

Site Name: (1013) Clinical Neuroscience Solutions Inc.

Subject Initials: ---

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

[Back to Form](#)

1. Category:

Date	Location	User	Value	Reason
Sep-16-2020 17:22:12 (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
Sep-16-2020 17:22:12 (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
Oct-08-2020 00:21:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 1: Closed	closed pending records
Oct-05-2020 08:32:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe.mstephens)	Query 1: Answered	CRC WILL UPDATE AS NECESSARY
Oct-02-2020 13:51:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 1: Opened	ClinQuery If information for a safety update on hospital lab tests (renal function, potassium) and other information about the clinical course of additional AEs (mental status) is available, please submit a follow-up form.
Sep-16-2020 17:22:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Monica Cooper (pfe.mcooper)	Data Entry: altered mental status	Initial Entry

4. Start Date Time:

090177e196ae2f66\Final\Final On: 01-Apr-2021 03:42 (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, Locked, Frozen

Site No: 1013

Site Name: (1013) Clinical Neuroscience Solutions Inc.

Subject No: 10131176

Subject Initials: ---

Generated By: pfe.levissc

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

Date	Location	User	Value	Reason
Sep-16-2020 17:22:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Monica Cooper (pfe.mcooper)	Data Entry: Aug/29/2020 UNK:UNK	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Sep-16-2020 17:22:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Monica Cooper (pfe.mcooper)	Data Entry: NO End Date Time: Sep/16/2020 UNK:UNK	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
Sep-16-2020 17:22:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Monica Cooper (pfe.mcooper)	Data Entry: 3	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
Oct-31-2020 09:47:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Ricell Ann Piojo (pfe.quitor)	Query 2: Closed	Response satisfies query
Oct-31-2020 06:45:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Nikita Singh (pfe.singhn98)	Query 3: Closed	Relevant SAE Recon query present.
Oct-30-2020 09:04:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe.mstephens)	Query 3: Answered	DATA HAS BEEN CHANGED TO NO.
Oct-30-2020 08:55:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Sonal K (pfe.ks66)	Query 3: Opened	For AE altered mental status: Response to "Is the adverse event serious?" is 'No' but "Serious Adverse Event Number" is present.

090177e196ae2f66\Final\Final On: 01-Apr-2021 03:42 (GMT)

Header Text: c4591001 Visit: Logs - Unscheduled Form Version: 22-Apr-2020 21:02 Site No: 1013 Subject No: 10131176 Generated By: pfe.levissc				
Form: ADVERSE EVENT REPORT - eCRF Audit Trail History Form Status: Data Complete, Locked, Frozen Site Name: (1013) Clinical Neuroscience Solutions Inc. Subject Initials: --- Generated Time (GMT): 29-Mar-2021 04:21				
Oct-30-2020 08:07:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 3: Candidate	For AE altered mental status: Response to "Is the adverse event serious?" is 'No' but "Serious Adverse Event Number" is present.
Oct-30-2020 08:07:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Answered	Changed Information
Oct-30-2020 08:07:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe mstephens)	Data Entry: NO	Changed Information
Oct-30-2020 01:23:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Ricell Ann Piojo (pfe.quiror)	Query 2: Reissued:Opened	SAE RECON 1: Form is now unfrozen. Please update accordingly
Oct-29-2020 10:02:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe mstephens)	Query 2: Answered	PLEASE UNLOCK AE SO DATA CAN BE UPDATED.
Oct-29-2020 06:51:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Ricell Ann Piojo (pfe.quiror)	Query 2: Opened	SAE RECON:AER#2020339639 Altered mental status(Onset date:29Aug2020) is not reported to Safety database but marked serious on AE CRF. Confirm seriousness and report to Pfizer immediately. If this event is not serious, downgrade the event on AE CRF
Sep-17-2020 22:12:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Sep-16-2020 17:22:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	For AE altered mental status: Response to "Is the adverse event serious?" is 'Yes' but "Serious Adverse Event Number" is blank.
Sep-16-2020 17:22:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Monica Cooper (pfe mcooper)	Data Entry: YES Is this serious event associat ed with congenital anomaly or birth defect?	Initial Entry

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1013

Subject No: 10131176

Generated By: pfe.levissc

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen

Site Name: (1013) Clinical Neuroscience Solutions Inc.

Subject Initials: ---

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

Date	Location	User	Value	Reason
Sep-16-2020 17:22:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Monica Cooper (pfe.mcooper)	Data Entry: NO	Initial Entry

9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Sep-23-2020 09:17:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Ahmed Hassan (pfe.hassaa38)	Query 1: Closed	Response satisfies query
Sep-22-2020 16:27:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Changed Information
Sep-22-2020 16:27:53	ACV0PFEINFP6000	Matthew	Data Entry:	Changed Information

090177e196ae2f66\Final\Final On: 01-Apr-2021 03:42 (GMT)

Header Text: c4591001**Visit:** Logs - Unscheduled**Form Version:** 22-Apr-2020 21:02**Site No:** 1013**Subject No:** 10131176**Generated By:** pfe.lewissc**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History**Form Status:** Data Complete, Locked, Frozen**Site Name:** (1013) Clinical Neuroscience Solutions Inc.**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 04:21

(UTC-05:00) Eastern Time (US & Canada)		Stephens (pfe.mstephens)	NOT RELATED If Not Related to study treatment (s), this event is due to: CONCOMITANT NON-DRUG TREATMENT	
Sep-22-2020 09:53:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 2: Closed	error in wording
Sep-22-2020 09:52:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 2: Opened	ClinQuery: SAE narrative states subject was septic; consider if this should be reported as an AE, and if sepsis (versus surgical procedure) could be causative for some of these symptoms, particularly if present pre-operatively
Sep-21-2020 21:50:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lingyan Zuo (pfe.zuol02)	Query 1: Opened	ClinQuery: altered mental status: Question 9 states this is related to 'prior surgery'. Please can you review and update as appropriate? Thanks
Sep-16-2020 17:22:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Monica Cooper (pfe.mcooper)	Data Entry: NOT RELATED If Not Related to study treatment (s), this event is due to: OTHER <i>If Other, specify:</i> prior surgery	Initial Entry

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Sep-16-2020 17:22:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Monica Cooper (pfe.mcooper)	Data Entry: NOT APPLICABLE	Initial Entry

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1013

Subject No: 10131176

Generated By: pfe.levissc

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen

Site Name: (1013) Clinical Neuroscience Solutions Inc.

Subject Initials: ---

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

11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
Sep-16-2020 17:22:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Monica Cooper (pfe.mcooper)	Data Entry: NO	Initial Entry

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Sep-16-2020 17:22:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Monica Cooper (pfe.mcooper)	Data Entry: NO	Initial Entry

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

Date	Location	User	Value	Reason
Sep-16-2020 17:22:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Monica Cooper (pfe.mcooper)	Data Entry: RECOVERED/RESOLVED	Initial Entry

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

Date	Location	User	Value	Reason
Sep-16-2020 17:22:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Monica Cooper (pfe.mcooper)	Data Entry: NO	Initial Entry

15. Serious Adverse Event Number: For Pfizer Use Only

Date	Location	User	Value	Reason
Nov-01-2020 10:01:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Ricell Ann Piojo (pfe.QUITOR)	Data Entry:	downgraded to non serious
Sep-17-2020 22:12:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Ricell Ann Piojo (pfe.QUITOR)	Data Entry: 2020339639	Initial Entry

090177e196ae2f66\Final\Final On: 01-Apr-2021 03:42 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1013

Subject No: 10131176

Generated By: pfe.lewissc

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen

Site Name: (1013) Clinical Neuroscience Solutions Inc.

Subject Initials: ---

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

[Back to Form](#)

1. Category:

Date	Location	User	Value	Reason
Sep-16-2020 17:23:38 (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
Sep-16-2020 17:23:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 3	Initial Entry

3. Adverse Event:

(If possible specify diagnosis, not individual symptoms)

Date	Location	User	Value	Reason
Sep-16-2020 17:23:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Monica Cooper (pfe.mcooper)	Data Entry: acute hypoxic respiratory failure	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason
Nov-07-2020 09:50:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Ricell Ann Piojo (pfe.quitor)	Query 1: Closed	Response satisfies query
Nov-07-2020 09:12:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Changed Information
Nov-07-2020 09:12:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Rebecca Klipper (pfe.rklipper)	Data Entry: Aug/30/2020 UNK:UNK	Changed Information
Nov-06-2020 05:20:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Ricell Ann Piojo (pfe.quitor)	Query 1: Opened	SAE RECON: AER#2020339639 onset date was updated to 30Aug2020 in SDB however, recorded as 29Aug2020 on AE CRF. Please confirm

090177e196ae2f66\Final\Final On: 01-Apr-2021 03:42 (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, Locked, Frozen

Site No: 1013

Site Name: (1013) Clinical Neuroscience Solutions Inc.

Subject No: 10131176

Subject Initials: ---

Generated By: pfe.levisss

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

				correct Onset Date. If safety update is required, please submit a follow-up SAE form.
Sep-16-2020 17:23:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Monica Cooper (pfe mcooper)	Data Entry: Aug/29/2020 UNK:UNK	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Sep-16-2020 17:23:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Monica Cooper (pfe.mcooper)	Data Entry: NO End Date Time: Sep/11/2020 UNK:UNK	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
Sep-16-2020 17:23:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Monica Cooper (pfe.mcooper)	Data Entry: 3	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
Sep-17-2020 22:12:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Sep-16-2020 17:23:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	For AE acute hypoxic respiratory failure: Response to "Is the adverse event serious?" is 'Yes' but "Serious Adverse Event Number" is blank.

090177e196ae2f66\Final\Final On: 01-Apr-2021 03:42 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1013

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Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen

Site Name: (1013) Clinical Neuroscience Solutions Inc.

Subject Initials: ---

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

Sep-16-2020 17:23:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Monica Cooper (pfe mcooper)	<p>Data Entry: YES</p> <p>Is this serious event associated with congenital anomaly or birth defect?</p> <p>NO</p> <p>Did this serious event result in death?</p> <p>NO</p> <p>Did this serious event require or prolong hospitalization?</p> <p>YES</p> <p>Did this serious event result in persistent or significant disability/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>	Initial Entry
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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
Sep-16-2020 17:23:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Monica Cooper (pfe.mcooper)	<p>Data Entry: NO</p>	Initial Entry

9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Sep-16-2020 17:23:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Monica Cooper (pfe mcooper)	<p>Data Entry: NOT RELATED</p> <p>If Not Related to study treatment(s)</p>	Initial Entry

090177e196ae2f66\Final\On: 01-Apr-2021 03:42 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1013

Subject No: 10131176

Generated By: pfe.levissc

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen

Site Name: (1013) Clinical Neuroscience Solutions Inc.

Subject Initials: ---

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

) , this event is due to: OTHER If Other, specify: prior surgery	
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10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Sep-16-2020 17:23:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Monica Cooper (pfe.mcooper)	Data Entry: NOT APPLICABLE	Initial Entry

11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
Sep-16-2020 17:23:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Monica Cooper (pfe.mcooper)	Data Entry: NO	Initial Entry

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Sep-16-2020 17:23:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Monica Cooper (pfe.mcooper)	Data Entry: NO	Initial Entry

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

Date	Location	User	Value	Reason
Sep-16-2020 17:23:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Monica Cooper (pfe.mcooper)	Data Entry: RECOVERED/RESOLVED	Initial Entry

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

Date	Location	User	Value	Reason
Sep-16-2020 17:23:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Monica Cooper (pfe.mcooper)	Data Entry: NO	Initial Entry

15. Serious Adverse Event Number: For Pfizer Use Only

Date	Location	User	Value	Reason

090177e196ae2f66\Final\Final On: 01-Apr-2021 03:42 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1013

Subject No: 10131176

Generated By: pfe.levissc

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen

Site Name: (1013) Clinical Neuroscience Solutions Inc.

Subject Initials: ---

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

Sep-17-2020 22:12:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Ricell Ann Piojo (pfe.quitor)	<u>Data Entry:</u> 2020339639	Initial Entry
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Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1013

Subject No: 10131176

Generated By: pfe.levisse

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen

Site Name: (1013) Clinical Neuroscience Solutions Inc.

Subject Initials: ---

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

[Back to Form](#)

1. Category:

Date	Location	User	Value	Reason
Sep-16-2020 17:24:39 (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
Sep-16-2020 17:24:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 4	Initial Entry

3. Adverse Event:

(If possible specify diagnosis, not individual symptoms)

Date	Location	User	Value	Reason
Nov-11-2020 10:47:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 6: Closed	Query closed; will follow for SAE update with requested term split
Nov-11-2020 10:46:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 5: Closed	Response satisfies query
Nov-11-2020 10:02:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe.mstephens)	Query 5: Answered	Changed data per query
Nov-11-2020 10:02:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe.mstephens)	Query 6: Answered	Changed data per query
Nov-10-2020 22:36:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 6: Opened	CLINICAL - SAE report on 09Nov20 has LVH included with CHF term; although mild LVH appears to be a non-serious event. Also 2 terms cannot be reported together; please separate in a SAE update.

090177e196ae2f66\Final\Final On: 01-Apr-2021 03:42 (GMT)

Header Text: c4591001**Visit:** Logs - Unscheduled**Form Version:** 22-Apr-2020 21:02**Site No:** 1013**Subject No:** 10131176**Generated By:** pfe.levissc**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History**Form Status:** Data Complete, Locked, Frozen**Site Name:** (1013) Clinical Neuroscience Solutions Inc.**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 04:21

Nov-10-2020 22:34:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 5: Opened	Clinical On review of the SAE (#2020339639, an event of Concentric Left Ventricular Hypertrophy was reported, not yet an AE. Please review LVH for safety and report as a SEPARATE AE on the CRF accordingly.
Nov-10-2020 22:32:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 4: Closed	reword
Nov-10-2020 22:30:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 4: Opened	Clinical On review of the SAE (#2020339639, an event of Concentric Left Ventricular Hypertrophy was reported, yet it does not appear in the CRF. Please review for safety and update AE log CRF accordingly.
Nov-06-2020 05:07:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Ricell Ann Piojo (pfe.quitor)	Query 3: Closed	sdb term updated
Nov-04-2020 23:54:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Ricell Ann Piojo (pfe.quitor)	Query 3: Opened	SAE RECON: AER#2020339639 Event term in Safety database has been updated to "CHRONIC congestive heart failure" while retained as CHF in AE log. Updates should be reflected in InForm. Please review term and update accordingly
Oct-08-2020 12:12:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 2: Closed	will review next SAE safety submission

Header Text: c4591001**Visit:** Logs - Unscheduled**Form Version:** 22-Apr-2020 21:02**Site No:** 1013**Subject No:** 10131176**Generated By:** pfe.levissc**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History**Form Status:** Data Complete, Locked, Frozen**Site Name:** (1013) Clinical Neuroscience Solutions Inc.**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 04:21

Oct-08-2020 07:57:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe.mstephens)	Query 2: Answered	CRC WILL UPDATE WITH SAFETY FOLLOW UP.
Oct-08-2020 00:13:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 2: Reissued:Opened	CLINICAL - the reported SAE term is still 'Chronic CHF'; however, the event is new CHF with onset date of 29 Aug 2020. Please update SAE term with a safety followup
Oct-05-2020 09:00:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Scott Salmon (pfe.ssalmon)	Query 2: Answered	Changed in source.
Oct-02-2020 13:42:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 2: Opened	ClinQuery - AE term of Congestive Heart Failure (new event, based on no past Med Hx) does not match the SAE term of Chronic Congestive Failure. Please review, and if a safety update is required, please submit a follow-up form.
Sep-22-2020 15:04:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 1: Closed	Response satisfies query
Sep-22-2020 14:10:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Changed Information
Sep-22-2020 14:10:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe.mstephens)	Data Entry: CONGESTIVE HEART FAILUR E	Changed Information
Sep-22-2020 09:58:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 1: Opened	ClinQuery please clarify the basis for 'Chronic' in this AE term, as CHF is not in medical history as a prior condition & this new event lasted 17 days; modify term as

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1013

Subject No: 10131176

Generated By: pfe.levissc

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen

Site Name: (1013) Clinical Neuroscience Solutions Inc.

Subject Initials: ---

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

				required
Sep-16-2020 17:24:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Monica Cooper (pfe.mcooper)	Data Entry: chronic congestive heart failure	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason
Nov-07-2020 09:51:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Ricell Ann Piojo (pfe.quitor)	Query 1: Closed	Response satisfies query
Nov-07-2020 09:13:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Changed Information
Nov-07-2020 09:13:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Rebecca Klipper (pfe.rklipper)	Data Entry: Aug/30/2020 UNK:UNK	Changed Information
Nov-06-2020 05:15:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Ricell Ann Piojo (pfe.quitor)	Query 1: Opened	SAE RECON: AER#2020339639 onset date was updated to 30Aug2020 in SDB however, recorded as 29Aug2020 on AE CRF. Please confirm correct Onset Date. If safety update is required, please submit a follow-up SAE form.
Sep-16-2020 17:24:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Monica Cooper (pfe.mcooper)	Data Entry: Aug/29/2020 UNK:UNK	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Sep-16-2020 17:24:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Monica Cooper (pfe.mcooper)	Data Entry: NO End Date Time: Sep/16/2020 UNK:UNK	Initial Entry

6. Toxicity Grade:

090177e196ae2f66\Final\Final On: 01-Apr-2021 03:42 (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, Locked, Frozen

Site No: 1013

Site Name: (1013) Clinical Neuroscience Solutions Inc.

Subject No: 10131176

Subject Initials: ---

Generated By: pfe.levissc

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

Date	Location	User	Value	Reason
Sep-16-2020 17:24:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Monica Cooper (pfe.mcooper)	Data Entry: 3	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
Nov-11-2020 13:11:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 3: Closed	Query closed; will follow for SAE update with the requested COVID test info
Nov-11-2020 11:17:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Ute Frantz (pfe frantu)	Query 2: Deleted	Query is invalid or does not apply
Nov-11-2020 10:47:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe mstephens)	Query 3: Answered	crc will update
Nov-11-2020 10:43:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 3: Reissued:Opened	CLINICAL - thank you for your reply. Please submit the CHANGE (to non-serious) for all 5 [CHF, Sepsis, Anemia, hypokalemia, acute renal failure] as a safety update, so SAE report will also have non-serious
Nov-11-2020 09:57:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe mstephens)	Query 3: Answered	CORRECT AS RECORDED. PER CRC AE EVENT WAS CHANGED TO A NON SAE.
Nov-10-2020 22:38:30 (UTC-05:00) Eastern	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 3: Opened	CLINICAL - Event of CHF is reported as

090177e196ae2f66\Final\Final On: 01-Apr-2021 03:42 (GMT)

Header Text: c4591001 Visit: Logs - Unscheduled Form Version: 22-Apr-2020 21:02 Site No: 1013 Subject No: 10131176 Generated By: pfe.levissc				
		Form: ADVERSE EVENT REPORT - eCRF Audit Trail History Form Status: Data Complete, Locked, Frozen Site Name: (1013) Clinical Neuroscience Solutions Inc. Subject Initials: --- Generated Time (GMT): 29-Mar-2021 04:21		
Time (US & Canada)				non-serious; however, SAE report as of 09Nov20 has CHF as serious. Please review, and harmonize serious status; updating where appropriate.
Nov-10-2020 12:51:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Candidate	For AE CONGESTIVE HEART FAILURE: Response to "Is the adverse event serious?" is 'No' but "Serious Adverse Event Number" is present.
Nov-10-2020 12:51:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Scott Salmon (pfe.ssalmon)	Data Entry: NO	Changed Information
Sep-17-2020 22:16:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Sep-16-2020 17:24:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	For AE chronic congestive heart failure: Response to "Is the adverse event serious?" is 'Yes' but "Serious Adverse Event Number" is blank.
Sep-16-2020 17:24:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Monica Cooper (pfe.mcooper)	Data Entry: YES Is this serious event associated with congenital anomaly or birth defect? NO Did this serious event result in death? NO Did this serious event require or prolong hospitalization?	Initial Entry

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1013

Subject No: 10131176

Generated By: pfe.lewissc

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen

Site Name: (1013) Clinical Neuroscience Solutions Inc.

Subject Initials: ---

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

			<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>	
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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
Sep-16-2020 17:24:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Monica Cooper (pfe.mcooper)	Data Entry: NO	Initial Entry

9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Sep-16-2020 17:24:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Monica Cooper (pfe mcooper)	Data Entry: NOT RELATED If Not Related to study treatment(s), this event is due to: OTHER <i>If Other, specify:</i> prior surgery	Initial Entry

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Sep-16-2020 17:24:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Monica Cooper (pfe.mcooper)	Data Entry: NOT APPLICABLE	Initial Entry

090177e196ae2f66\Final\Final On: 01-Apr-2021 03:42 (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, Locked, Frozen

Site No: 1013

Site Name: (1013) Clinical Neuroscience Solutions Inc.

Subject No: 10131176

Subject Initials: ---

Generated By: pfe.levissc

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

11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
Sep-16-2020 17:24:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Monica Cooper (pfe.mcooper)	Data Entry: NO	Initial Entry

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Sep-16-2020 17:24:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Monica Cooper (pfe.mcooper)	Data Entry: NO	Initial Entry

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

Date	Location	User	Value	Reason
Sep-16-2020 17:24:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Monica Cooper (pfe.mcooper)	Data Entry: RECOVERED/RESOLVED	Initial Entry

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

Date	Location	User	Value	Reason
Sep-16-2020 17:24:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Monica Cooper (pfe.mcooper)	Data Entry: NO	Initial Entry

15. Serious Adverse Event Number: For Pfizer Use Only

Date	Location	User	Value	Reason
Nov-13-2020 05:49:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Ricell Ann Piojo (pfe.QUITOR)	Data Entry:	downgraded to non serious
Sep-17-2020 22:16:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Ricell Ann Piojo (pfe.QUITOR)	Data Entry: 2020339639	Initial Entry

090177e196ae2f66\Final\Final On: 01-Apr-2021 03:42 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1013

Subject No: 10131176

Generated By: pfe.lewissc

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen

Site Name: (1013) Clinical Neuroscience Solutions Inc.

Subject Initials: ---

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

[Back to Form](#)

1. Category:

Date	Location	User	Value	Reason
Sep-16-2020 17:25:41 (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
Sep-16-2020 17:25:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 5	Initial Entry

3. Adverse Event:

(If possible specify diagnosis, not individual symptoms)

Date	Location	User	Value	Reason
Sep-16-2020 17:25:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Monica Cooper (pfe.mcooper)	Data Entry: hypokalemia	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason
Nov-07-2020 09:48:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Ricell Ann Piojo (pfe.quitor)	Query 1: Closed	Response satisfies query
Nov-07-2020 09:14:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Changed Information
Nov-07-2020 09:14:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Rebecca Klipper (pfe.rklipper)	Data Entry: Aug/30/2020 UNK:UNK	Changed Information
Nov-06-2020 05:22:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Ricell Ann Piojo (pfe.quitor)	Query 1: Opened	SAE RECON: AER#2020339639 onset date was updated to 30Aug2020 in SDB however, recorded as 29Aug2020 on AE CRF. Please confirm

090177e196ae2f66\Final\Final On: 01-Apr-2021 03:42 (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, Locked, Frozen

Site No: 1013

Site Name: (1013) Clinical Neuroscience Solutions Inc.

Subject No: 10131176

Subject Initials: ---

Generated By: pfe.levisss

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

				correct Onset Date. If safety update is required, please submit a follow-up SAE form.
Sep-16-2020 17:25:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Monica Cooper (pfe mcooper)	Data Entry: Aug/29/2020 UNK:UNK	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Sep-16-2020 17:25:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Monica Cooper (pfe.mcooper)	Data Entry: NO End Date Time: Sep/16/2020 UNK:UNK	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
Sep-16-2020 17:25:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Monica Cooper (pfe.mcooper)	Data Entry: 3	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
Nov-11-2020 11:18:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Ute Frantz (pfe frantu)	Query 2: Deleted	Query is invalid or does not apply
Nov-11-2020 10:44:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 3: Closed	Response satisfies query
Nov-11-2020 10:03:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe mstephens)	Query 3: Answered	CORRECT AS RECORDED PER CRC. DATA WAS CHANGED FROM SAE TO AE

090177e196ae2f66\Final\Final On: 01-Apr-2021 03:42 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1013

Subject No: 10131176

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Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen

Site Name: (1013) Clinical Neuroscience Solutions Inc.

Subject Initials: ---

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

				EVENT.
Nov-10-2020 22:39:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 3: Opened	CLINICAL - Event of hypokalemia is reported as non-serious; however, SAE report as of 09Nov20 has hypokalemia as serious. Please review, and harmonize serious status; updating where appropriate.
Nov-10-2020 12:49:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Candidate	For AE hypokalemia: Response to "Is the adverse event serious?" is 'No' but "Serious Adverse Event Number" is present.
Nov-10-2020 12:49:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Scott Salmon (pfe.ssalmon)	Data Entry: NO	Initial Entry
Nov-10-2020 12:49:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Scott Salmon (pfe.ssalmon)	Data Entry:	Changed Information
Sep-17-2020 22:16:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Sep-16-2020 17:25:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	For AE hypokalemia: Response to "Is the adverse event serious?" is 'Yes' but "Serious Adverse Event Number" is blank.
Sep-16-2020 17:25:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Monica Cooper (pfe mcooper)	Data Entry: YES Is this serious event associated with congenital anomaly or birth defect? NO	Initial Entry

090177e196ae2f66\Final\Final On: 01-Apr-2021 03:42 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1013

Subject No: 10131176

Generated By: pfe.lewissc

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen

Site Name: (1013) Clinical Neuroscience Solutions Inc.

Subject Initials: ---

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

			<p>Did this serious event result in death?</p> <p>NO</p> <p>Did this serious event require or prolong hospitalization?</p> <p>YES</p> <p>Did this serious event result in persistent or significant disability/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>	
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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
Sep-16-2020 17:25:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Monica Cooper (pfe.mcooper)	Data Entry: NO	Initial Entry

9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Sep-16-2020 17:25:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Monica Cooper (pfe.mcooper)	Data Entry: NOT RELATED If Not Related to study treatment(s), this event is due to: OTHER <i>If Other, specify:</i> prior surgery	Initial Entry

090177e196ae2f66\Final\Final On: 01-Apr-2021 03:42 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1013

Subject No: 10131176

Generated By: pfe.levissc

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen

Site Name: (1013) Clinical Neuroscience Solutions Inc.

Subject Initials: ---

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

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Sep-16-2020 17:25:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Monica Cooper (pfe.mcooper)	Data Entry: NOT APPLICABLE	Initial Entry

11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
Sep-16-2020 17:25:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Monica Cooper (pfe.mcooper)	Data Entry: NO	Initial Entry

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Sep-16-2020 17:25:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Monica Cooper (pfe.mcooper)	Data Entry: NO	Initial Entry

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

Date	Location	User	Value	Reason
Sep-16-2020 17:25:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Monica Cooper (pfe.mcooper)	Data Entry: RECOVERED/RESOLVED	Initial Entry

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

Date	Location	User	Value	Reason
Sep-16-2020 17:25:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Monica Cooper (pfe.mcooper)	Data Entry: NO	Initial Entry

15. Serious Adverse Event Number: For Pfizer Use Only

Date	Location	User	Value	Reason
Nov-13-2020 05:50:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Ricell Ann Piojo (pfe.quitor)	Data Entry:	downgraded to non serious
Sep-17-2020 22:16:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Ricell Ann Piojo (pfe.quitor)	Data Entry: 2020339639	Initial Entry

090177e196ae2f66\Final\Final On: 01-Apr-2021 03:42 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1013

Subject No: 10131176

Generated By: pfe.levisse

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen

Site Name: (1013) Clinical Neuroscience Solutions Inc.

Subject Initials: ---

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

[Back to Form](#)

1. Category:

Date	Location	User	Value	Reason
Sep-16-2020 17:26:28 (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
Sep-16-2020 17:26:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 6	Initial Entry

3. Adverse Event:

(If possible specify diagnosis, not individual symptoms)

Date	Location	User	Value	Reason
Sep-21-2020 20:50:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lingyan Zuo (pfe.zuol02)	Query 1: Closed	Response satisfies query
Sep-18-2020 10:36:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe.mstephens)	Query 1: Answered	PER CRC NO INFORMATION HAS BEE RECEIVED AS OF YET. WILL UPDATE AS INFORMATION IS GIVEN TO SITE.
Sep-17-2020 19:53:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lingyan Zuo (pfe.zuol02)	Query 1: Opened	ClinQuery: anemia: Please can you confirm if subject was given any bloods as a result of this AE?
Sep-16-2020 17:26:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Monica Cooper (pfe.mcooper)	Data Entry: anemia	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason
Nov-07-2020 09:52:06 (UTC-05:00) Eastern	ACV0PFEINFP6000	Ricell Ann Piojo	Query 1: Closed	Response satisfies query

090177e196ae2f66\Final\Final On: 01-Apr-2021 03:42 (GMT)

Header Text: c4591001**Visit:** Logs - Unscheduled**Form Version:** 22-Apr-2020 21:02**Site No:** 1013**Subject No:** 10131176**Generated By:** pfe.levissc**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History**Form Status:** Data Complete, Locked, Frozen**Site Name:** (1013) Clinical Neuroscience Solutions Inc.**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 04:21

Time (US & Canada)		(pfe.quitor)		
Nov-07-2020 09:14:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Changed Information
Nov-07-2020 09:14:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Rebecca Klipper (pfe.rklipper)	Data Entry: Aug/30/2020 UNK:UNK	Changed Information
Nov-06-2020 05:11:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Ricell Ann Piojo (pfe.quitor)	Query 1: Opened	SAE RECON: AER#2020339639 onset date was updated to 30Aug2020 in SDB however, recorded as 29Aug2020 on AE CRF. Please confirm correct Onset Date. If safety update is required, please submit a follow-up SAE form.
Sep-16-2020 17:26:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Monica Cooper (pfe.mcooper)	Data Entry: Aug/29/2020 UNK:UNK	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Sep-16-2020 17:26:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Monica Cooper (pfe.mcooper)	Data Entry: NO End Date Time: Sep/16/2020 UNK:UNK	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
Sep-16-2020 17:26:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Monica Cooper (pfe.mcooper)	Data Entry: 3	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**

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, Locked, Frozen

Site No: 1013

Site Name: (1013) Clinical Neuroscience Solutions Inc.

Subject No: 10131176

Subject Initials: ---

Generated By: pfe.levissc

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

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

Date	Location	User	Value	Reason
Nov-11-2020 11:19:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Ute Frantz (pfe.frantu)	Query 2: Deleted	Query is invalid or does not apply
Nov-11-2020 10:44:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 3: Closed	Response satisfies query
Nov-11-2020 10:03:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe.mstephens)	Query 3: Answered	CORRECT AS RECORDED PER CRC. EVENT WAS CHANGED FROM SAE TO AE.
Nov-10-2020 22:40:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 3: Opened	CLINICAL - Event of anemia is reported as non-serious; however, SAE report as of 09Nov20 has anemia as serious. Please review, and harmonize serious status; updating where appropriate.
Nov-10-2020 12:50:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Candidate	For AE anemia: Response to "Is the adverse event serious?" is 'No' but "Serious Adverse Event Number" is present.
Nov-10-2020 12:50:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Scott Salmon (pfe.ssalmon)	Data Entry: NO	Changed Information
Sep-18-2020 05:46:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Sep-16-2020 17:26:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	For AE anemia: Response to "Is the adverse event serious?" is 'Yes' but "Serious Adverse Event Number" is

090177e196ae2f66\Final\Final On: 01-Apr-2021 03:42 (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, Locked, Frozen

Site No: 1013

Site Name: (1013) Clinical Neuroscience Solutions Inc.

Subject No: 10131176

Subject Initials: ---

Generated By: pfe.lewissc

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

				blank.
Sep-16-2020 17:26:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Monica Cooper (pfe mcooper)	<p>Data Entry: YES</p> <p>Is this serious event associated with congenital anomaly or birth defect?</p> <p>NO</p> <p>Did this serious event result in death?</p> <p>NO</p> <p>Did this serious event require or prolong hospitalization?</p> <p>YES</p> <p>Did this serious event result in persistent or significant disability/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>	Initial Entry

8. Is this adverse event the result of a study Medication Error?
If Yes, record the type of medication error on the Medication Error Log.

Date	Location	User	Value	Reason
Sep-16-2020 17:26:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Monica Cooper (pfe.mcooper)	Data Entry: NO	Initial Entry

9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Sep-16-2020 17:26:28	ACV0PFEINFP6000	Monica	Data Entry:	Initial Entry

090177e196ae2f66\Final\Final On: 01-Apr-2021 03:42 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1013

Subject No: 10131176

Generated By: pfe.levissc

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen

Site Name: (1013) Clinical Neuroscience Solutions Inc.

Subject Initials: ---

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

(UTC-05:00) Eastern Time (US & Canada)		Cooper (pfe.mcooper)	NOT RELATED If Not Related to study treatment(s) , this event is due to: OTHER If Other, specify: prior surgery	
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10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Sep-16-2020 17:26:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Monica Cooper (pfe.mcooper)	Data Entry: NOT APPLICABLE	Initial Entry

11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
Sep-16-2020 17:26:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Monica Cooper (pfe.mcooper)	Data Entry: NO	Initial Entry

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Sep-16-2020 17:26:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Monica Cooper (pfe.mcooper)	Data Entry: NO	Initial Entry

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

Date	Location	User	Value	Reason
Sep-16-2020 17:26:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Monica Cooper (pfe.mcooper)	Data Entry: RECOVERED/RESOLVED	Initial Entry

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

Date	Location	User	Value	Reason
Sep-16-2020 17:26:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Monica Cooper (pfe.mcooper)	Data Entry: NO	Initial Entry

15. Serious Adverse Event Number: For Pfizer Use Only

090177e196ae2f66\Final\Final On: 01-Apr-2021 03:42 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1013

Subject No: 10131176

Generated By: pfe.levissc

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen

Site Name: (1013) Clinical Neuroscience Solutions Inc.

Subject Initials: ---

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

Date	Location	User	Value	Reason
Nov-13-2020 05:51:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Ricell Ann Piojo (pfe.quitor)	Data Entry:	downgraded to non serious
Sep-18-2020 05:46:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Ricell Ann Piojo (pfe.quitor)	Data Entry: 2020339639	Initial Entry

090177e196ae2f66\Final\Final On: 01-Apr-2021 03:42 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1013

Subject No: 10131176

Generated By: pfe.levisse

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen

Site Name: (1013) Clinical Neuroscience Solutions Inc.

Subject Initials: ---

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

[Back to Form](#)

1. Category:

Date	Location	User	Value	Reason
Sep-16-2020 17:27:27 (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
Sep-16-2020 17:27:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 7	Initial Entry

3. Adverse Event:

(If possible specify diagnosis, not individual symptoms)

Date	Location	User	Value	Reason
Sep-16-2020 17:27:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Monica Cooper (pfe.mcooper)	Data Entry: acute renal failure	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason
Sep-16-2020 17:27:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Monica Cooper (pfe.mcooper)	Data Entry: Aug/29/2020 UNK:UNK	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Sep-16-2020 17:27:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Monica Cooper (pfe.mcooper)	Data Entry: NO End Date Time: Sep/16/2020 UNK:UNK	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
Sep-16-2020 17:27:27 (UTC-05:00) Eastern Time	ACV0PFEINFP6000	Monica Cooper	Data Entry: 3	Initial Entry

090177e196ae2f66\Final\Final On: 01-Apr-2021 03:42 (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, Locked, Frozen

Site No: 1013

Site Name: (1013) Clinical Neuroscience Solutions Inc.

Subject No: 10131176

Subject Initials: ---

Generated By: pfe.lewissc

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

(US & Canada)

(pfe.mcooper)

7. Is the adverse event serious?

If Yes, NOTIFY PFIZER IMMEDIATELY.

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

Date	Location	User	Value	Reason
Nov-11-2020 11:19:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Ute Frantz (pfe.frantu)	Query 2: Deleted	Query is invalid or does not apply
Nov-11-2020 10:45:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 3: Closed	Response satisfies query
Nov-11-2020 10:02:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe.mstephens)	Query 3: Answered	CORRECT AS RECORDED PER CRC. DATA WAS CHANGED FROM SAE TO AE.
Nov-10-2020 22:42:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 3: Opened	CLINICAL - Event of acute renal failure is reported as non-serious; however, SAE report as of 09Nov20 has ARF as serious. Please review, and harmonize serious status; updating where appropriate.
Nov-10-2020 12:47:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Candidate	For AE acute renal failure: Response to "Is the adverse event serious?" is 'No' but "Serious Adverse Event Number" is present.
Nov-10-2020 12:47:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Scott Salmon (pfe.ssalmon)	Data Entry: NO	Changed Information
Sep-17-2020 22:19:00	ACV0PFEINFP6000	auto query	Query 1: Deleted	Close Auto Query

090177e196ae2f66\Final\Final On: 01-Apr-2021 03:42 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1013

Subject No: 10131176

Generated By: pfe.lewissc

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen

Site Name: (1013) Clinical Neuroscience Solutions Inc.

Subject Initials: ---

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

(UTC-05:00) Eastern Time (US & Canada)		(autoquery)		
Sep-16-2020 17:27:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	For AE acute renal failure: Response to "Is the adverse event serious?" is 'Yes' but "Serious Adverse Event Number" is blank.
Sep-16-2020 17:27:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Monica Cooper (pfe mcooper)	<p>Data Entry:</p> <p>YES</p> <p>Is this serious event associated with congenital anomaly or birth defect?</p> <p>NO</p> <p>Did this serious event result in death?</p> <p>NO</p> <p>Did this serious event require or prolong hospitalization?</p> <p>YES</p> <p>Did this serious event result in persistent or significant disability/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>	Initial Entry

8. Is this adverse event the result of a study Medication Error?
If Yes, record the type of medication error on the Medication Error Log.

Date	Location	User	Value	Reason
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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, Locked, Frozen

Site No: 1013

Site Name: (1013) Clinical Neuroscience Solutions Inc.

Subject No: 10131176

Subject Initials: ---

Generated By: pfe.levissc

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

Sep-16-2020 17:27:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Monica Cooper (pfe.mcooper)	Data Entry: NO	Initial Entry
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9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Sep-16-2020 17:27:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Monica Cooper (pfe mcooper)	Data Entry: NOT RELATED If Not Related to study treatment(s) , this event is due to: OTHER If Other, specify: prior surgery	Initial Entry

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Sep-16-2020 17:27:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Monica Cooper (pfe.mcooper)	Data Entry: NOT APPLICABLE	Initial Entry

11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
Sep-16-2020 17:27:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Monica Cooper (pfe.mcooper)	Data Entry: NO	Initial Entry

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Sep-16-2020 17:27:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Monica Cooper (pfe.mcooper)	Data Entry: NO	Initial Entry

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

Date	Location	User	Value	Reason
Sep-16-2020 17:27:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Monica Cooper (pfe.mcooper)	Data Entry: RECOVERED/RESOLVED	Initial Entry

090177e196ae2f66\Final\Final On: 01-Apr-2021 03:42 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1013

Subject No: 10131176

Generated By: pfe.levissc

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen

Site Name: (1013) Clinical Neuroscience Solutions Inc.

Subject Initials: ---

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

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

Date	Location	User	Value	Reason
Sep-16-2020 17:27:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Monica Cooper (pfe.mcooper)	Data Entry: NO	Initial Entry

15. Serious Adverse Event Number: For Pfizer Use Only

Date	Location	User	Value	Reason
Nov-13-2020 05:51:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Ricell Ann Piojo (pfe.quiton)	Data Entry:	downgraded to non serious
Sep-17-2020 22:19:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Ricell Ann Piojo (pfe.quiton)	Data Entry: 2020339639	Initial Entry

090177e196ae2f66\Final\Final On: 01-Apr-2021 03:42 (GMT)

Header Text: c4591001**Visit:** Logs - Unscheduled**Form Version:** 22-Apr-2020 21:02**Site No:** 1013**Subject No:** 10131176**Generated By:** pfe.levisse**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History**Form Status:** Data Complete, Locked, Frozen**Site Name:** (1013) Clinical Neuroscience Solutions Inc.**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 04:21[Back to Form](#)**1. Category:**

Date	Location	User	Value	Reason
Sep-16-2020 17:28:09 (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
Sep-16-2020 17:28:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 8	Initial Entry

3. Adverse Event:*(If possible specify diagnosis, not individual symptoms)*

Date	Location	User	Value	Reason
Sep-16-2020 17:28:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Monica Cooper (pfe.mcooper)	Data Entry: sepsis	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason
Sep-16-2020 17:28:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Monica Cooper (pfe.mcooper)	Data Entry: Aug/29/2020 UNK:UNK	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Sep-16-2020 17:28:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Monica Cooper (pfe.mcooper)	Data Entry: NO End Date Time: Sep/16/2020 UNK:UNK	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
Sep-16-2020 17:28:09 (UTC-05:00) Eastern Time	ACV0PFEINFP6000	Monica Cooper	Data Entry: 3	Initial Entry

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, Locked, Frozen

Site No: 1013

Site Name: (1013) Clinical Neuroscience Solutions Inc.

Subject No: 10131176

Subject Initials: ---

Generated By: pfe.levissc

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

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

If Yes, NOTIFY PFIZER IMMEDIATELY.

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

Date	Location	User	Value	Reason
Nov-11-2020 11:20:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Ute Frantz (pfe.frantu)	Query 2: Deleted	Query is invalid or does not apply
Nov-11-2020 10:45:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 3: Closed	Response satisfies query
Nov-11-2020 09:59:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe.mstephens)	Query 3: Answered	CORRECT AS RECORDED. PER CRC SAE WAS CHANGED TO NON SAE EVENT.
Nov-10-2020 22:43:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 3: Opened	CLINICAL - Event of Sepsis is reported as non-serious; however, SAE report as of 09Nov20 has sepsis as serious. Please review, and harmonize serious status; updating where appropriate.
Nov-10-2020 12:49:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Candidate	For AE sepsis: Response to "Is the adverse event serious?" is 'No' but "Serious Adverse Event Number" is present.
Nov-10-2020 12:49:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Scott Salmon (pfe.ssalmon)	Data Entry: NO	Changed Information
Sep-17-2020 22:19:16 (UTC-05:00) Eastern	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query

090177e196ae2f66\Final\Final On: 01-Apr-2021 03:42 (GMT)

Header Text: c4591001
Visit: Logs - Unscheduled
Form Version: 22-Apr-2020 21:02
Site No: 1013
Subject No: 10131176
Generated By: pfe.levissc

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History
Form Status: Data Complete, Locked, Frozen
Site Name: (1013) Clinical Neuroscience Solutions Inc.
Subject Initials: ---
Generated Time (GMT): 29-Mar-2021 04:21

Time (US & Canada)				
Sep-16-2020 17:28:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	For AE sepsis: Response to "Is the adverse event serious?" is 'Yes' but "Serious Adverse Event Number" is blank.
Sep-16-2020 17:28:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Monica Cooper (pfe.mcooper)	<p>Data Entry:</p> <p>YES</p> <p>Is this serious event associated with congenital anomaly or birth defect?</p> <p>NO</p> <p>Did this serious event result in death?</p> <p>NO</p> <p>Did this serious event require or prolong hospitalization?</p> <p>YES</p> <p>Did this serious event result in persistent or significant disability/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>	Initial Entry

8. Is this adverse event the result of a study Medication Error?
If Yes, record the type of medication error on the Medication Error Log.

Date	Location	User	Value	Reason
Sep-16-2020 17:28:09	ACV0PFEINFP6000	Monica	Data Entry:	Initial Entry

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, Locked, Frozen

Site No: 1013

Site Name: (1013) Clinical Neuroscience Solutions Inc.

Subject No: 10131176

Subject Initials: ---

Generated By: pfe.levissc

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

(UTC-05:00) Eastern Time (US & Canada)		Cooper (pfe.mcooper)	NO	
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9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Sep-16-2020 17:28:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Monica Cooper (pfe.mcooper)	Data Entry: NOT RELATED If Not Related to study treatment(s) , this event is due to: OTHER If Other, specify: prior surgery	Initial Entry

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Sep-16-2020 17:28:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Monica Cooper (pfe.mcooper)	Data Entry: NOT APPLICABLE	Initial Entry

11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
Sep-16-2020 17:28:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Monica Cooper (pfe.mcooper)	Data Entry: NO	Initial Entry

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Sep-16-2020 17:28:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Monica Cooper (pfe.mcooper)	Data Entry: NO	Initial Entry

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

Date	Location	User	Value	Reason
Sep-16-2020 17:28:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Monica Cooper (pfe.mcooper)	Data Entry: RECOVERED/RESOLVED	Initial Entry

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

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090177e196ae2f66\Final\Final On: 01-Apr-2021 03:42 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1013

Subject No: 10131176

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Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen

Site Name: (1013) Clinical Neuroscience Solutions Inc.

Subject Initials: ---

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

Date	Location	User	Value	Reason
Sep-16-2020 17:28:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Monica Cooper (pfe.mcooper)	Data Entry: NO	Initial Entry

15. Serious Adverse Event Number: For Pfizer Use Only

Date	Location	User	Value	Reason
Nov-13-2020 05:58:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Ricell Ann Piojo (pfe.quitor)	Data Entry:	downgraded to non serious
Sep-17-2020 22:19:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Ricell Ann Piojo (pfe.quitor)	Data Entry: 2020339639	Initial Entry

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1013

Subject No: 10131176

Generated By: pfe.levisse

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen

Site Name: (1013) Clinical Neuroscience Solutions Inc.

Subject Initials: ---

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

[Back to Form](#)

1. Category:

Date	Location	User	Value	Reason
Oct-28-2020 14:48:27 (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
Oct-28-2020 14:48:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 9	Initial Entry

3. Adverse Event:

(If possible specify diagnosis, not individual symptoms)

Date	Location	User	Value	Reason
Oct-28-2020 14:48:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe mstephens)	Data Entry: HYPONATREMIA	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason
Oct-28-2020 14:48:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe mstephens)	Data Entry: Aug/29/2020 UNK:UNK	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Oct-28-2020 14:48:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe mstephens)	Data Entry: NO End Date Time: Sep/7/2020 UNK:UNK	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
Oct-28-2020 14:48:27 (UTC-05:00) Eastern	ACV0PFEINFP6000	Matthew Stephens	Data Entry: 2	Initial Entry

090177e196ae2f66\Final\Final On: 01-Apr-2021 03:42 (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, Locked, Frozen

Site No: 1013

Site Name: (1013) Clinical Neuroscience Solutions Inc.

Subject No: 10131176

Subject Initials: ---

Generated By: pfe.levissc

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

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

If Yes, NOTIFY PFIZER IMMEDIATELY.

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

Date	Location	User	Value	Reason
Oct-30-2020 06:04:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Ricell Ann Piojo (pfe.quitor)	Query 2: Closed	Response satisfies query
Oct-29-2020 10:03:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Answered	Transcription Error
Oct-29-2020 10:03:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe.mstephens)	Data Entry: NO	Transcription Error
Oct-29-2020 06:43:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Ricell Ann Piojo (pfe.quitor)	Query 1: Deleted	Query can be addressed internally
Oct-29-2020 06:43:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Ricell Ann Piojo (pfe.quitor)	Query 2: Opened	SAE RECON: HYPONATREMIA(Onset date:29Aug2020) is not reported to Safety database but marked serious on AE CRF. Confirm seriousness and report to Pfizer immediately. If this event is not serious, downgrade the event on AE CRF
Oct-28-2020 14:48:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	For AE HYPONATREMIA: Response to "Is the adverse event serious?" is 'Yes' but "Serious Adverse Event Number" is blank.
Oct-28-2020 14:48:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe.mstephens)	Data Entry: YES Is this serious event associate	Initial Entry

090177e196ae2f66\Final\Final On: 01-Apr-2021 03:42 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1013

Subject No: 10131176

Generated By: pfe.levissc

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen

Site Name: (1013) Clinical Neuroscience Solutions Inc.

Subject Initials: ---

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

			<p>d with congenital anomaly or birth defect?</p> <p>NO</p> <p>Did this serious event result in death?</p> <p>NO</p> <p>Did this serious event require or prolong hospitalization?</p> <p>YES</p> <p>Did this serious event result in persistent or significant disability/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>
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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
Oct-28-2020 14:48:27 (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
Oct-28-2020 14:48:27 (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: OTHER	Initial Entry

090177e196ae2f66\Final\Final On: 01-Apr-2021 03:42 (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, Locked, Frozen

Site No: 1013

Site Name: (1013) Clinical Neuroscience Solutions Inc.

Subject No: 10131176

Subject Initials: ---

Generated By: pfe.lewissc

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

				<i>If Other, specify:</i>
				BOWEL OBSTRUCTION

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Oct-28-2020 14:48:27 (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
Oct-28-2020 14:48:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe mstephens)	Data Entry: YES	Initial Entry

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Oct-28-2020 14:48:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe mstephens)	Data Entry: NO	Initial Entry

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

Date	Location	User	Value	Reason
Oct-28-2020 14:48:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe mstephens)	Data Entry: RECOVERED/RESOLVED	Initial Entry

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

Date	Location	User	Value	Reason
Oct-28-2020 14:48:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe mstephens)	Data Entry: NO	Initial Entry

090177e196ae2f66\Final\Final On: 01-Apr-2021 03:42 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1013

Subject No: 10131176

Generated By: pfe.levisse

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen

Site Name: (1013) Clinical Neuroscience Solutions Inc.

Subject Initials: ---

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

[Back to Form](#)

1. Category:

Date	Location	User	Value	Reason
Oct-28-2020 14:49:32 (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
Oct-28-2020 14:49:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 10	Initial Entry

3. Adverse Event:

(If possible specify diagnosis, not individual symptoms)

Date	Location	User	Value	Reason
Oct-31-2020 13:04:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Sian Jones (pfe.jones111)	Query 1: Closed	Response satisfies query
Oct-30-2020 12:53:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe.mstephens)	Query 1: Answered	the lab value is 1.9 per crc.
Oct-30-2020 12:30:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Sian Jones (pfe.jones111)	Query 1: Opened	clinical: pls provide lab values. Thank you
Oct-28-2020 14:49:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe.mstephens)	Data Entry: LEUKOPENIA	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason
Oct-28-2020 14:49:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe mstephens)	Data Entry: Aug/29/2020 UNK:UNK	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
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090177e196ae2f66\Final\Final On: 01-Apr-2021 03:42 (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, Locked, Frozen

Site No: 1013

Site Name: (1013) Clinical Neuroscience Solutions Inc.

Subject No: 10131176

Subject Initials: ---

Generated By: pfe.levissc

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

Oct-28-2020 14:49:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe.mstephens)	Data Entry: NO End Date Time: Sep/7/2020 UNK:UNK	Initial Entry
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6. Toxicity Grade:

Date	Location	User	Value	Reason
Oct-28-2020 14:49:32 (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
Oct-30-2020 06:04:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Ricell Ann Piojo (pfe.quitor)	Query 2: Closed	Response satisfies query
Oct-29-2020 10:03:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Answered	Transcription Error
Oct-29-2020 10:03:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Oct-29-2020 10:03:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe.mstephens)	Data Entry: NO	Transcription Error
Oct-29-2020 06:44:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Ricell Ann Piojo (pfe.quitor)	Query 2: Opened	SAE RECON: LEUKOPENIA(Onset date:29Aug2020) is not reported to Safety database but marked serious on AE CRF. Confirm seriousness and report to Pfizer immediately. If this event is not serious, downgrade the event

090177e196ae2f66\Final\Final On: 01-Apr-2021 03:42 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1013

Subject No: 10131176

Generated By: pfe.levissc

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen

Site Name: (1013) Clinical Neuroscience Solutions Inc.

Subject Initials: ---

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

				on AE CRF
Oct-28-2020 14:49:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	For AE LEUKOPENIA: Response to "Is the adverse event serious?" is 'Yes' but "Serious Adverse Event Number" is blank.
Oct-28-2020 14:49:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe mstephens)	<p>Data Entry: YES</p> <p>Is this serious event associated with congenital anomaly or birt h defect?</p> <p>NO</p> <p>Did this serious event result in death?</p> <p>NO</p> <p>Did this serious event require o r prolong hospitalization?</p> <p>YES</p> <p>Did this serious event result in persistent or significant disabili ty/incapacity?</p> <p>NO</p> <p>Is this serious event life threate ning?</p> <p>NO</p> <p>Other medically important seri ous event</p> <p>NO</p>	Initial Entry

8. Is this adverse event the result of a study Medication Error?
If Yes, record the type of medication error on the Medication Error Log.

Date	Location	User	Value	Reason
Oct-28-2020 14:49:32	ACV0PFEINFP6000	Matthew	Data Entry:	Initial Entry

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, Locked, Frozen

Site No: 1013

Site Name: (1013) Clinical Neuroscience Solutions Inc.

Subject No: 10131176

Subject Initials: ---

Generated By: pfe.levissc

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

(UTC-05:00) Eastern Time (US & Canada)		Stephens (pfe mstephens)	NO	
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9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Oct-28-2020 14:49:32 (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: OTHER If Other, specify: BOWEL OBSTRUCTION	Initial Entry

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Oct-28-2020 14:49:32 (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
Oct-28-2020 14:49:32 (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
Oct-28-2020 14:49:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe mstephens)	Data Entry: YES	Initial Entry

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

Date	Location	User	Value	Reason
Oct-28-2020 14:49:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe mstephens)	Data Entry: RECOVERED/RESOLVED	Initial Entry

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

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090177e196ae2f66\Final\Final On: 01-Apr-2021 03:42 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1013

Subject No: 10131176

Generated By: pfe.levissc

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen

Site Name: (1013) Clinical Neuroscience Solutions Inc.

Subject Initials: ---

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

Date	Location	User	Value	Reason
Oct-28-2020 14:49:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe mstephens)	Data Entry: NO	Initial Entry

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1013

Subject No: 10131176

Generated By: pfe.levisse

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen

Site Name: (1013) Clinical Neuroscience Solutions Inc.

Subject Initials: ---

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

[Back to Form](#)

1. Category:

Date	Location	User	Value	Reason
Oct-28-2020 14:50:42 (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
Oct-28-2020 14:50:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 11	Initial Entry

3. Adverse Event:

(If possible specify diagnosis, not individual symptoms)

Date	Location	User	Value	Reason
Oct-28-2020 14:50:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe mstephens)	Data Entry: SMALL BOWEL OBSTRUCTIO N	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason
Oct-28-2020 14:50:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe mstephens)	Data Entry: Aug/29/2020 UNK:UNK	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Oct-28-2020 14:50:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe mstephens)	Data Entry: NO End Date Time: Aug/30/2020 UNK:UNK	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
Oct-28-2020 14:50:42 (UTC-05:00) Eastern	ACV0PFEINFP6000	Matthew Stephens	Data Entry: 2	Initial Entry

090177e196ae2f66\Final\Final On: 01-Apr-2021 03:42 (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, Locked, Frozen

Site No: 1013

Site Name: (1013) Clinical Neuroscience Solutions Inc.

Subject No: 10131176

Subject Initials: ---

Generated By: pfe.levissc

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

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

If Yes, NOTIFY PFIZER IMMEDIATELY.

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

Date	Location	User	Value	Reason
Oct-30-2020 06:06:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Deleted	Close Auto Query
Oct-30-2020 06:05:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Ricell Ann Piojo (pfe.quoter)	Query 1: Closed	Response satisfies query
Oct-29-2020 10:04:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Candidate	For AE SMALL BOWEL OBSTRUCTION: Response to "Is the adverse event serious?" is 'Yes' but "Serious Adverse Event Number" is blank.
Oct-29-2020 10:04:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Changed Information
Oct-29-2020 10:04:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe mstephens)	Data Entry: YES Is this serious event associat ed with congenital anomaly or birth defect? NO Did this serious event result in death? NO Did this serious event requir e or prolong hospitalization? YES Did this serious event result in persistent or significant di	Changed Information

090177e196ae2f66\Final\Final On: 01-Apr-2021 03:42 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1013

Subject No: 10131176

Generated By: pfe.lewissc

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen

Site Name: (1013) Clinical Neuroscience Solutions Inc.

Subject Initials: ---

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

			sability/incapacity? NO Is this serious event life threatening? NO Other medically important serious event NO	
Oct-29-2020 06:35:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Ricell Ann Piojo (pfe.quitor)	Query 1: Opened	SAE RECON:AER#2020339639 Small bowel obstruction(onset date:29Aug2020)was reported as serious in Safety database but non serious in AE CRF. Please confirm and update CRF. If safety update is required, submit a follow-up SAE Form.
Oct-28-2020 14:50:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe.mstephens)	Data Entry: NO	Initial Entry

8. Is this adverse event the result of a study Medication Error?
If Yes, record the type of medication error on the Medication Error Log.

Date	Location	User	Value	Reason
Oct-28-2020 14:50:42 (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
Oct-28-2020 14:50:42 (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: OTHER	Initial Entry

090177e196ae2f66\Final\Final On: 01-Apr-2021 03:42 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1013

Subject No: 10131176

Generated By: pfe.levissc

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen

Site Name: (1013) Clinical Neuroscience Solutions Inc.

Subject Initials: ---

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

(US & Canada)		(pfe.QUITOR)		
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090177e196ae2f66\Final\Final On: 01-Apr-2021 03:42 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1013

Subject No: 10131176

Generated By: pfe.levisse

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen

Site Name: (1013) Clinical Neuroscience Solutions Inc.

Subject Initials: ---

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

[Back to Form](#)

1. Category:

Date	Location	User	Value	Reason
Oct-28-2020 14:51:51 (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
Oct-28-2020 14:51:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 12	Initial Entry

3. Adverse Event:

(If possible specify diagnosis, not individual symptoms)

Date	Location	User	Value	Reason
Nov-10-2020 23:57:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Salim Bouguermouh (pfe.bogus)	Query 1: Closed	Response satisfies query
Nov-09-2020 13:05:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe.mstephens)	Query 1: Answered	Changed data per query
Nov-04-2020 15:28:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Salim Bouguermouh (pfe.bogus)	Query 1: Reissued:Opened	Medical monitor: Despite telehealth visit was not done, please complete the potential COVID-19 Illness Visit CRF forms with all information available. Should be captured only on the SOD CRF form and a NASAL SWAB will not be collected.
Nov-04-2020 09:35:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe.mstephens)	Query 1: Answered	PER CRC NO COVID ILLNESS VISIT REUIRED AS ASPIRATION PNEUMONIA WAS FOUND IN THE

090177e196ae2f66\Final\Final On: 01-Apr-2021 03:42 (GMT)

Header Text: c4591001**Visit:** Logs - Unscheduled**Form Version:** 22-Apr-2020 21:02**Site No:** 1013**Subject No:** 10131176**Generated By:** pfe.levissc**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History**Form Status:** Data Complete, Locked, Frozen**Site Name:** (1013) Clinical Neuroscience Solutions Inc.**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 04:21

				HOSPITAL.
Nov-03-2020 16:53:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Salim Bouguermouh (pfe.bougus)	Query 1: Reissued:Opened	Clin: Per Prot Sect 8.13., potential COVID-19 related ASPIRATION PNEUMONIA should have please triggered a COVID Illness Visit irrespective if the subject was hospitalized or not. Please complete the COVID-19 CRF forms. Nasal swab not collected
Nov-02-2020 13:32:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe.mstephens)	Query 1: Answered	PER CRC, EVENT WAS FOUND WHEN SUBJECT WAS HOPSITALIZED. SO NO ILLNESS VISIT REQUIRED.
Nov-02-2020 11:36:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Salim Bouguermouh (pfe.bougus)	Query 1: Opened	Clin: Per Prot Sect 8.13., potential COVID-19 related ASPIRATION PNEUMONIA should have please triggered a COVID Illness Visit irrespective of perceived etiology or clinical significance. Please complete the COVID-19 CRF forms. Nasal swab not collected
Oct-28-2020 14:51:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe.mstephens)	Data Entry: ASPIRATION PNEUMONIA	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason
Nov-05-2020 22:33:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Ricell Ann Piojo (pfe.quiror)	Query 1: Closed	Per PSSR response 'Onset date has bene updated in the Safety Database (Argus) to

Header Text: c4591001**Visit:** Logs - Unscheduled**Form Version:** 22-Apr-2020 21:02**Site No:** 1013**Subject No:** 10131176**Generated By:** pfe.levissc**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History**Form Status:** Data Complete, Locked, Frozen**Site Name:** (1013) Clinical Neuroscience Solutions Inc.**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 04:21

				30-Aug-2020. ' Issue resolved
Nov-05-2020 05:18:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Ricell Ann Piojo (pfe.quitor)	Query 1: Reissued:Candidate	For PSSR review
Nov-04-2020 09:32:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe.mstephens)	Query 1: Answered	CRC WILL UPDATE TODAY.
Nov-04-2020 05:38:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Ricell Ann Piojo (pfe.quitor)	Query 1: Reissued:Opened	SAE RECON 2: Onset date in SDB for Aspiration Pneumonia is still 29Aug2020 while 30Aug2020. Please confirm and update accordingly.
Nov-03-2020 07:25:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Ricell Ann Piojo (pfe.quitor)	Query 1: Reissued:Candidate	SAE RECON: Pending SDB update
Nov-02-2020 08:11:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe.mstephens)	Query 1: Answered	CRC WILL UPDATE
Oct-31-2020 09:52:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Ricell Ann Piojo (pfe.quitor)	Query 1: Reissued:Opened	SAE RECON 1: onset date was reported as 29Aug2020 in Safety database, please confirm if a follow up AEM form was submitted to correct onset date in Safety database.
Oct-30-2020 09:15:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Scott Salmon (pfe.ssalmon)	Query 1: Answered	August 30, 2020 is the correct date.
Oct-30-2020 06:11:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Ricell Ann Piojo (pfe.quitor)	Query 1: Opened	SAE RECON: AER#2020339639 ,onset date was reported as 29Aug2020 in Safety database however, recorded as 30Aug2020 on AE CRF. Please confirm correct Onset Date. If

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, Locked, Frozen

Site No: 1013

Site Name: (1013) Clinical Neuroscience Solutions Inc.

Subject No: 10131176

Subject Initials: ---

Generated By: pfe.levissc

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

				safety update is required, please submit a follow-up SAE form.
Oct-28-2020 14:51:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe.mstephens)	Data Entry: Aug/30/2020 UNK:UNK	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Oct-28-2020 14:51:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe mstephens)	Data Entry: NO End Date Time: Sep/16/2020 UNK:UNK	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
Oct-28-2020 14:51:51 (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
Oct-30-2020 06:10:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Deleted	Close Auto Query
Oct-30-2020 06:06:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Ricell Ann Piojo (pfe.quitor)	Query 1: Closed	Response satisfies query
Oct-29-2020 10:05:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Candidate	For AE ASPIRATION PNEUMONIA: Response to "Is the adverse event serious?" is 'Yes' but "Serious Adverse Event Number" is blank.

090177e196ae2f66\Final\Final On: 01-Apr-2021 03:42 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1013

Subject No: 10131176

Generated By: pfe.levisss

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen

Site Name: (1013) Clinical Neuroscience Solutions Inc.

Subject Initials: ---

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

Oct-29-2020 10:05:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Changed Information
Oct-29-2020 10:05:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe.mstephens)	Data Entry: YES Is this serious event associ- ated with congenital anomaly or birth defect? NO Did this serious event result in death? NO Did this serious event requir- e or prolong hospitalization? YES Did this serious event result in persistent or significant di- sability/incapacity? NO Is this serious event life thre- atening? NO Other medically important s- erious event NO	Changed Information
Oct-29-2020 06:36:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Ricell Ann Piojo (pfe.quitor)	Query 1: Opened	SAE RECON:AER#2020339639 Aspiration Pneumonia(onset date:29Aug2020)was reported as serious in Safety database but non serious in AE CRF. Please confirm and update CRF. If safety update is required, submit a follow-up SAE Form.

090177e196ae2f66\Final\Final On: 01-Apr-2021 03:42 (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, Locked, Frozen

Site No: 1013

Site Name: (1013) Clinical Neuroscience Solutions Inc.

Subject No: 10131176

Subject Initials: ---

Generated By: pfe.levissc

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

Oct-28-2020 14:51:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe mstephens)	Data Entry: NO	Initial Entry
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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
Oct-28-2020 14:51:51 (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
Oct-29-2020 07:05:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Amita Sushant Surve (pfe.survea03)	Query 1: Clos ed	raised in error , AE already recorded
Oct-29-2020 07:03:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	PFE SDQ PROD (pfe.PFESDQ_PROD)	Query 1: Ope ned	Please review "If not related to study treatment other" field, the following text was indicated in the comment field [adhesions]. Any symptoms, AEs or other key data should be collected on the appropriate page. Please review and update as necessary. "[survea03 SDQ=26280]"
Oct-28-2020 14:51:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe mstephens)	Data Entry: NOT RELAT ED If Not Relate d to study tr	Initial Entry

090177e196ae2f66\Final\Final On: 01-Apr-2021 03:42 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1013

Subject No: 10131176

Generated By: pfe.levissc

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen

Site Name: (1013) Clinical Neuroscience Solutions Inc.

Subject Initials: ---

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

			eatment(s), t his event is due to: OTHER <i>If Other, s pecify:</i> ADHES IONS
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10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Oct-28-2020 14:51:51 (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
Oct-28-2020 14:51:51 (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
Oct-28-2020 14:51:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe mstephens)	Data Entry: YES	Initial Entry

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

Date	Location	User	Value	Reason
Oct-28-2020 14:51:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe mstephens)	Data Entry: RECOVERED/RESOLVED	Initial Entry

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

Date	Location	User	Value	Reason
Oct-28-2020 14:51:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe mstephens)	Data Entry: NO	Initial Entry

090177e196ae2f66\Final\On: 01-Apr-2021 03:42 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1013

Subject No: 10131176

Generated By: pfe.levissc

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen

Site Name: (1013) Clinical Neuroscience Solutions Inc.

Subject Initials: ---

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

15. Serious Adverse Event Number: For Pfizer Use Only

Date	Location	User	Value	Reason
Oct-30-2020 06:10:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Ricell Ann Piojo (pfe.quitor)	Data Entry: 2020339639	Initial Entry

090177e196ae2f66\Final\Final On: 01-Apr-2021 03:42 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1013

Subject No: 10131176

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Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete

Site Name: (1013) Clinical Neuroscience Solutions Inc.

Subject Initials: ---

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

[Back to Form](#)

1. Category:

Date	Location	User	Value	Reason
Nov-11-2020 10:04:49 (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
Nov-11-2020 10:04:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 13	Initial Entry

3. Adverse Event:

(If possible specify diagnosis, not individual symptoms)

Date	Location	User	Value	Reason
Dec-16-2020 19:21:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 1: Closed	followup per monitor
Dec-14-2020 10:11:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe.mstephens)	Query 1: Answered	PER CRC ALL DOCUMENTAION HAS BEEN SUBMITTED
Dec-10-2020 10:27:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 1: Reissued:Opened	CLINICAL Thank you. The only mention of HTN in the most recent SAE update (12Nov20) is in the indication for amlodipine; not include in the past med Hx section with a start date (so not in narrative).
Dec-08-2020 13:23:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Scott Salmon (pfe.ssalmon)	Query 1: Answered	PER CRC ALL DOCUMENTATION SUBMITTED.
Dec-06-2020 12:00:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 1: Reissued:Opened	CLINICAL Follwup - please submit a SAE safety update with past

090177e196ae2f66\Final\Final On: 01-Apr-2021 03:42 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1013

Subject No: 10131176

Generated By: pfe.lewissc

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete

Site Name: (1013) Clinical Neuroscience Solutions Inc.

Subject Initials: ---

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

				med Hx of HTN
Nov-30-2020 13:41:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe.mstephens)	Query 1: Answered	CRC WILL SUBMIT A SAFETY UPDATE.
Nov-25-2020 00:15:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 1: Opened	CLINICAL - please submit a SAE safety update (AER #2020339639) to add HTN to SAE medical history section
Nov-11-2020 10:04:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Scott Salmon (pfe.ssalmon)	Data Entry: MILD CONCENTRIC LEFT VE NTRICULAR HYPERTROPHY	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason
Nov-11-2020 10:04:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Scott Salmon (pfe.ssalmon)	Data Entry: Sep/16/2020 UNK:UNK	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Nov-11-2020 10:04:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Scott Salmon (pfe.ssalmon)	Data Entry: YES	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
Nov-11-2020 10:04:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Scott Salmon (pfe.ssalmon)	Data Entry: 1	Initial Entry

7. Is the adverse event serious?

If Yes, NOTIFY PFIZER IMMEDIATELY.

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

Date	Location	User	Value	Reason
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090177e196ae2f66\Final\Final On: 01-Apr-2021 03:42 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete

Site No: 1013

Site Name: (1013) Clinical Neuroscience Solutions Inc.

Subject No: 10131176

Subject Initials: ---

Generated By: pfe.levissc

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

Nov-11-2020 10:04:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Scott Salmon (pfe.ssalmon)	<u>Data Entry:</u> NO	Initial Entry
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8. Is this adverse event the result of a study Medication Error?
If Yes, record the type of medication error on the Medication Error Log.

Date	Location	User	Value	Reason
Nov-11-2020 10:04:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Scott Salmon (pfe.ssalmon)	<u>Data Entry:</u> NO	Initial Entry

9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Nov-11-2020 10:04:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Scott Salmon (pfe.ssalmon)	<u>Data Entry:</u> NOT RELATED If Not Related to study treatment(s) , this event is due to: OTHER <i>If Other, specify:</i> UNKNOWN	Initial Entry

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Nov-11-2020 10:04:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Scott Salmon (pfe.ssalmon)	<u>Data Entry:</u> NOT APPLICABLE	Initial Entry

11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
Nov-11-2020 10:04:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Scott Salmon (pfe.ssalmon)	<u>Data Entry:</u> NO	Initial Entry

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Nov-11-2020 10:04:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Scott Salmon (pfe.ssalmon)	<u>Data Entry:</u> NO	Initial Entry

090177e196ae2f66\Final\Final On: 01-Apr-2021 03:42 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1013

Subject No: 10131176

Generated By: pfe.levissc

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete

Site Name: (1013) Clinical Neuroscience Solutions Inc.

Subject Initials: ---

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

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

Date	Location	User	Value	Reason
Nov-11-2020 10:04:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Scott Salmon (pfe.ssalmon)	Data Entry: RECOVERING/RESOLVING	Initial Entry

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

Date	Location	User	Value	Reason
Nov-11-2020 10:04:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Scott Salmon (pfe.ssalmon)	Data Entry: NO	Initial Entry

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1013

Subject No: 10131176

Generated By: pfe.levisse

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Frozen

Site Name: (1013) Clinical Neuroscience Solutions Inc.

Subject Initials: ---

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

[Back to Form](#)

1. Category:

Date	Location	User	Value	Reason
Mar-08-2021 15:23:29 (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
Mar-08-2021 15:23:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 14	Initial Entry

3. Adverse Event:

(If possible specify diagnosis, not individual symptoms)

Date	Location	User	Value	Reason
Mar-08-2021 15:23:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Scott Salmon (pfe.ssalmon)	Data Entry: URINARY TRACT INFECTION	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason
Mar-08-2021 15:23:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Scott Salmon (pfe.ssalmon)	Data Entry: Jan/13/2021 UNK:UNK	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Mar-08-2021 15:23:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Scott Salmon (pfe.ssalmon)	Data Entry: NO End Date Time: Jan/22/2021 UNK:UNK	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
Mar-08-2021 15:23:29 (UTC-05:00) Eastern Time	ACV0PFEINFP6000	Scott Salmon (pfe.ssalmon)	Data Entry: 1	Initial Entry

090177e196ae2f66\Final\Final On: 01-Apr-2021 03:42 (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: 10131176

Subject Initials: ---

Generated By: pfe.lewissc

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

(US & Canada)

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
Mar-08-2021 15:23:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Scott Salmon (pfe.ssalmon)	Data Entry: NO	Initial Entry

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

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

Date	Location	User	Value	Reason
Mar-08-2021 15:23:29 (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
Mar-08-2021 15:23:29 (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 If Other, specify: UNKNOWN	Initial Entry

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Mar-08-2021 15:23:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Scott Salmon (pfe.ssalmon)	Data Entry: NOT APPLICABLE	Initial Entry

11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
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090177e196ae2f66\Final\Final On: 01-Apr-2021 03:42 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1013

Subject No: 10131176

Generated By: pfe.levissc

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Frozen

Site Name: (1013) Clinical Neuroscience Solutions Inc.

Subject Initials: ---

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

Mar-08-2021 15:23:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Scott Salmon (pfe.ssalmon)	Data Entry: YES	Initial Entry
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12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Mar-08-2021 15:23:29 (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
Mar-08-2021 15:23:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Scott Salmon (pfe.ssalmon)	Data Entry: RECOVERED/RESOLVED	Initial Entry

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

Date	Location	User	Value	Reason
Mar-08-2021 15:23:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Scott Salmon (pfe.ssalmon)	Data Entry: NO	Initial Entry

090177e196ae2f66\Final\Final On: 01-Apr-2021 03:42 (GMT)

Header Text: c4591001

Visit: Potential ReVax Initial Contact -
Unscheduled

Form: DATE OF VISIT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen, Verified

Site No: 1013

Site Name: (1013) Clinical Neuroscience Solutions Inc.

Subject No: 10131176

Subject Initials: ---

Generated By: pfe.levisse

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

[Back to Form](#)

1. Date of Visit

Date	Location	User	Value	Reason
Dec-31-2020 11:56:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Scott Salmon (pfe.ssalmon)	Data Entry: Dec/30/2020	Initial Entry

Header Text: c4591001

Visit: Potential ReVax Initial Contact -
Unscheduled

Form Version: 10-Dec-2020 02:25

Site No: 1013

Subject No: 10131176

Generated By: pfe.levissc

Form: FURTHER VACCINATION CONFIRMATION - eCRF Audit Trail
History

Form Status: Data Complete, Frozen

Site Name: (1013) Clinical Neuroscience Solutions Inc.

Subject Initials: ---

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

[Back to Form](#)

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

Date	Location	User	Value	Reason
Feb-25-2021 10:04:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Scott Salmon (pfe.ssalmon)	Data Entry: Participant is willing to return for V accination 3 Participant is: eligible and NOT confirmed to h ave received only placebo at Vac cination 1/2	Changed Information
Dec-31-2020 11:56:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Scott Salmon (pfe.ssalmon)	Data Entry: Participant is NOT willing to return for Vaccination 3 OR otherwise not eligible	Initial Entry

090177e196ae2f66\Final\Final On: 01-Apr-2021 03:42 (GMT)

Header Text: c4591001

Visit: Disposition - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1013

Subject No: 10131176

Generated By: pfe.levisse

Form: TREATMENT UNBLINDED - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1013) Clinical Neuroscience Solutions Inc.

Subject Initials: ---

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

[Back to Form](#)

1. Date Treatment Unblinded :

Date	Location	User	Value	Reason
Dec-31-2020 11:56:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Scott Salmon (pfe.ssalmon)	Data Entry: Dec/30/2020	Initial Entry

2. Primary Reason for Unblinding:

Date	Location	User	Value	Reason
Feb-26-2021 00:37:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Amol Shinde (pfe.shinda18)	Query 2: Closed	Response satisfies query
Feb-25-2021 10:05:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Scott Salmon (pfe.ssalmon)	Query 2: Answered	CRF UPDATED; THANK YOU.
Feb-24-2021 17:18:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Katerina Trpeski (pfe.TRPEsk)	Query 2: Reissued :Opened	DM: REVAX CONT visit has been unfrozen for data updates. Thank you.
Feb-24-2021 11:49:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Scott Salmon (pfe.ssalmon)	Query 2: Answered	REVAX CONT IS STILL FROZEN. PLEASE UNFREEZE; THANK YOU.
Feb-23-2021 14:12:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Katerina Trpeski (pfe.TRPEsk)	Query 2: Reissued :Opened	DM: REVAX CONT visit has been unfrozen for data update. Thank you.
Feb-23-2021 08:30:43	ACV0PFEINFP6000	Scott Salmon (pfe.ssalmon)	Query 2: Answered	PLEASE UNFREEZE "REVAX CONT" CRF;

090177e196ae2f66\Final\Final On: 01-Apr-2021 03:42 (GMT)

Header Text: c4591001

Visit: Disposition - Unscheduled

Form: TREATMENT UNBLINDED - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1013

Site Name: (1013) Clinical Neuroscience Solutions Inc.

Subject No: 10131176

Subject Initials: ---

Generated By: pfe.levissc

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

(UTC-05:00) Eastern Time (US & Canada)			d	WILL UPDATE.
Feb-22-2021 22:47:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mina Francisco (pfe.francm73)	Query 2: Reissued :Opened	DM: Primary Reason for Unblinding is "ASSESS ELIGIBILITY FOR ADDITIONAL VACCINATION", but "Participant is NOT willing to return for Vaccination 3 OR otherwise not eligible". Please refer to CRF CR for guidance, and review and update as appropriate.
Feb-22-2021 07:50:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Scott Salmon (pfe.ssalmon)	Query 2: Answered	WILL UPDATE WHEN "REVAX CONT" IS UNFROZEN
Feb-22-2021 02:15:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (pfe.DMW_QUERY)	Query 2: Opened	DMW7348642;Primary Reason for Unblinding is "ASSESS ELIGIBILITY FOR ADDITIONAL VACCINATION", but "Participant is willing to return for Vaccination 3" is not selected in the Further Vaccination Confirmation CRF. Please review and update as appropriate.
Jan-06-2021 00:35:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Pratiksha Mahadik (pfe.mahadp07)	Query 1: Closed	Closed as data updated.
Jan-05-2021 09:22:41	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Transcription Error

090177e196ae2f66\Final\Final On: 01-Apr-2021 03:42 (GMT)

Header Text: c4591001

Visit: Disposition - Unscheduled

Form: TREATMENT UNBLINDED - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1013

Site Name: (1013) Clinical Neuroscience Solutions Inc.

Subject No: 10131176

Subject Initials: ---

Generated By: pfe.levissc

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

(UTC-05:00) Eastern Time (US & Canada)			d	
Jan-05-2021 09:22:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Monica Cooper (pfe.mcooper)	Data Entry: ASSESS ELIGIBILITY FOR ADDITIONAL VACCINATION	Transcription Error
Jan-04-2021 04:43:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Amol Deshmukh (pfe.deshma24)	Query 1: Opened	IVRS Reconciliation: Please confirm reason for Un-blinding marked is per CCG section 8.65.2. If the Reason for Un-blinding is for the assessment of eligibility to receive Vaccination 3 and 4, please select 'ASSESS ELIGIBILITY FOR ADDITIONAL VACCINATION'.
Dec-31-2020 11:56:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Scott Salmon (pfe.ssalmon)	Data Entry: SUBJECT SAFE CONCERN	Initial Entry

090177e196ae2f66\Final\Final On: 01-Apr-2021 03:42 (GMT)

Header Text: c4591001

Visit: Subject Status - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1013

Subject No: 10131176

Generated By: pfe.levisse

Form: SUBJECT STATUS - eCRF Audit Trail History

Form Status: Data Complete, Verified

Site Name: (1013) Clinical Neuroscience Solutions Inc.

Subject Initials: ---

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

[Back to Form](#)

1. Subject Status

Date	Location	User	Value	Reason
Nov-04-2020 17:13:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: FOLLOW-UP	Initial Entry
Aug-13-2020 16:09:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: ENROLLED/RANDOMIZED	Initial Entry
Aug-13-2020 16:03:24 (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
Nov-04-2020 17:13:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Nov/4/2020	Initial Entry
Aug-13-2020 16:09:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Aug/13/2020	Initial Entry
Aug-13-2020 16:03:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Aug/13/2020	Initial Entry

090177e196ae2f66\Final\Final On: 01-Apr-2021 03:42 (GMT)

Header Text: c4591001

Visit: Investigator Signature - Unscheduled

Form Version: 22-Apr-2020 21:04

Site No: 1013

Subject No: 10131176

Generated By: pfe.levisse

Form: CASEBOOK SIGNATURE FORM - eCRF Audit Trail History

Form Status: Data Complete, Signed, Verified

Site Name: (1013) Clinical Neuroscience Solutions Inc.

Subject Initials: ---

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

[Back to Form](#)

I. Casebook Signature

Date	Location	User	Value	Reason
Sep-14-2020 16:30:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe mstephens)	Data Entry: Click Here to Enable	Initial Entry