

**Header Text:** c4591001

**Visit:** COHORT\_SELECTION

**Form:** COHORT\_SELECTION

**Form Version:** 30-Jul-2020 21:29

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

**Site No:** 1013

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

**Subject No:** 10131165

**Subject Initials:** ---

**Generated By:** pfe.levisse

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

[eCRF Audit Trail History](#)

**Cohort Selection**

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

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

**Header Text:** c4591001

**Visit:** COHORT\_SELECTION

**Form:** MAIN INFORMED CONSENT

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

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

**Site No:** 1013

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

**Subject No:** 10131165

**Subject Initials:** ---

**Generated By:** pfe.levissc

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

[eCRF Audit Trail History](#)

**Informed Consent**

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

**Visit:** COHORT\_SELECTION

**Form:** DEMOGRAPHY

**Form Version:** 06-Jul-2020 21:55

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

**Site No:** 1013

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

**Subject No:** 10131165

**Subject Initials:** ---

**Generated By:** pfe.levisc

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

[eCRF Audit Trail History](#)

**Demography**

1.	Subject ID	[10131165]
2.	Birth Date:	(b) (6) 1992
3.	Sex:	MALE
4.	Ethnicity:	HISPANIC OR LATINO(A) OR OF SPANISH ORIGIN
5.	Race: (Check X all that apply):	WHITE
6.	Racial Designation:	

090177e196ae2f61\Final\Final On: 01-Apr-2021 03:41 (GMT)

**Header Text:** c4591001

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

**Form:** DATE OF VISIT

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

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

**Site No:** 1013

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

**Subject No:** 10131165

**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	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:** 10131165

**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 _____
----	--	-------------------------

090177e196ae2f61\Final\Final On: 01-Apr-2021 03:41 (GMT)

**Header Text:** c4591001

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

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

**Site No:** 1013

**Subject No:** 10131165

**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:** GENERAL MEDICAL HISTORY

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

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

**Site No:** 1013

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

**Subject No:** 10131165

**Subject Initials:** ---

**Generated By:** pfe.levissc

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

**eCRF Audit Trail History**

**Medical History Details**

1.a	Line/MH Number:	[1]
	Disease/Syndrome /Surgery/Non-Drug Allergies/Drug Allergies:	[ELEVATED TRIGLYCERIDES]
	Start Date:	UNK/UNK/2018
	Ongoing:	YES
1.b	Line/MH Number:	[2]
	Disease/Syndrome /Surgery/Non-Drug Allergies/Drug Allergies:	[GENITAL HERPES]
	Start Date:	Aug/10/2019
	Ongoing:	YES
1.c	Line/MH Number:	[3]
	Disease/Syndrome /Surgery/Non-Drug Allergies/Drug Allergies:	[SEASONAL ALLERGIES]
	Start Date:	UNK/UNK/1982
	Ongoing:	YES

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**Header Text:** c4591001

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

**Form:** GENERAL MEDICAL HISTORY

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

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

**Site No:** 1013

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

**Subject No:** 10131165

**Subject Initials:** ---

**Generated By:** pfe.levisse

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

1.d	Line/MH Number:	[4]
	Disease/Syndrome /Surgery/Non-Drug Allergies/Drug Allergies:	[VAPING]
	Start Date:	UNK/UNK/2016
	Ongoing:	YES

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**Header Text:** c4591001

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

**Form:** VITAL SIGNS - BASELINE

**Form Version:** 30-Jul-2020 21:28

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

**Site No:** 1013

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

**Subject No:** 10131165

**Subject Initials:** ---

**Generated By:** pfe.levissc

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

**eCRF Audit Trail History**

**Vital Signs**

1.	Date:	Aug/13/2020
2.	Weight:	[86.0]
3.	Unit:	kg
4.	Height:	[183.0]
5.	Unit:	cm
6.	Body Mass Index:	[25.7]

**Vital Signs Details**

7.a	Record Identifier:	1
	Temperature:	[35.8]
	Unit:	C
	Temperature Location:	ORAL CAVITY

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**Header Text:** c4591001

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

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

**Site No:** 1013

**Subject No:** 10131165

**Generated By:** pfe.levisse

**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:	[48413]
3.	Randomization Group:	[ ]

**Header Text:** c4591001

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

**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

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

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

**Site No:** 1013

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

**Subject No:** 10131165

**Subject Initials:** ---

**Generated By:** pfe.levisse

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

[eCRF Audit Trail History](#)

**Electronic Sample Tracking**

1.	Data Origin	SITE
2.	Sample Type	SERUM
3.	Sample Collected?	YES Date of Collection: Aug/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	[BPYW9Z]
5.b	Sample ID	[BPYWB0]
5.c	Sample ID	[BPYWB1]
5.d	Sample ID	[BNWHGG]
5.e	Sample ID	[BNWHGH]

090177e196ae2f61\Final\Final On: 01-Apr-2021 03:41 (GMT)

**Header Text:** c4591001

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

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

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

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

**Site No:** 1013

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

**Subject No:** 10131165

**Subject Initials:** ---

**Generated By:** pfe.lewissc

**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	[BM8S3Z]
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090177e196ae2f61\Final\Final On: 01-Apr-2021 03:41 (GMT)

**Header Text:** c4591001

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

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

**Site No:** 1013

**Subject No:** 10131165

**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 10:36
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

090177e196ae2f61\Final\Final On: 01-Apr-2021 03:41 (GMT)

**Header Text:** c4591001

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

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

**Site No:** 1013

**Subject No:** 10131165

**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
----	---	--

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

**Form:** DATE OF VISIT

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

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

**Site No:** 1013

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

**Subject No:** 10131165

**Subject Initials:** ---

**Generated By:** pfe.levisse

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

[eCRF Audit Trail History](#)

**Date of Visit**

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

090177e196ae2f61\Final\Final On: 01-Apr-2021 03:41 (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:** 10131165

**Subject Initials:** ---

**Generated By:** pfe.lewissc

**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

090177e196ae2f61\Final\Final On: 01-Apr-2021 03:41 (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:** 10131165

**Subject Initials:** ---

**Generated By:** pfe.lewissc

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

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
2.h	Symptom:	NEW OR WORSENERED JOINT PAIN
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO
3.	Injection Site Location:	DELTOID MUSCLE

090177e196ae2f61\Final\Final On: 01-Apr-2021 03:41 (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:** 10131165

**Subject Initials:** ---

**Generated By:** pfe.lewissc

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

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

090177e196ae2f61\Final\Final On: 01-Apr-2021 03:41 (GMT)

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

**Form Version:** 21-Aug-2020 02:51

**Site No:** 1013

**Subject No:** 10131165

**Generated By:** pfe.levissc

**Form:** VITAL SIGNS - TEMP

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

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

**Subject Initials:** ---

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

[eCRF Audit Trail History](#)

**Vital Signs**

1.	Date:	Sep/2/2020
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**Vital Signs Details**

2.a	Record Identifier:	1
	Temperature:	[36.4]
	Unit:	C
	Temperature Location:	ORAL CAVITY

090177e196ae2f61\Final\Final On: 01-Apr-2021 03:41 (GMT)

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

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

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

**Site No:** 1013

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

**Subject No:** 10131165

**Subject Initials:** ---

**Generated By:** pfe.levissc

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

[eCRF Audit Trail History](#)

**Electronic Sample Tracking**

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Sep/2/2020
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	[BN625V]
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090177e196ae2f61\Final\Final On: 01-Apr-2021 03:41 (GMT)

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1013

**Subject No:** 10131165

**Generated By:** pfe.levissc

**Form:** VACCINATION

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

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

**Subject Initials:** ---

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

**eCRF Audit Trail History**

**Vaccination**

1.	Was there a temporary delay of vaccination?	NO
2.	Treatment Name	[BLINDED THERAPY]
3.	Formulation:	INJECTION
4.	Dose Date Time:	Sep/2/2020 14:10
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

090177e196ae2f61\Final\Final On: 01-Apr-2021 03:41 (GMT)

**Header Text:** c4591001

**Visit:** V3\_MONTH1\_POSTVAX2\_L **Form:** DATE OF VISIT

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

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

**Subject No:** 10131165 **Subject Initials:** ---

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

[eCRF Audit Trail History](#)

**Date of Visit**

1.	Date of Visit	Sep/30/2020
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:** 10131165 **Subject Initials:** ---

**Generated By:** pfe.lewissc **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

090177e196ae2f61\Final\Final On: 01-Apr-2021 03:41 (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:** 10131165 **Subject Initials:** ---

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

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
2.h	Symptom:	NEW OR WORSENERED JOINT PAIN
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO
3.	Injection Site Location:	DELTOID MUSCLE

090177e196ae2f61\Final\Final On: 01-Apr-2021 03:41 (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:** 10131165 **Subject Initials:** ---

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

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

090177e196ae2f61\Final\Final On: 01-Apr-2021 03:41 (GMT)

**Header Text:** c4591001

**Visit:** V3\_MONTH1\_POSTVAX2\_L **Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

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

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

**Subject No:** 10131165 **Subject Initials:** ---

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

[eCRF Audit Trail History](#)

**Electronic Sample Tracking**

1.	Data Origin	SITE
2.	Sample Type	SERUM
3.	Sample Collected?	YES Date of Collection: Sep/30/2020
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	[BRG2H6]
5.b	Sample ID	[BRG2H7]
5.c	Sample ID	[BRG2H8]
5.d	Sample ID	[BS6Z7B]
5.e	Sample ID	[BS6Z7C]

090177e196ae2f61\Final\Final On: 01-Apr-2021 03:41 (GMT)

**Header Text:** c4591001

**Visit:** V4\_MONTH6\_L

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

**Site No:** 1013

**Subject No:** 10131165

**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	Feb/24/2021
2.	Erroneous Visit	

**Header Text:** c4591001

**Visit:** V4\_MONTH6\_L

**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

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

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

**Site No:** 1013

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

**Subject No:** 10131165

**Subject Initials:** ---

**Generated By:** pfe.levisse

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

[eCRF Audit Trail History](#)

**Electronic Sample Tracking**

1.	Data Origin	SITE
2.	Sample Type	SERUM
3.	Sample Collected?	YES Date of Collection: Feb/24/2021
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[ ]

**Aliquot**

Please enter barcode for each aliquot.

5.a	Sample ID	[BV09X8]
5.b	Sample ID	[BV09X9]
5.c	Sample ID	[BV09XB]
5.d	Sample ID	[BS49D0]
5.e	Sample ID	[BS49D1]

090177e196ae2f61\Final\Final On: 01-Apr-2021 03:41 (GMT)

**Header Text:** c4591001

**Visit:** V5\_MONTH12\_L

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

**Site No:** 1013

**Subject No:** 10131165

**Generated By:** pfe.levissc

**Form:** DATE OF VISIT

**Form Status:** Not Started

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

**Subject Initials:** ---

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

**Date of Visit**

1.	Date of Visit	//
2.	Erroneous Visit	

**Header Text:** c4591001

**Visit:** V5\_MONTH12\_L

**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

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

**Form Status:** Not Started

**Site No:** 1013

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

**Subject No:** 10131165

**Subject Initials:** ---

**Generated By:** pfe.lewissc

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

**Electronic Sample Tracking**

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

**Aliquot**

Please enter barcode for each aliquot.

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

090177e196ae2f61\Final\Final On: 01-Apr-2021 03:41 (GMT)

**Header Text:** c4591001

**Visit:** V6\_MONTH24\_L

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

**Site No:** 1013

**Subject No:** 10131165

**Generated By:** pfe.lewissc

**Form:** DATE OF VISIT

**Form Status:** Not Started

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

**Subject Initials:** ---

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

**Date of Visit**

1.	Date of Visit	//
2.	Erroneous Visit	

**Header Text:** c4591001

**Visit:** V6\_MONTH24\_L

**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

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

**Form Status:** Not Started

**Site No:** 1013

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

**Subject No:** 10131165

**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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090177e196ae2f61\Final\Final On: 01-Apr-2021 03:41 (GMT)



**Header Text:** c4591001

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

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

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

**Form Status:** Not Started

**Site No:** 1013

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

**Subject No:** 10131165

**Subject Initials:** ---

**Generated By:** pfe.lewissc

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

**Date of Visit**

1.	Date of Visit	//
2.	Erroneous Visit	

**COVID-19 Illness Visit**

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

**Header Text:** c4591001

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

**Form Version:** 20-Feb-2021 02:17

**Site No:** 1013

**Subject No:** 10131165

**Generated By:** pfe.lewissc

**Form:** SIGNS AND SYMPTOMS OF POTENTIAL  
COVID-19

**Form Status:** Not Started

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

**Subject Initials:** ---

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

**Signs and Symptoms**

1.	Date of Assessment:	//
2.	Date of First Symptom Started:	//
3.	Symptoms Ongoing?	

**Symptoms**

4.	Symptoms:	
	Was symptom present?	

**Symptoms - Other**

5.	Symptoms - Other Text:	[ ]
----	------------------------	-----

090177e196ae2f61\Final\Final On: 01-Apr-2021 03:41 (GMT)

**Header Text:** c4591001

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

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

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

**Form Status:** Not Started

**Site No:** 1013

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

**Subject No:** 10131165

**Subject Initials:** ---

**Generated By:** pfe.lewissc

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

**Electronic Sample Tracking**

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

**Aliquot**

Please enter barcode for each aliquot.

5.	Sample ID	[ ]
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090177e196ae2f61\Final\Final On: 01-Apr-2021 03:41 (GMT)

**Header Text:** c4591001**Visit:** POT\_COVID\_ILL - New  
Unscheduled Visit**Form:** ELECTRONIC SAMPLE TRACKING - NASAL  
SWAB**Form Version:** 22-Apr-2020 21:03**Form Status:** Not Started**Site No:** 1013**Site Name:** (1013) Clinical Neuroscience Solutions Inc.**Subject No:** 10131165**Subject Initials:** ---**Generated By:** pfe.lewissc**Generated Time (GMT):** 29-Mar-2021 04:21**Electronic Sample Tracking**

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

**Aliquot**

Please enter barcode for each aliquot.

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

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

**Form:** HEALTH CARE UTILIZATION

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

**Form Status:** Not Started

**Site No:** 1013

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

**Subject No:** 10131165

**Subject Initials:** ---

**Generated By:** pfe.levisse

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

**Health Care Utilization**

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

**Health Care Utilization Other**

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

**Health Care Utilization**

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

090177e196ae2f61\Final\Final On: 01-Apr-2021 03:41 (GMT)

**Header Text:** c4591001

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

**Form:** ILLNESS DETAILS

**Form Version:** 06-Jul-2020 21:52

**Form Status:** Not Started

**Site No:** 1013

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

**Subject No:** 10131165

**Subject Initials:** ---

**Generated By:** pfe.lewissc

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

**Illness Details**

1.	Category of Clinical Event:	
2.	Was a diagnosis obtained for Potential COVID-19 Illness?	
3.	Toxicity Grade:	

**Header Text:** c4591001

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

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

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

**Form Status:** Not Started

**Site No:** 1013

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

**Subject No:** 10131165

**Subject Initials:** ---

**Generated By:** pfe.lewissc

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

**Date of Visit**

1.	Date of Visit	//
2.	Erroneous Visit	

**COVID-19 Illness Visit**

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

**Header Text:** c4591001**Visit:** POT\_COVID\_CONVA - New  
Unscheduled Visit**Form:** ELECTRONIC SAMPLE TRACKING -  
IMMUNOGENICITY**Form Version:** 22-Apr-2020 21:03**Form Status:** Not Started**Site No:** 1013**Site Name:** (1013) Clinical Neuroscience Solutions Inc.**Subject No:** 10131165**Subject Initials:** ---**Generated By:** pfe.levisse**Generated Time (GMT):** 29-Mar-2021 04:21**Electronic Sample Tracking**

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

**Aliquot**

Please enter barcode for each aliquot.

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

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

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

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

**Subject No:** 10131165 **Subject Initials:** ---

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

**Date of Visit**

1.	Date of Visit	//
2.	Erroneous Visit	

**Header Text:** c4591001

**Visit:** Unplanned - New Unscheduled Visit    **Form:** UNPLANNED VISIT

**Form Version:** 22-Apr-2020 21:04    **Form Status:** Not Started

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

**Subject No:** 10131165    **Subject Initials:** ---

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

**Unplanned Assessments**

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

**Header Text:** c4591001

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

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

**Site No:** 1013

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

**Subject No:** 10131165

**Subject Initials:** ---

**Generated By:** pfe.levisse

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

[eCRF Audit Trail History](#)

**Disposition - Treatment**

1.	Date of Completion/Discontinuation/Death :	Sep/30/2020
2.	Phase of Disposition:	VACCINATION
3.	Status:	COMPLETED
4.	Specify Status:	[ ]

**Header Text:** c4591001

**Visit:** Follow-Up - Unscheduled

**Form:** DISPOSITION - FOLLOW-UP

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

**Form Status:** Not Started

**Site No:** 1013

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

**Subject No:** 10131165

**Subject Initials:** ---

**Generated By:** pfe.levisse

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

**Disposition - Follow-Up**

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

**Header Text:** c4591001

**Visit:** POT\_COVID\_REPEAT\_SWAB **Form:** DATE OF VISIT - REPEAT SWAB  
- New Unscheduled Visit

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

**Site No:** 1013

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

**Subject No:** 10131165

**Subject Initials:** ---

**Generated By:** pfe.lewissc

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

**Date of Visit**

1.	Date of Visit	//
2.	Erroneous Visit	

**COVID-19 Repeat Swab**

3.	COVID-19 Repeat Swab:	
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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:** 10131165**Subject Initials:** ---**Generated By:** pfe.levisse**Generated Time (GMT):** 29-Mar-2021 04:21**Electronic Sample Tracking**

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

**Aliquot**

Please enter barcode for each aliquot.

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

**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:** 10131165

**Subject Initials:** ---

**Generated By:** pfe.lewissc

**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	Pulmonary Embolism Bilateral	Dec/14/2020 UNK:UNK	YES	<a href="#">Repeating Pages</a>

090177e196ae2f61\Final\Final On: 01-Apr-2021 03:41 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

**Form:** ADVERSE EVENT REPORT

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

**Form Status:** Data Complete, Not Complete

**Site No:** 1013

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

**Subject No:** 10131165

**Subject Initials:** ---

**Generated By:** pfe.levisse

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

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[eCRF Audit Trail History](#)

[Form Audit Trail](#)

**Adverse Event Report**

1.	Category:	ADVERSE EVENT
2.	AE ID:	[1]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[Pulmonary Embolism Bilateral]
4.	Start Date Time:	Dec/14/2020 UNK:UNK
5.	Is the adverse event still ongoing?	YES
6.	Toxicity Grade:	3

090177e196ae2f61\Final\Final On: 01-Apr-2021 03:41 (GMT)



**Header Text:** c4591001**Visit:** Logs - Unscheduled**Form Version:** 22-Apr-2020 21:02**Site No:** 1013**Subject No:** 10131165**Generated By:** pfe.levisse**Form:** ADVERSE EVENT REPORT**Form Status:** Data Complete, Not Complete**Site Name:** (1013) Clinical Neuroscience Solutions Inc.**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 04:21

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

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

**Form:** ADVERSE EVENT REPORT

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

**Form Status:** Data Complete, Not Complete

**Site No:** 1013

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

**Subject No:** 10131165

**Subject Initials:** ---

**Generated By:** pfe.levisse

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

11.	Was a Concomitant Medication given?	YES
12.	Was a Non-Drug Treatment given?	NO
13.	What was the outcome of this adverse event?:	RECOVERING/RESOLVING
14.	Did the adverse event cause the subject to be discontinued from the study?	NO
15.	Serious Adverse Event Number: For Pfizer Use Only	[2020503549]

090177e196ae2f61\Final\Final On: 01-Apr-2021 03:41 (GMT)

**Header Text:** c4591001

**Visit:** Logs

**Form:** MEDICATION ERROR

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

**Site No:** 1013

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

**Subject No:** 10131165

**Subject Initials:** ---

**Generated By:** pfe.levissc

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

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

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

**Form:** MEDICATION ERROR

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

**Form Status:** Not Started

**Site No:** 1013

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

**Subject No:** 10131165

**Subject Initials:** ---

**Generated By:** pfe.levisse

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

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**Medication Error**

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

090177e196ae2f61\Final\Final On: 01-Apr-2021 03:41 (GMT)

**Header Text:** c4591001

**Visit:** Logs

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

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

**Site No:** 1013

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

**Subject No:** 10131165

**Subject Initials:** ---

**Generated By:** pfe.lewissc

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

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

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

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

**Form Status:** Not Started

**Site No:** 1013

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

**Subject No:** 10131165

**Subject Initials:** ---

**Generated By:** pfe.lewissc

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

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**Concomitant Medications**

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

090177e196ae2f61\Final\Final On: 01-Apr-2021 03:41 (GMT)

**Header Text:** c4591001

**Visit:** Logs

**Form:** CONCOMITANT MEDICATIONS - PROHIBITED

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

**Site No:** 1013

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

**Subject No:** 10131165

**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.						<a href="#">Repeating Pages</a>

090177e196ae2f61\Final\Final On: 01-Apr-2021 03:41 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

**Form:** CONCOMITANT MEDICATIONS - PROHIBITED

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

**Form Status:** Not Started

**Site No:** 1013

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

**Subject No:** 10131165

**Subject Initials:** ---

**Generated By:** pfe.lewissc

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

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**Concomitant Medications**

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

090177e196ae2f61\Final\Final On: 01-Apr-2021 03:41 (GMT)



**Header Text:** c4591001

**Visit:** Logs

**Form:** RADIATION TREATMENT

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

**Site No:** 1013

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

**Subject No:** 10131165

**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.						<a href="#">Repeating Pages</a>

090177e196ae2f61\Final\Final On: 01-Apr-2021 03:41 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

**Form:** RADIATION TREATMENT

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

**Form Status:** Not Started

**Site No:** 1013

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

**Subject No:** 10131165

**Subject Initials:** ---

**Generated By:** pfe.levisse

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

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**Radiation Treatment**

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

090177e196ae2f61\Final\Final On: 01-Apr-2021 03:41 (GMT)

**Header Text:** c4591001

**Visit:** Logs

**Form:** TRANSFUSIONS

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

**Site No:** 1013

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

**Subject No:** 10131165

**Subject Initials:** ---

**Generated By:** pfe.levissc

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

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

090177e196ae2f61\Final\Final On: 01-Apr-2021 03:41 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

**Form:** TRANSFUSIONS

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

**Form Status:** Not Started

**Site No:** 1013

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

**Subject No:** 10131165

**Subject Initials:** ---

**Generated By:** pfe.levisse

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

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

**Header Text:** c4591001

**Visit:** Unplanned Vaccination -  
Unscheduled

**Form:** DATE OF VISIT

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

**Form Status:** Not Started

**Site No:** 1013

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

**Subject No:** 10131165

**Subject Initials:** ---

**Generated By:** pfe.levissc

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

**Date of Visit**

1.	Date of Visit	//
2.	Erroneous Visit	

**Header Text:** c4591001

**Visit:** Unplanned 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:** 10131165

**Subject Initials:** ---

**Generated By:** pfe.lewissc

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

**Vital Signs**

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

**Vital Signs Details**

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

090177e196ae2f61\Final\Final On: 01-Apr-2021 03:41 (GMT)

**Header Text:** c4591001

**Visit:** Unplanned Vaccination -  
Unscheduled

**Form:** VACCINATION

**Form Version:** 10-Dec-2020 02:26

**Form Status:** Not Started

**Site No:** 1013

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

**Subject No:** 10131165

**Subject Initials:** ---

**Generated By:** pfe.levisse

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

**Vaccination**

1.	Was there a temporary delay of vaccination?	
2.	Treatment Name	[ ]
3.	Formulation:	
4.	Dose Date Time:	//
5.	Anatomical Location:	
6.	Body Side:	
7.	Route:	
8.	Actual Dose:	[ ]
9.	Unit:	
10.	Timeframe Subject Was Observed	
11.	Was the subject observed for at least the protocol specified observation period after investigational product administration?	

090177e196ae2f61\Final\Final On: 01-Apr-2021 03:41 (GMT)

**Header Text:** c4591001

**Visit:** Unplanned Vaccination -  
Unscheduled

**Form:** CONTACT OUTCOME - MONTH 1

**Form Version:** 10-Oct-2020 15:57

**Form Status:** Not Started

**Site No:** 1013

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

**Subject No:** 10131165

**Subject Initials:** ---

**Generated By:** pfe.levisse

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

**Contact Outcome**

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



**Header Text:** c4591001

**Visit:** Unplanned Vaccination -  
Unscheduled

**Form:** CONTACT OUTCOME - MONTH 6

**Form Version:** 10-Oct-2020 16:01

**Form Status:** Not Started

**Site No:** 1013

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

**Subject No:** 10131165

**Subject Initials:** ---

**Generated By:** pfe.lewissc

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

**Contact Outcome**

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

**Header Text:** c4591001

**Visit:** V201\_SURVEIL\_CONSENT - **Form:** DATE OF VISIT  
Unscheduled

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

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

**Subject No:** 10131165 **Subject Initials:** ---

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

**Date of Visit**

1.	Date of Visit	//
2.	Erroneous Visit	

**Header Text:** c4591001

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

**Form:** INFORMED CONSENT - ASYMPTOMATIC  
SURVEILLANCE

**Form Version:** 14-Jan-2021 02:29

**Form Status:** Not Started

**Site No:** 1013

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

**Subject No:** 10131165

**Subject Initials:** ---

**Generated By:** pfe.lewissc

**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:** 10131165**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:** 10131165

**Subject Initials:** ---

**Generated By:** pfe.lewissc

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

**Electronic Sample Tracking**

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

**Aliquot**

Please enter barcode for each aliquot.

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

090177e196ae2f61\Final\Final On: 01-Apr-2021 03:41 (GMT)

**Header Text:** c4591001

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

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

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

**Site No:** 1013

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

**Subject No:** 10131165

**Subject Initials:** ---

**Generated By:** pfe.lewissc

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

[eCRF Audit Trail History](#)

Date of Visit		
1.	Date of Visit	Jan/20/2021
2.	Erroneous Visit	

**Header Text:** c4591001

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

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

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

**Subject No:** 10131165      **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:** TREATMENT UNBLINDED

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

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

**Site No:** 1013

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

**Subject No:** 10131165

**Subject Initials:** ---

**Generated By:** pfe.levisse

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

[eCRF Audit Trail History](#)

**Treatment Unblinded**

1.	Date Treatment Unblinded :	Jan/20/2021
2.	Primary Reason for Unblinding:	ASSESS ELIGIBILITY FOR ADDITIONAL VACCINATION



**Header Text:** c4591001

**Visit:** Disposition - Unscheduled

**Form:** WITHDRAWAL OF CONSENT

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

**Form Status:** Not Started

**Site No:** 1013

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

**Subject No:** 10131165

**Subject Initials:** ---

**Generated By:** pfe.levissc

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

**Withdrawal Of Consent**

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

**Header Text:** c4591001

**Visit:** Disposition - Unscheduled

**Form:** DEATH DETAILS CODED

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

**Form Status:** Not Started

**Site No:** 1013

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

**Subject No:** 10131165

**Subject Initials:** ---

**Generated By:** pfe.levissc

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

**Death Details**

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

**Cause of Death**

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

**Header Text:** c4591001

**Visit:** Subject Status - Unscheduled

**Form:** SUBJECT STATUS

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

**Form Status:** Data Complete, Verified

**Site No:** 1013

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

**Subject No:** 10131165

**Subject Initials:** ---

**Generated By:** pfe.levisse

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

[eCRF Audit Trail History](#)

**Subject Status**

1.	Subject Status	FOLLOW-UP
2.	Subject Status Date	Sep/30/2020

**Header Text:** c4591001

**Visit:** Investigator Signature -  
Unscheduled

**Form:** CASEBOOK SIGNATURE FORM

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

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

**Site No:** 1013

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

**Subject No:** 10131165

**Subject Initials:** ---

**Generated By:** pfe.lewissc

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

[eCRF Audit Trail History](#)

**Casebook Signature Form**

1.	Casebook Signature	Click Here to Enable
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**Header Text:** c4591001

**Visit:** Investigator Signature -  
Unscheduled

**Form:** CASEBOOK SIGNATURE FORM

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

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

**Site No:** 1013

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

**Subject No:** 10131165

**Subject Initials:** ---

**Generated By:** pfe.lewissc

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

[Audit Trail](#)

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

- CRF\_Sign

Name	Signature Meaning	Date	Type	Action
Michael Dever	Approved	Mar-04-2021 07:04:20 (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.

090177e196ae2f61\Final\Final On: 01-Apr-2021 03:41 (GMT)

**Header Text:** c4591001

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

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

**Form Version:** 30-Jul-2020 21:29

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

**Site No:** 1013

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

**Subject No:** 10131165

**Subject Initials:** ---

**Generated By:** pfe.levissc

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

[Back to Form](#)

Item	Date	User	Comment
Form	Aug-13-2020 14:24:34 (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:** 10131165

**Subject Initials:** ---

**Generated By:** pfe.lewissc

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

[Back to Form](#)

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

- CRF\_Sign

Name	Signature Meaning	Date	Type	Action
Michael Dever	Approved	Mar-04-2021 07:04:20 (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	Feb-25-2021 13:39:17 (UTC-05:00) Eastern Time (US & Canada)		Edit - All signatures invalidated
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**Affidavit:**

N/A

Patricia Brown	Approved	Feb-25-2021 13:38:16 (UTC-05:00) Eastern Time (US & Canada)	BOOK	Signed
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090177e196ae2f61\Final\Final On: 01-Apr-2021 03:41 (GMT)

**Header Text:** c4591001

**Visit:** Investigator Signature -  
Unscheduled

**Form:** CASEBOOK SIGNATURE FORM - Signature  
History

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

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

**Site No:** 1013

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

**Subject No:** 10131165

**Subject Initials:** ---

**Generated By:** pfe.lewissc

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

**Affidavit:**

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

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

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

Scott Salmon	N/A	Feb-11-2021 13:48:21 (UTC-05:00) Eastern Time (US & Canada)		Edit - All signatures invalidated
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**Affidavit:**

N/A

Michael Dever	Approved	Jan-26-2021 07:45:04 (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.

090177e196ae2f61\Final\Final On: 01-Apr-2021 03:41 (GMT)



**Header Text:** c4591001

**Visit:** Investigator Signature -  
Unscheduled

**Form:** CASEBOOK SIGNATURE FORM - Signature  
History

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

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

**Site No:** 1013

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

**Subject No:** 10131165

**Subject Initials:** ---

**Generated By:** pfe.levissc

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

Scott Salmon	N/A	Jan-25-2021 08:09:17 (UTC-05:00) Eastern Time (US & Canada)		Edit - All signatures invalidated
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**Affidavit:**

N/A

Michael Dever	Approved	Jan-21-2021 08:41:42 (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	Dec-18-2020 14:00:05 (UTC-05:00) Eastern Time (US & Canada)		Edit - All signatures invalidated
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**Affidavit:**

N/A

Michael Dever	Approved	Oct-02-2020 11:51:21 (UTC-05:00) Eastern Time (US & Canada)	BOOK	Signed
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090177e196ae2f61\Final\Final On: 01-Apr-2021 03:41 (GMT)

**Header Text:** c4591001

**Visit:** Investigator Signature -  
Unscheduled

**Form:** CASEBOOK SIGNATURE FORM - Signature  
History

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

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

**Site No:** 1013

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

**Subject No:** 10131165

**Subject Initials:** ---

**Generated By:** pfe.lewissc

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

**Affidavit:**

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

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

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

Scott Salmon	N/A	Sep-30-2020 17:11:05 (UTC-05:00) Eastern Time (US & Canada)		Edit - All signatures invalidated
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**Affidavit:**

N/A

Michael Dever	Approved	Sep-15-2020 06:25:12 (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.

090177e196ae2f61\Final\Final On: 01-Apr-2021 03:41 (GMT)

**Header Text:** c4591001

**Visit:** COHORT\_SELECTION

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

**Form Version:** 30-Jul-2020 21:29

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

**Site No:** 1013

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

**Subject No:** 10131165

**Subject Initials:** ---

**Generated By:** pfe.lewissc

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

[Back to Form](#)

*1. Select appropriate response - Protocol version*

Date	Location	User	Value	Reason
Aug-13-2020 14:23:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe.mstephens)	<b>Data Entry:</b> 24 JUL 2020	Initial Entry

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

Date	Location	User	Value	Reason
Aug-13-2020 14:23:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe.mstephens)	<b>Data Entry:</b> STAGE 3 COHOR TS	Initial Entry

090177e196ae2f61\Final\Final On: 01-Apr-2021 03:41 (GMT)

**Header Text:** c4591001

**Visit:** COHORT\_SELECTION

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

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

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

**Site No:** 1013

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

**Subject No:** 10131165

**Subject Initials:** ---

**Generated By:** pfe.levissc

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

[Back to Form](#)

**1. Consent Was:**

<b>Date</b>	<b>Location</b>	<b>User</b>	<b>Value</b>	<b>Reason</b>
Aug-13-2020 14:24:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe.mstephens)	<b>Data Entry:</b> OBTAINED Date Written Cons ent Obtained  Aug/13/2020	Initial Entry

**Header Text:** c4591001

**Visit:** COHORT\_SELECTION

**Form Version:** 06-Jul-2020 21:55

**Site No:** 1013

**Subject No:** 10131165

**Generated By:** pfe.lewissc

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

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

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

**Subject Initials:** ---

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

[Back to Form](#)

**1. Subject ID**

Date	Location	User	Value	Reason
Aug-13-2020 14:23:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 10131165	Item copied from previous form

**2. Birth Date:**

Date	Location	User	Value	Reason
Aug-13-2020 14:23:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> (b) (6) 1992	Enrollment Entry

**3. Sex:**

Date	Location	User	Value	Reason
Aug-13-2020 14:24:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe.mstephens)	<b>Data Entry:</b> MALE	Initial Entry

**4. Ethnicity:**

Date	Location	User	Value	Reason
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090177e196ae2f61\Final\Final On: 01-Apr-2021 03:41 (GMT)

**Header Text:** c4591001

**Visit:** COHORT\_SELECTION

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

**Form Version:** 06-Jul-2020 21:55

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

**Site No:** 1013

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

**Subject No:** 10131165

**Subject Initials:** ---

**Generated By:** pfe.levissc

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

Aug-13-2020 14:24:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe.mstephens)	<b>Data Entry:</b> HISPANIC OR LA TINO(A) OR OF S PANISH ORIGIN	Initial Entry
---	-----------------	--	--	---------------

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

Date	Location	User	Value	Reason
Aug-13-2020 14:24:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe.mstephens)	<b>Data Entry:</b> WHITE	Initial Entry

090177e196ae2f61\Final\Final On: 01-Apr-2021 03:41 (GMT)

**Header Text:** c4591001

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

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

**Site No:** 1013

**Subject No:** 10131165

**Generated By:** pfe.lewissc

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

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

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

**Subject Initials:** ---

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

[Back to Form](#)

*1. Date of Visit*

<b>Date</b>	<b>Location</b>	<b>User</b>	<b>Value</b>	<b>Reason</b>
Aug-13-2020 14:24:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe.mstephens)	<b>Data Entry:</b> Aug/13/2020	Initial Entry

090177e196ae2f61\Final\Final On: 01-Apr-2021 03:41 (GMT)

**Header Text:** c4591001

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

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

**Site No:** 1013

**Subject No:** 10131165

**Generated By:** pfe.levisse

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

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

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

**Subject Initials:** ---

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

[Back to Form](#)

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

Date	Location	User	Value	Reason
Aug-13-2020 14:24:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe.mstephens)	<b>Data Entry:</b> Aug/13/2020	Initial Entry

**2. Phase of Disposition:**

Date	Location	User	Value	Reason
Aug-13-2020 14:24:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SCREENING	Initial Entry

**3. Status:**

Date	Location	User	Value	Reason
Aug-13-2020 14:24:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe.mstephens)	<b>Data Entry:</b> COMPLETED	Initial Entry

090177e196ae2f61\Final\Final On: 01-Apr-2021 03:41 (GMT)



**Header Text:** c4591001**Visit:** V1\_DAY1\_VAX1\_L**Form:** GENERAL MEDICAL HISTORY - eCRF Audit Trail History**Form Version:** 22-Apr-2020 21:03**Form Status:** Data Complete, Locked, Frozen, Verified**Site No:** 1013**Site Name:** (1013) Clinical Neuroscience Solutions Inc.**Subject No:** 10131165**Subject Initials:** ---**Generated By:** pfe.lewissc**Generated Time (GMT):** 29-Mar-2021 04:21[Back to Form](#)*1.a*

Date	Location	User	Value	Reason
Aug-13-2020 14:25:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Line/MH 1</b> <b>Number:</b> <b>Medical ELEVATE</b> <b>History D TRIGLY</b> <b>Term: CERIDES</b> <b>Start Dat UNK/UNK/</b> <b>e: 2018</b> <b>Ongoing YES</b> :	Initial Entry

*1.a Line/MH Number:*

Date	Location	User	Value	Reason
Aug-13-2020 14:25:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 1	Initial Entry

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

Date	Location	User	Value	Reason
Feb-15-2021 18:55:55 (UTC-05:00)	ACV0PFEINFP6000	Hao Hu (pfe.huh17)	Query 1: Closed	Response satisfies query

**Header Text:** c4591001**Visit:** V1\_DAY1\_VAX1\_L**Form:** GENERAL MEDICAL HISTORY - eCRF Audit Trail History**Form Version:** 22-Apr-2020 21:03**Form Status:** Data Complete, Locked, Frozen, Verified**Site No:** 1013**Site Name:** (1013) Clinical Neuroscience Solutions Inc.**Subject No:** 10131165**Subject Initials:** ---**Generated By:** pfe.levisse**Generated Time (GMT):** 29-Mar-2021 04:21

Eastern Time (US & Canada)				
Feb-11-2021 13:48:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Scott Salmon (pfe.ssalmon)	Query 1: Answered	VAPING ADDED TO MED HX
Feb-07-2021 19:20:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hao Hu (pfe.huh17)	Query 1: Opened	ClinQuery: Please add 'Vaping' in medical history, thanks!
Aug-13-2020 14:25:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe.mstephens)	<b>Data Entry:</b> ELEVATED TRIG LYCERIDES	Initial Entry

***1.a Start Date:***

<b>Date</b>	<b>Location</b>	<b>User</b>	<b>Value</b>	<b>Reason</b>
Aug-13-2020 14:25:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe.mstephens)	<b>Data Entry:</b> UNK/UNK/2018	Initial Entry

***1.a Ongoing:***

<b>Date</b>	<b>Location</b>	<b>User</b>	<b>Value</b>	<b>Reason</b>
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**Header Text:** c4591001

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

**Form:** GENERAL MEDICAL HISTORY - eCRF Audit Trail History

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

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

**Site No:** 1013

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

**Subject No:** 10131165

**Subject Initials:** ---

**Generated By:** pfe.levisse

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

Aug-13-2020 14:25:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe.mstephens)	<b>Data Entry:</b> YES	Initial Entry
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***1.b***

<b>Date</b>	<b>Location</b>	<b>User</b>	<b>Value</b>	<b>Reason</b>
Aug-13-2020 14:25:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Line/MH</b> 2 <b>Number:</b> <b>Medical Hi</b> GENITA <b>story Term</b> L HERPE : S <b>Start Date:</b> Aug/10/2 019 <b>Ongoing:</b> YES	Initial Entry

090177e196ae2f61\Final\Final On: 01-Apr-2021 03:41 (GMT)

**Header Text:** c4591001

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

**Form:** GENERAL MEDICAL HISTORY - eCRF Audit Trail History

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

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

**Site No:** 1013

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

**Subject No:** 10131165

**Subject Initials:** ---

**Generated By:** pfe.lewissc

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

**1.b Line/MH Number:**

Date	Location	User	Value	Reason
Aug-13-2020 14:25:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 2	Initial Entry

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

Date	Location	User	Value	Reason
Aug-13-2020 14:25:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe.mstephens)	<b>Data Entry:</b> GENITAL HERPE S	Initial Entry

**1.b Start Date:**

Date	Location	User	Value	Reason
Aug-13-2020 14:25:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe.mstephens)	<b>Data Entry:</b> Aug/10/2019	Initial Entry

**1.b Ongoing:**

Date	Location	User	Value	Reason
Aug-13-2020 14:25:36	ACV0PFEINFP6000	Matthew Stephens	<b>Data Entry:</b> YES	Initial Entry

090177e196ae2f61\Final\Final On: 01-Apr-2021 03:41 (GMT)

**Header Text:** c4591001

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

**Form:** GENERAL MEDICAL HISTORY - eCRF Audit Trail History

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

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

**Site No:** 1013

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

**Subject No:** 10131165

**Subject Initials:** ---

**Generated By:** pfe.lewissc

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

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

(pfe.mstephens)

*I.c*

Date	Location	User	Value	Reason
Aug-13-2020 14:25:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Line/MH</b> 3 <b>Number:</b> <b>Medical</b> SEASON <b>History T</b> AL ALLE <b>erm:</b> RGIES <b>Start Dat</b> UNK/UN <b>e:</b> K/1982 <b>Ongoing:</b> YES	Initial Entry

090177e196ae2f61\Final\Final On: 01-Apr-2021 03:41 (GMT)

**Header Text:** c4591001

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

**Form:** GENERAL MEDICAL HISTORY - eCRF Audit Trail History

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

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

**Site No:** 1013

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

**Subject No:** 10131165

**Subject Initials:** ---

**Generated By:** pfe.lewissc

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

***1.c Line/MH Number:***

Date	Location	User	Value	Reason
Aug-13-2020 14:25:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 3	Initial Entry

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

Date	Location	User	Value	Reason
Aug-13-2020 14:25:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe.mstephens)	<b>Data Entry:</b> SEASONAL ALLERGIES	Initial Entry

***1.c Start Date:***

Date	Location	User	Value	Reason
Aug-13-2020 14:25:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe.mstephens)	<b>Data Entry:</b> UNK/UNK/1982	Initial Entry

***1.c Ongoing:***

Date	Location	User	Value	Reason
Aug-13-2020 14:25:50	ACV0PFEINFP6000	Matthew Stephens	<b>Data Entry:</b> YES	Initial Entry

090177e196ae2f61\Final\Final On: 01-Apr-2021 03:41 (GMT)

**Header Text:** c4591001

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

**Form:** GENERAL MEDICAL HISTORY - eCRF Audit Trail History

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

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

**Site No:** 1013

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

**Subject No:** 10131165

**Subject Initials:** ---

**Generated By:** pfe.lewissc

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

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

(pfe.mstephens)

*1.d*

Date	Location	User	Value	Reason
Feb-11-2021 13:48:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Line/MH N umber:</b> 4 <b>Medical History Term:</b> VAPING <b>Start Date:</b> UNK/UNK/2016 <b>Ongoing:</b> YES	Initial Entry

090177e196ae2f61\Final\Final On: 01-Apr-2021 03:41 (GMT)

**Header Text:** c4591001

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

**Form:** GENERAL MEDICAL HISTORY - eCRF Audit Trail History

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

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

**Site No:** 1013

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

**Subject No:** 10131165

**Subject Initials:** ---

**Generated By:** pfe.lewissc

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

***1.d Line/MH Number:***

Date	Location	User	Value	Reason
Feb-11-2021 13:48:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 4	Initial Entry

***1.d Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:***

Date	Location	User	Value	Reason
Feb-11-2021 13:48:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Scott Salmon (pfe.ssalmon)	<b>Data Entry:</b> VAPING	Initial Entry

***1.d Start Date:***

Date	Location	User	Value	Reason
Feb-11-2021 13:48:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Scott Salmon (pfe.ssalmon)	<b>Data Entry:</b> UNK/UNK/2016	Initial Entry

***1.d Ongoing:***

Date	Location	User	Value	Reason
Feb-11-2021 13:48:21	ACV0PFEINFP6000	Scott Salmon (pfe.ssalmon)	<b>Data Entry:</b> YES	Initial Entry

090177e196ae2f61\Final\Final On: 01-Apr-2021 03:41 (GMT)



**Header Text:** c4591001

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

**Form:** GENERAL MEDICAL HISTORY - eCRF Audit Trail History

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

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

**Site No:** 1013

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

**Subject No:** 10131165

**Subject Initials:** ---

**Generated By:** pfe.lewissc

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

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

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

**Form Version:** 30-Jul-2020 21:28

**Site No:** 1013

**Subject No:** 10131165

**Generated By:** pfe.lewissc

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

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

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

**Subject Initials:** ---

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

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**1. Date:**

Date	Location	User	Value	Reason
Aug-13-2020 14:26:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe.mstephens)	<b>Data Entry:</b> Aug/13/2020	Initial Entry

**2. Weight:**

Date	Location	User	Value	Reason
Aug-13-2020 14:26:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe.mstephens)	<b>Data Entry:</b> 86.0	Initial Entry

**3. Unit:**

Date	Location	User	Value	Reason
Aug-13-2020 14:26:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe.mstephens)	<b>Data Entry:</b> kg	Initial Entry

**4. Height:**

Date	Location	User	Value	Reason
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090177e196ae2f61\Final\Final On: 01-Apr-2021 03:41 (GMT)

**Header Text:** c4591001

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

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

**Form Version:** 30-Jul-2020 21:28

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

**Site No:** 1013

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

**Subject No:** 10131165

**Subject Initials:** ---

**Generated By:** pfe.levisse

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

Aug-13-2020 14:26:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe.mstephens)	<b>Data Entry:</b> 183.0	Initial Entry
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**5. Unit:**

Date	Location	User	Value	Reason
Aug-13-2020 14:26:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe.mstephens)	<b>Data Entry:</b> cm	Initial Entry

**6. Body Mass Index:**

Date	Location	User	Value	Reason
Aug-13-2020 14:26:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 25.7	Initial Entry

**7.a**

Date	Location	User	Value	Reason
Aug-13-2020 14:26:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe.mstephens)	<b>Data Entry:</b> <b>Record Id 1</b> <b>entifier::</b> <b>Temperat 35.8</b> <b>ure:</b>	Initial Entry

090177e196ae2f61\Final\Final On: 01-Apr-2021 03:41 (GMT)

**Header Text:** c4591001

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

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

**Form Version:** 30-Jul-2020 21:28

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

**Site No:** 1013

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

**Subject No:** 10131165

**Subject Initials:** ---

**Generated By:** pfe.lewissc

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

			<b>Temperat C ure Unit:</b> <b>Temperat ORAL ure Locati CAVIT on:: Y</b>	
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**7.a Record Identifier:**

Date	Location	User	Value	Reason
Aug-13-2020 14:26:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe.mstephens)	<b>Data Entry:</b> 1	Initial Entry

**7.a Temperature:**

Date	Location	User	Value	Reason
Aug-14-2020 08:16:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Cavin van Schalkwyk (pfe.vanscc01)	Query 1: Closed	Response satisfies query
Aug-13-2020 14:28:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe.mstephens)	Query 1: Answered	CORRECT AS RECORDED PER SOURCE
Aug-13-2020 14:26:14 (UTC-05:00)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	Temperature 35.8 C is outside of

090177e196ae2f61\Final\Final On: 01-Apr-2021 03:41 (GMT)

**Header Text:** c4591001

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

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

**Form Version:** 30-Jul-2020 21:28

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

**Site No:** 1013

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

**Subject No:** 10131165

**Subject Initials:** ---

**Generated By:** pfe.lewissc

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

Eastern Time (US & Canada)				Normal Range 36.1 - 37.5 C.
Aug-13-2020 14:26:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe.mstephens)	<b>Data Entry:</b> 35.8	Initial Entry

**7.a Unit:**

Date	Location	User	Value	Reason
Aug-13-2020 14:26:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe.mstephens)	<b>Data Entry:</b> C	Initial Entry

**7.a Temperature Location:**

Date	Location	User	Value	Reason
Aug-13-2020 14:26:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe.mstephens)	<b>Data Entry:</b> ORAL CAVITY	Initial Entry

090177e196ae2f61\Final\Final On: 01-Apr-2021 03:41 (GMT)

**Header Text:** c4591001

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

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

**Site No:** 1013

**Subject No:** 10131165

**Generated By:** pfe.lewissc

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

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

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

**Subject Initials:** ---

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

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**1. Randomization Date :**

Date	Location	User	Value	Reason
Aug-13-2020 14:27:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe.mstephens)	<b>Data Entry:</b> Aug/13/2020	Initial Entry

**2. Randomization Number:**

Date	Location	User	Value	Reason
Aug-13-2020 14:27:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe.mstephens)	<b>Data Entry:</b> 48413	Initial Entry

090177e196ae2f61\Final\Final On: 01-Apr-2021 03:41 (GMT)

**Header Text:** c4591001

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

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

**Site No:** 1013

**Subject No:** 10131165

**Generated By:** pfe.levisse

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

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

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

**Subject Initials:** ---

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

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**1. Data Origin**

Date	Location	User	Value	Reason
Aug-13-2020 14:27:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SITE	Initial Entry

**2. Sample Type**

Date	Location	User	Value	Reason
Aug-13-2020 14:27:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SERUM	Initial Entry

**3. Sample Collected?**

Date	Location	User	Value	Reason
Aug-13-2020 17:34:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Aug-13-2020 14:27:31 (UTC-05:00)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however

090177e196ae2f61\Final\Final On: 01-Apr-2021 03:41 (GMT)

**Header Text:** c4591001

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

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

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

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

**Site No:** 1013

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

**Subject No:** 10131165

**Subject Initials:** ---

**Generated By:** pfe.lewissc

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

Eastern Time (US & Canada)				no barcodes are entered. Please review and correct as appropriate.
Aug-13-2020 14:27:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe.mstephens)	<b>Data Entry:</b> YES Date of Collection:  Aug/13/2020	Initial Entry

**5.a**

Date	Location	User	Value	Reason
Aug-13-2020 17:34:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe.mstephens)	<b>Data Entry:</b> <b>Sample I</b> BPYW9 <b>D:</b> Z	Initial Entry

**5.a Sample ID**

Date	Location	User	Value	Reason
Aug-13-2020 17:34:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe.mstephens)	<b>Data Entry:</b> BPYW9Z	Initial Entry

**5.b**

090177e196ae2f61\Final\Final On: 01-Apr-2021 03:41 (GMT)



**Header Text:** c4591001

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

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

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

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

**Site No:** 1013

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

**Subject No:** 10131165

**Subject Initials:** ---

**Generated By:** pfe.levissc

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

Date	Location	User	Value	Reason
Aug-13-2020 17:34:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe.mstephens)	<b>Data Entry:</b> <b>Sample I</b> BPYW <b>D:</b> B0	Initial Entry

**5.b Sample ID**

Date	Location	User	Value	Reason
Aug-13-2020 17:34:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe.mstephens)	<b>Data Entry:</b> BPYWBO	Initial Entry

**5.c**

Date	Location	User	Value	Reason
Aug-13-2020 17:34:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe.mstephens)	<b>Data Entry:</b> <b>Sample I</b> BPYW <b>D:</b> B1	Initial Entry

090177e196ae2f61\Final\Final On: 01-Apr-2021 03:41 (GMT)

**Header Text:** c4591001

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

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

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

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

**Site No:** 1013

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

**Subject No:** 10131165

**Subject Initials:** ---

**Generated By:** pfe.lewissc

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

**5.c Sample ID**

Date	Location	User	Value	Reason
Aug-13-2020 17:34:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe.mstephens)	<b>Data Entry:</b> BPYWB1	Initial Entry

**5.d**

Date	Location	User	Value	Reason
Aug-13-2020 17:35:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe.mstephens)	<b>Data Entry:</b> <b>Sample I BNWH</b> <b>D: GG</b>	Initial Entry

**5.d Sample ID**

Date	Location	User	Value	Reason
Aug-13-2020 17:35:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe.mstephens)	<b>Data Entry:</b> BNWHGG	Initial Entry

**5.e**

Date	Location	User	Value	Reason
Aug-13-2020 17:35:06	ACV0PFEINFP6000	Matthew Stephens	<b>Data Entry:</b> <b>Sample I BNWH</b>	Initial Entry

090177e196ae2f61\Final\Final On: 01-Apr-2021 03:41 (GMT)

**Header Text:** c4591001

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

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

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

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

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

**Subject No:** 10131165

**Subject Initials:** ---

**Generated By:** pfe.lewissc

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

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

(pfe.mstephens)

**D:** GH

**5.e Sample ID**

<b>Date</b>	<b>Location</b>	<b>User</b>	<b>Value</b>	<b>Reason</b>
Aug-13-2020 17:35:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe.mstephens)	<b>Data Entry:</b> BNWHGH	Initial Entry

090177e196ae2f61\Final\Final On: 01-Apr-2021 03:41 (GMT)

**Header Text:** c4591001

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

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

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

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

**Site No:** 1013

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

**Subject No:** 10131165

**Subject Initials:** ---

**Generated By:** pfe.levisse

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

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**1. Data Origin**

Date	Location	User	Value	Reason
Aug-13-2020 14:27:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SITE	Initial Entry

**2. Sample Type**

Date	Location	User	Value	Reason
Aug-13-2020 14:27:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> NASAL_SWAB	Initial Entry

**3. Sample Collected?**

Date	Location	User	Value	Reason
Aug-13-2020 17:35:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Aug-13-2020 14:27:39 (UTC-05:00)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however

090177e196ae2f61\Final\Final On: 01-Apr-2021 03:41 (GMT)

**Header Text:** c4591001

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

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

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

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

**Site No:** 1013

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

**Subject No:** 10131165

**Subject Initials:** ---

**Generated By:** pfe.lewissc

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

Eastern Time (US & Canada)				no barcodes are entered. Please review and correct as appropriate.
Aug-13-2020 14:27:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe.mstephens)	<b>Data Entry:</b> YES Date of Collection:  Aug/13/2020	Initial Entry

**5.a**

Date	Location	User	Value	Reason
Aug-13-2020 17:35:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe.mstephens)	<b>Data Entry:</b> <b>Sample I</b> BM8S3 <b>D:</b> Z	Initial Entry

**5.a Sample ID**

Date	Location	User	Value	Reason
Aug-13-2020 17:35:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe.mstephens)	<b>Data Entry:</b> BM8S3Z	Initial Entry

090177e196ae2f61\Final\Final On: 01-Apr-2021 03:41 (GMT)

**Header Text:** c4591001

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

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

**Site No:** 1013

**Subject No:** 10131165

**Generated By:** pfe.levissc

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

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

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

**Subject Initials:** ---

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

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

Date	Location	User	Value	Reason
Aug-13-2020 14:37:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe.mstephens)	<b>Data Entry:</b> NO	Initial Entry

**2. Treatment Name**

Date	Location	User	Value	Reason
Aug-13-2020 14:37:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> BLINDED THERAPY	Initial Entry

**3. Formulation:**

Date	Location	User	Value	Reason
Aug-13-2020 14:37:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> INJECTION	Initial Entry

**4. Dose Date Time:**

Date	Location	User	Value	Reason
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090177e196ae2f61\Final\Final On: 01-Apr-2021 03:41 (GMT)

**Header Text:** c4591001

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

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

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

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

**Site No:** 1013

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

**Subject No:** 10131165

**Subject Initials:** ---

**Generated By:** pfe.levissc

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

Aug-13-2020 14:37:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe.mstephens)	<b>Data Entry:</b> Aug/13/2020 10:36	Initial Entry
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**5. Anatomical Location:**

Date	Location	User	Value	Reason
Aug-13-2020 14:37:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> DELTOID MUSCLE	Initial Entry

**6. Body Side:**

Date	Location	User	Value	Reason
Aug-13-2020 14:37:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe.mstephens)	<b>Data Entry:</b> LEFT	Initial Entry

**7. Route:**

Date	Location	User	Value	Reason
Aug-13-2020 14:37:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> INTRAMUSCULAR	Initial Entry

090177e196ae2f61\Final\Final On: 01-Apr-2021 03:41 (GMT)

**Header Text:** c4591001

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

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

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

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

**Site No:** 1013

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

**Subject No:** 10131165

**Subject Initials:** ---

**Generated By:** pfe.levissc

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

**10. Timeframe Subject Was Observed**

Date	Location	User	Value	Reason
Aug-13-2020 14:37:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> THE PROTOCOL SPE CIFIED OBSERVATIO N PERIOD	Initial Entry

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

Date	Location	User	Value	Reason
Aug-13-2020 14:37:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe.mstephens)	<b>Data Entry:</b> YES	Initial Entry

090177e196ae2f61\Final\Final On: 01-Apr-2021 03:41 (GMT)



**Header Text:** c4591001

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

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

**Site No:** 1013

**Subject No:** 10131165

**Generated By:** pfe.lewissc

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

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

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

**Subject Initials:** ---

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

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*1. Select appropriate response - Reactogenicity diary collection*

Date	Location	User	Value	Reason
Aug-13-2020 14:27:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe.mstephens)	<b>Data Entry:</b> YES - REACTOGE NICITY E-DIARY COLLECTED FOR THIS SUBJECT	Initial Entry

090177e196ae2f61\Final\Final On: 01-Apr-2021 03:41 (GMT)

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1013

**Subject No:** 10131165

**Generated By:** pfe.lewissc

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

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

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

**Subject Initials:** ---

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

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*1. Date of Visit*

<b>Date</b>	<b>Location</b>	<b>User</b>	<b>Value</b>	<b>Reason</b>
Sep-02-2020 16:35:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe.mstephens)	<b>Data Entry:</b> Sep/2/2020	Initial Entry

090177e196ae2f61\Final\Final On: 01-Apr-2021 03:41 (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:** 10131165

**Subject Initials:** ---

**Generated By:** pfe.lewissc

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

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

Date	Location	User	Value	Reason
Sep-02-2020 16:36:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe.mstephens)	<b>Data Entry:</b> NO	Initial Entry

**2.a**

Date	Location	User	Value	Reason
Sep-02-2020 16:36:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe.mstephens)	<b>Data Entry:</b> <b>Symptom::</b> F E V E R  <b>Were fever or systemic symptoms present on the last day the Subject Diary was completed?:</b> N O	Initial Entry

**2.a Symptom:**

Date	Location	User	Value	Reason
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090177e196ae2f61\Final\Final On: 01-Apr-2021 03:41 (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:** 10131165

**Subject Initials:** ---

**Generated By:** pfe.levisse

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

Sep-02-2020 16:36:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe.mstephens)	<b>Data Entry:</b> FEVER	Initial Entry
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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
Sep-02-2020 16:36:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe.mstephens)	<b>Data Entry:</b> NO	Initial Entry

**2.b**

Date	Location	User	Value	Reason
Sep-02-2020 16:36:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe.mstephens)	<b>Data Entry:</b> <b>Symptom::</b> FA TI G U E  <b>Were fever or systemic symp toms present o n the last day t he Subject Dia ry was comple ted?:</b> N O	Initial Entry

090177e196ae2f61\Final\Final On: 01-Apr-2021 03:41 (GMT)

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

**Form:** VACCINATION SYMPTOMS DIARY -  
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**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:** 10131165

**Subject Initials:** ---

**Generated By:** pfe.levisse

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**2.b Symptom:**

Date	Location	User	Value	Reason
Sep-02-2020 16:36:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe.mstephens)	<b>Data Entry:</b> 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
Sep-02-2020 16:36:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe.mstephens)	<b>Data Entry:</b> NO	Initial Entry

**2.c**

Date	Location	User	Value	Reason
Sep-02-2020 16:37:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe.mstephens)	<b>Data Entry:</b> <b>Symptom::</b> HE A D A C HE	Initial Entry

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**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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**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:** 10131165

**Subject Initials:** ---

**Generated By:** pfe.levisse

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

			<p><b>Were fever or N systemic symp O toms present on the last da y the Subject Diary was co mpleted?:</b></p>	
<p>Sep-02-2020 16:36:31 (UTC-05:00) Eastern Time (US &amp; Canada)</p>	ACV0PFEINFP6000	<p>Matthew Stephens (pfe.mstephens)</p>	<p><b>Data Entry:</b> <b>Symptom::</b> HE A D A C HE</p> <p><b>Were fever or systemic symp toms present on the last da y the Subject Diary was co mpleted?:</b></p>	Initial Entry

090177e196ae2f61\Final\Final On: 01-Apr-2021 03:41 (GMT)

Header Text: c4591001

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Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1013

Site Name: (1013) Clinical Neuroscience Solutions Inc.

Subject No: 10131165

Subject Initials: ---

Generated By: pfe.lewissc

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

2.c Symptom:

Date	Location	User	Value	Reason
Sep-02-2020 16:36:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe.mstephens)	<b>Data Entry:</b> 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
Sep-02-2020 16:37:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe.mstephens)	<b>Data Entry:</b> NO	Initial Entry

2.d

Date	Location	User	Value	Reason
Sep-02-2020 16:36:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe.mstephens)	<b>Data Entry:</b> <b>Symptom::</b> C HI L L S	Initial Entry

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**Header Text:** c4591001

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**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:** 10131165

**Subject Initials:** ---

**Generated By:** pfe.levisse

**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.d Symptom:**

Date	Location	User	Value	Reason
Sep-02-2020 16:36:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe.mstephens)	<b>Data Entry:</b> 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
Sep-02-2020 16:36:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe.mstephens)	<b>Data Entry:</b> NO	Initial Entry

**2.e**

Date	Location	User	Value	Reason
Sep-02-2020 16:36:31	ACV0PFEINFP6000	Matthew Stephens	<b>Data Entry:</b> <b>Symptom::</b> VO	Initial Entry

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**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

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

**Site No:** 1013

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

**Subject No:** 10131165

**Subject Initials:** ---

**Generated By:** pfe.levisse

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

(UTC-05:00) Eastern Time (US & Canada)		(pfe.mstephens)	MI TI NG  <b>Were fever or systemic sym ptoms present on the last da y the Subject Diary was co mpleted?:</b>	NO
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**2.e Symptom:**

Date	Location	User	Value	Reason
Sep-02-2020 16:36:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe.mstephens)	<b>Data Entry:</b> 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
Sep-02-2020 16:36:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe.mstephens)	<b>Data Entry:</b> NO	Initial Entry

**2.f**

Date	Location	User	Value	Reason
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**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

**Form:** VACCINATION SYMPTOMS DIARY -  
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**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:** 10131165

**Subject Initials:** ---

**Generated By:** pfe.levisse

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

<p>Sep-02-2020 16:36:31 (UTC-05:00) Eastern Time (US &amp; Canada)</p>	<p>ACV0PFEINFP6000</p>	<p>Matthew Stephens (pfe.mstephens)</p>	<p><b>Data Entry:</b> <b>Symptom::</b>   DI                   A                   R                   R                   H                   E                   A  <b>Were fever or N</b> <b>systemic symp O</b> <b>toms present</b> <b>on the last da</b> <b>y the Subject</b> <b>Diary was co</b> <b>mpleted?:</b></p>	<p>Initial Entry</p>
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090177e196ae2f61\Final\Final On: 01-Apr-2021 03:41 (GMT)

Header Text: c4591001

Visit: V2\_VAX2\_L

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Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1013

Site Name: (1013) Clinical Neuroscience Solutions Inc.

Subject No: 10131165

Subject Initials: ---

Generated By: pfe.levisse

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

2.f Symptom:

Date	Location	User	Value	Reason
Sep-02-2020 16:36:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe.mstephens)	<b>Data Entry:</b> 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
Sep-02-2020 16:36:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe.mstephens)	<b>Data Entry:</b> NO	Initial Entry

2.g

Date	Location	User	Value	Reason
Sep-02-2020 16:36:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe.mstephens)	<b>Data Entry:</b> <b>Symptom::</b> NEW OR WOR SENE D M USCL E PAI N	Initial Entry

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**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:** 10131165

**Subject Initials:** ---

**Generated By:** pfe.levisse

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

			Were fever NO or systemic symptoms present on the last day the Subject Diary was completed? :	
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**2.g Symptom:**

Date	Location	User	Value	Reason
Sep-02-2020 16:36:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe.mstephens)	<b>Data Entry:</b> NEW OR WORSE NED MUSCLE PAI N	Initial Entry

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

Date	Location	User	Value	Reason
Sep-02-2020 16:36:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe.mstephens)	<b>Data Entry:</b> NO	Initial Entry

**2.h**

Date	Location	User	Value	Reason
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090177e196ae2f61\Final\Final On: 01-Apr-2021 03:41 (GMT)

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

**Form:** VACCINATION SYMPTOMS DIARY -  
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**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:** 10131165

**Subject Initials:** ---

**Generated By:** pfe.levisse

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

<p>Sep-02-2020 16:36:31 (UTC-05:00) Eastern Time (US &amp; Canada)</p>	<p>ACV0PFEINFP6000</p>	<p>Matthew Stephens (pfe.mstephens)</p>	<p><b>Data Entry:</b> <b>Symptom::</b> NEW OR WOR SEN ED J OINT PAIN  <b>Were fever NO or systemic symptoms present on t he last day the Subject Diary was c ompleted?:</b></p>	<p>Initial Entry</p>
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**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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**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:** 10131165

**Subject Initials:** ---

**Generated By:** pfe.levisse

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

**2.h Symptom:**

Date	Location	User	Value	Reason
Sep-02-2020 16:36:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe.mstephens)	<b>Data Entry:</b> NEW OR WORSE NED 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
Sep-02-2020 16:36:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe.mstephens)	<b>Data Entry:</b> NO	Initial Entry

**3. Injection Site Location:**

Date	Location	User	Value	Reason
Sep-02-2020 16:36:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> DELTOID MUSCLE	Initial Entry

**4. Injection Site Body Side:**

Date	Location	User	Value	Reason
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090177e196ae2f61\Final\Final On: 01-Apr-2021 03:41 (GMT)

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

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

**Site No:** 1013

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

**Subject No:** 10131165

**Subject Initials:** ---

**Generated By:** pfe.levisse

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

Sep-02-2020 16:36:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe.mstephens)	<b>Data Entry:</b> LEFT	Initial Entry
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**5.a**

Date	Location	User	Value	Reason
Sep-02-2020 16:36:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe.mstephens)	<b>Data Entry:</b> <b>Injection Site</b> R <b>Reaction::</b> E D N ES S  <b>Were injection N</b> <b>site reactions O</b> <b>present on the</b> <b>last day the S</b> <b>ubject Diary</b> <b>was completed</b> <b>?:</b>	Initial Entry

**5.a Injection Site Reaction:**

Date	Location	User	Value	Reason
Sep-02-2020 16:36:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe.mstephens)	<b>Data Entry:</b> REDNESS	Initial Entry

090177e196ae2f61\Final\Final On: 01-Apr-2021 03:41 (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:** 10131165

**Subject Initials:** ---

**Generated By:** pfe.levisse

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

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

Date	Location	User	Value	Reason
Sep-02-2020 16:36:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe.mstephens)	<b>Data Entry:</b> NO	Initial Entry

**5.b**

Date	Location	User	Value	Reason
Sep-02-2020 16:36:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe.mstephens)	<b>Data Entry:</b> <b>Injection Site</b> SW <b>Reaction::</b> EL LI NG  <b>Were injection site reactions present on the last day the Subject Diary was completed?:</b> NO	Initial Entry

090177e196ae2f61\Final\Final On: 01-Apr-2021 03:41 (GMT)



**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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**Form Version:** 30-Jul-2020 21:30

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**Site No:** 1013

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**Subject No:** 10131165

**Subject Initials:** ---

**Generated By:** pfe.levisse

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

**5.b Injection Site Reaction:**

Date	Location	User	Value	Reason
Sep-02-2020 16:36:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe.mstephens)	<b>Data Entry:</b> SWELLING	Initial Entry

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

Date	Location	User	Value	Reason
Sep-02-2020 16:36:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe.mstephens)	<b>Data Entry:</b> NO	Initial Entry

**5.c**

Date	Location	User	Value	Reason
Sep-02-2020 16:36:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe.mstephens)	<b>Data Entry:</b> <b>Injection Site Reaction::</b> PAI N A T IN JEC TIO N SI TE	Initial Entry

090177e196ae2f61\Final\Final On: 01-Apr-2021 03:41 (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:** 10131165

**Subject Initials:** ---

**Generated By:** pfe.levisse

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

			<b>Were injection site reactions present on the last day the Subject Diary was completed?:</b>	
--	--	--	--	--

**5.c Injection Site Reaction:**

Date	Location	User	Value	Reason
Sep-02-2020 16:36:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe.mstephens)	<b>Data Entry:</b> 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
Sep-02-2020 16:36:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe.mstephens)	<b>Data Entry:</b> NO	Initial Entry

090177e196ae2f61\Final\Final On: 01-Apr-2021 03:41 (GMT)

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

**Form Version:** 21-Aug-2020 02:51

**Site No:** 1013

**Subject No:** 10131165

**Generated By:** pfe.lewissc

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

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

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

**Subject Initials:** ---

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

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**1. Date:**

Date	Location	User	Value	Reason
Sep-02-2020 16:36:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe.mstephens)	<b>Data Entry:</b> Sep/2/2020	Initial Entry

**2.a**

Date	Location	User	Value	Reason
Sep-02-2020 16:36:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe.mstephens)	<b>Data Entry:</b> <b>Record Id 1</b> <b>entifier::</b> <b>Temperat 36.4</b> <b>ure:</b> <b>Temperat C</b> <b>ure Unit:</b> <b>Temperat ORAL</b> <b>ure Locati CAVIT</b> <b>on:: Y</b>	Initial Entry

**2.a Record Identifier:**

Date	Location	User	Value	Reason
Sep-02-2020 16:36:49 (UTC-05:00) Eastern Time (US	ACV0PFEINFP6000	Matthew Stephens (pfe.mstephens)	<b>Data Entry:</b> 1	Initial Entry

090177e196ae2f61\Final\Final On: 01-Apr-2021 03:41 (GMT)

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

**Form Version:** 21-Aug-2020 02:51

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

**Site No:** 1013

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

**Subject No:** 10131165

**Subject Initials:** ---

**Generated By:** pfe.levisse

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

& Canada)

**2.a Temperature:**

Date	Location	User	Value	Reason
Sep-02-2020 16:36:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe.mstephens)	<b>Data Entry:</b> 36.4	Initial Entry

**2.a Unit:**

Date	Location	User	Value	Reason
Sep-02-2020 16:36:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe.mstephens)	<b>Data Entry:</b> C	Initial Entry

**2.a Temperature Location:**

Date	Location	User	Value	Reason
Sep-02-2020 16:36:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe.mstephens)	<b>Data Entry:</b> ORAL CAVITY	Initial Entry

090177e196ae2f61\Final\Final On: 01-Apr-2021 03:41 (GMT)

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

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

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

**Site No:** 1013

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

**Subject No:** 10131165

**Subject Initials:** ---

**Generated By:** pfe.levisse

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

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**1. Data Origin**

Date	Location	User	Value	Reason
Sep-02-2020 16:36:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SITE	Initial Entry

**2. Sample Type**

Date	Location	User	Value	Reason
Sep-02-2020 16:36:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> NASAL_SWAB	Initial Entry

**3. Sample Collected?**

Date	Location	User	Value	Reason
Sep-02-2020 17:53:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Sep-02-2020 16:36:56 (UTC-05:00)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however

090177e196ae2f61\Final\Final On: 01-Apr-2021 03:41 (GMT)

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

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

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

**Site No:** 1013

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

**Subject No:** 10131165

**Subject Initials:** ---

**Generated By:** pfe.lewissc

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

Eastern Time (US & Canada)				no barcodes are entered. Please review and correct as appropriate.
Sep-02-2020 16:36:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe.mstephens)	<b>Data Entry:</b> YES Date of Collection:  Sep/2/2020	Initial Entry

**5.a**

Date	Location	User	Value	Reason
Sep-02-2020 17:53:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe.mstephens)	<b>Data Entry:</b> <b>Sample I</b> BN625 <b>D:</b> V	Initial Entry

**5.a Sample ID**

Date	Location	User	Value	Reason
Sep-02-2020 17:53:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe.mstephens)	<b>Data Entry:</b> BN625V	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:** 10131165

**Generated By:** pfe.lewissc

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

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

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

**Subject Initials:** ---

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

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

Date	Location	User	Value	Reason
Sep-02-2020 16:37:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe.mstephens)	<b>Data Entry:</b> NO	Initial Entry

**2. Treatment Name**

Date	Location	User	Value	Reason
Sep-02-2020 16:37:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> BLINDED THERAPY	Initial Entry

**3. Formulation:**

Date	Location	User	Value	Reason
Sep-02-2020 16:37:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> INJECTION	Initial Entry

**4. Dose Date Time:**

Date	Location	User	Value	Reason
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090177e196ae2f61\Final\Final On: 01-Apr-2021 03:41 (GMT)

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

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

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

**Site No:** 1013

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

**Subject No:** 10131165

**Subject Initials:** ---

**Generated By:** pfe.lewissc

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

Sep-02-2020 16:37:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe.mstephens)	<b>Data Entry:</b> Sep/2/2020 14:10	Initial Entry
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**5. Anatomical Location:**

Date	Location	User	Value	Reason
Sep-02-2020 16:37:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> DELTOID MUSCLE	Initial Entry

**6. Body Side:**

Date	Location	User	Value	Reason
Sep-02-2020 16:37:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe.mstephens)	<b>Data Entry:</b> LEFT	Initial Entry

**7. Route:**

Date	Location	User	Value	Reason
Sep-02-2020 16:37:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> INTRAMUSCULAR	Initial Entry

090177e196ae2f61\Final\Final On: 01-Apr-2021 03:41 (GMT)



**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

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

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

**Site No:** 1013

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

**Subject No:** 10131165

**Subject Initials:** ---

**Generated By:** pfe.levissc

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

**10. Timeframe Subject Was Observed**

Date	Location	User	Value	Reason
Sep-02-2020 16:37:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> THE PROTOCOL SPE CIFIED OBSERVATIO N PERIOD	Initial Entry

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

Date	Location	User	Value	Reason
Sep-02-2020 16:37:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe.mstephens)	<b>Data Entry:</b> YES	Initial Entry

090177e196ae2f61\Final\Final On: 01-Apr-2021 03:41 (GMT)

**Header Text:** c4591001

**Visit:** V3\_MONTH1\_POSTVAX2\_L **Form:** DATE OF VISIT - eCRF Audit Trail History

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

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

**Subject No:** 10131165 **Subject Initials:** ---

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

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*1. Date of Visit*

<b>Date</b>	<b>Location</b>	<b>User</b>	<b>Value</b>	<b>Reason</b>
Sep-30-2020 17:11:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Scott Salmon (pfe.ssalmon)	<b>Data Entry:</b> Sep/30/2020	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:** 10131165 **Subject Initials:** ---

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

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

Date	Location	User	Value	Reason
Sep-30-2020 17:11:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Scott Salmon (pfe.ssalmon)	<b>Data Entry:</b> NO	Initial Entry

**2.a**

Date	Location	User	Value	Reason
Sep-30-2020 17:11:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Scott Salmon (pfe.ssalmon)	<b>Data Entry:</b> <b>Symptom::</b> F E V E R  Were fever or s N ystemic sympto O ms present on t he last day the S ubject Diary wa s completed?:	Initial Entry

**2.a Symptom:**

Date	Location	User	Value	Reason
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**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:** 10131165 **Subject Initials:** ---

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

Sep-30-2020 17:11:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Scott Salmon (pfe.ssalmon)	<b>Data Entry:</b> FEVER	Initial Entry
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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
Sep-30-2020 17:11:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Scott Salmon (pfe.ssalmon)	<b>Data Entry:</b> NO	Initial Entry

**2.b**

Date	Location	User	Value	Reason
Sep-30-2020 17:11:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Scott Salmon (pfe.ssalmon)	<b>Data Entry:</b> <b>Symptom::</b> FA TI G U E  Were fever or s N ystemic sympto O ms present on t he last day the Subject Diary was completed? : :	Initial Entry

090177e196ae2f61\Final\Final On: 01-Apr-2021 03:41 (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:** 10131165 **Subject Initials:** ---

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

**2.b Symptom:**

Date	Location	User	Value	Reason
Sep-30-2020 17:11:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Scott Salmon (pfe.ssalmon)	<b>Data Entry:</b> 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
Sep-30-2020 17:11:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Scott Salmon (pfe.ssalmon)	<b>Data Entry:</b> NO	Initial Entry

**2.c**

Date	Location	User	Value	Reason
Sep-30-2020 17:11:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Scott Salmon (pfe.ssalmon)	<b>Data Entry:</b> <b>Symptom::</b> HE A D AC HE	Initial Entry

090177e196ae2f61\Final\Final On: 01-Apr-2021 03:41 (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:** 10131165**Subject Initials:** ---**Generated By:** pfe.levisse**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
Sep-30-2020 17:11:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Scott Salmon (pfe.ssalmon)	<b>Data Entry:</b> 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
Sep-30-2020 17:11:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Scott Salmon (pfe.ssalmon)	<b>Data Entry:</b> NO	Initial Entry

**2.d**

Date	Location	User	Value	Reason
Sep-30-2020 17:11:39	ACV0PFEINFP6000	Scott Salmon (pfe.ssalmon)	<b>Data Entry:</b> <b>Symptom::</b> C	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:** 10131165 **Subject Initials:** ---

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

(UTC-05:00) Eastern Time (US & Canada)			HI L L S N O <b>Were fever or systemic symptoms present on the last day the Subject Diary was completed?:</b>	
--	--	--	---	--

**2.d Symptom:**

Date	Location	User	Value	Reason
Sep-30-2020 17:11:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Scott Salmon (pfe.ssalmon)	<b>Data Entry:</b> 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
Sep-30-2020 17:11:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Scott Salmon (pfe.ssalmon)	<b>Data Entry:</b> NO	Initial Entry

**2.e**

Date	Location	User	Value	Reason
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090177e196ae2f61\Final\Final On: 01-Apr-2021 03:41 (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:** 10131165 **Subject Initials:** ---

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

Sep-30-2020 17:11:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Scott Salmon (pfe.ssalmon)	<b>Data Entry:</b> <b>Symptom::</b> VO MI TI NG  <b>Were fever or s NO ystemic sympt oms present on the last day the Subject Diary was completed ?:</b>	Initial Entry
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**2.e Symptom:**

Date	Location	User	Value	Reason
Sep-30-2020 17:11:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Scott Salmon (pfe.ssalmon)	<b>Data Entry:</b> 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
Sep-30-2020 17:11:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Scott Salmon (pfe.ssalmon)	<b>Data Entry:</b> NO	Initial Entry

090177e196ae2f61\Final\Final On: 01-Apr-2021 03:41 (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:** 10131165 **Subject Initials:** ---

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

2.f

Date	Location	User	Value	Reason
Sep-30-2020 17:11:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Scott Salmon (pfe.ssalmon)	<b>Data Entry:</b> <b>Symptom::</b> DI A RR HE A  <b>Were fever or s N</b> <b>ystemic sympto O</b> <b>ms present on t</b> <b>he last day the</b> <b>Subject Diary</b> <b>was completed</b> <b>?:</b>	Initial Entry

090177e196ae2f61\Final\Final On: 01-Apr-2021 03:41 (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:** 10131165 **Subject Initials:** ---

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

**2.f Symptom:**

Date	Location	User	Value	Reason
Sep-30-2020 17:11:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Scott Salmon (pfe.ssalmon)	<b>Data Entry:</b> 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
Sep-30-2020 17:11:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Scott Salmon (pfe.ssalmon)	<b>Data Entry:</b> NO	Initial Entry

**2.g**

Date	Location	User	Value	Reason
Sep-30-2020 17:11:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Scott Salmon (pfe.ssalmon)	<b>Data Entry:</b> <b>Symptom::</b> NEW OR W ORSE NED MUS CLE P AIN	Initial Entry

090177e196ae2f61\Final\Final On: 01-Apr-2021 03:41 (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:** 10131165 **Subject Initials:** ---

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

			Were fever or systemic symptoms present on the last day the Subject Diary was completed?:	NO
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**2.g Symptom:**

Date	Location	User	Value	Reason
Sep-30-2020 17:11:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Scott Salmon (pfe.ssalmon)	<b>Data Entry:</b> NEW OR WORSENED 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
Sep-30-2020 17:11:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Scott Salmon (pfe.ssalmon)	<b>Data Entry:</b> NO	Initial Entry

**2.h**

Date	Location	User	Value	Reason
Sep-30-2020	ACV0PFEINFP6000	Scott Salmon	<b>Data Entry:</b>	Initial Entry

090177e196ae2f61\Final\Final On: 01-Apr-2021 03:41 (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:** 10131165 **Subject Initials:** ---

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

17:11:39 (UTC-05:00) Eastern Time (US & Canada)		(pfe.ssalmon)	<b>Symptom::</b> NEW OR W ORSE NED JOIN T PAI N  <b>Were fever o</b> NO <b>r systemic sy</b> <b>mptoms pre</b> <b>sent on the l</b> <b>ast day the S</b> <b>ubject Diary</b> <b>was complet</b> <b>ed?:</b>	
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090177e196ae2f61\Final\Final On: 01-Apr-2021 03:41 (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:** 10131165 **Subject Initials:** ---

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

**2.h Symptom:**

Date	Location	User	Value	Reason
Sep-30-2020 17:11:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Scott Salmon (pfe.ssalmon)	<b>Data Entry:</b> NEW OR WORSEN ED 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
Sep-30-2020 17:11:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Scott Salmon (pfe.ssalmon)	<b>Data Entry:</b> NO	Initial Entry

**3. Injection Site Location:**

Date	Location	User	Value	Reason
Sep-30-2020 17:11:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> DELTOID MUSCLE	Initial Entry

**4. Injection Site Body Side:**

Date	Location	User	Value	Reason
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090177e196ae2f61\Final\Final On: 01-Apr-2021 03:41 (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:** 10131165 **Subject Initials:** ---

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

Sep-30-2020 17:11:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Scott Salmon (pfe.ssalmon)	<b>Data Entry:</b> LEFT	Initial Entry
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**5.a**

Date	Location	User	Value	Reason
Sep-30-2020 17:11:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Scott Salmon (pfe.ssalmon)	<b>Data Entry:</b> <b>Injection Site Reaction:</b> D N ES S  <b>Were injection site reactions present on the last day the Subject Diary was completed?:</b> N O	Initial Entry

**5.a Injection Site Reaction:**

Date	Location	User	Value	Reason
Sep-30-2020 17:11:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Scott Salmon (pfe.ssalmon)	<b>Data Entry:</b> REDNESS	Initial Entry

090177e196ae2f61\Final\Final On: 01-Apr-2021 03:41 (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:** 10131165 **Subject Initials:** ---

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

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

Date	Location	User	Value	Reason
Sep-30-2020 17:11:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Scott Salmon (pfe.ssalmon)	<b>Data Entry:</b> NO	Initial Entry

**5.b**

Date	Location	User	Value	Reason
Sep-30-2020 17:11:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Scott Salmon (pfe.ssalmon)	<b>Data Entry:</b> <b>Injection Site</b> SW <b>Reaction::</b> EL LI NG <b>Were injection</b> NO <b>site reactions p</b> <b>resent on the l</b> <b>ast day the Su</b> <b>bject Diary wa</b> <b>s completed?:</b>	Initial Entry

090177e196ae2f61\Final\Final On: 01-Apr-2021 03:41 (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:** 10131165 **Subject Initials:** ---

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

**5.b Injection Site Reaction:**

Date	Location	User	Value	Reason
Sep-30-2020 17:11:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Scott Salmon (pfe.ssalmon)	<b>Data Entry:</b> SWELLING	Initial Entry

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

Date	Location	User	Value	Reason
Sep-30-2020 17:11:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Scott Salmon (pfe.ssalmon)	<b>Data Entry:</b> NO	Initial Entry

**5.c**

Date	Location	User	Value	Reason
Sep-30-2020 17:11:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Scott Salmon (pfe.ssalmon)	<b>Data Entry:</b> <b>Injection Site</b> PAI <b>Reaction::</b> N A T IN JEC TIO N SI TE	Initial Entry

090177e196ae2f61\Final\Final On: 01-Apr-2021 03:41 (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:** 10131165 **Subject Initials:** ---

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

			<b>Were injection site reactions present on the last day the Subject Diary was completed?:</b>	
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**5.c Injection Site Reaction:**

Date	Location	User	Value	Reason
Sep-30-2020 17:11:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Scott Salmon (pfe.ssalmon)	<b>Data Entry:</b> 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
Sep-30-2020 17:11:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Scott Salmon (pfe.ssalmon)	<b>Data Entry:</b> NO	Initial Entry

090177e196ae2f61\Final\Final On: 01-Apr-2021 03:41 (GMT)

**Header Text:** c4591001

**Visit:** V3\_MONTH1\_POSTVAX2\_L **Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF Audit Trail History

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

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

**Subject No:** 10131165 **Subject Initials:** ---

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

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**1. Data Origin**

Date	Location	User	Value	Reason
Sep-30-2020 17:11:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SITE	Initial Entry

**2. Sample Type**

Date	Location	User	Value	Reason
Sep-30-2020 17:11:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SERUM	Initial Entry

**3. Sample Collected?**

Date	Location	User	Value	Reason
Oct-01-2020 08:00:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Oct-01-2020 05:09:44 (UTC-05:00)	ACV0PFEINFP6000	Roshni Nair (pfe.nairr29)	Query 1: Opened	'Sample Collected?' is Yes, however

090177e196ae2f61\Final\Final On: 01-Apr-2021 03:41 (GMT)

**Header Text:** c4591001**Visit:** V3\_MONTH1\_POSTVAX2\_L **Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF Audit Trail History**Form Version:** 22-Apr-2020 21:03 **Form Status:** Data Complete, Locked, Frozen, Verified**Site No:** 1013**Site Name:** (1013) Clinical Neuroscience Solutions Inc.**Subject No:** 10131165**Subject Initials:** ---**Generated By:** pfe.lewissc**Generated Time (GMT):** 29-Mar-2021 04:21

Eastern Time (US & Canada)				no barcodes are entered. Please review and correct as appropriate.
Sep-30-2020 17:11:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Sep-30-2020 17:11:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Scott Salmon (pfe.ssalmon)	<b>Data Entry:</b> YES Date of Collection :  Sep/30/2020	Initial Entry

**5.a**

Date	Location	User	Value	Reason
Oct-01-2020 08:00:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe.mstephens)	<b>Data Entry:</b> <b>Sample I</b> BRG2H <b>D:</b> 6	Initial Entry

**5.a Sample ID**

Date	Location	User	Value	Reason
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**Header Text:** c4591001

**Visit:** V3\_MONTH1\_POSTVAX2\_L **Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF Audit Trail History

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

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

**Subject No:** 10131165 **Subject Initials:** ---

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

Oct-01-2020 08:00:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe.mstephens)	<b>Data Entry:</b> BRG2H6	Initial Entry
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**5.b**

Date	Location	User	Value	Reason
Oct-01-2020 08:00:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe.mstephens)	<b>Data Entry:</b> <b>Sample I</b> BRG2H <b>D:</b> 7	Initial Entry

**5.b Sample ID**

Date	Location	User	Value	Reason
Oct-01-2020 08:00:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe.mstephens)	<b>Data Entry:</b> BRG2H7	Initial Entry

**5.c**

Date	Location	User	Value	Reason
Oct-01-2020 08:00:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe.mstephens)	<b>Data Entry:</b> <b>Sample I</b> BRG2H <b>D:</b> 8	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:** 10131165 **Subject Initials:** ---

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

**5.c Sample ID**

Date	Location	User	Value	Reason
Oct-01-2020 08:00:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe.mstephens)	<b>Data Entry:</b> BRG2H8	Initial Entry

**5.d**

Date	Location	User	Value	Reason
Oct-01-2020 08:00:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe.mstephens)	<b>Data Entry:</b> <b>Sample I</b> BS6Z7 <b>D:</b> B	Initial Entry

**5.d Sample ID**

Date	Location	User	Value	Reason
Oct-01-2020 08:00:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe.mstephens)	<b>Data Entry:</b> BS6Z7B	Initial Entry

**5.e**

Date	Location	User	Value	Reason
Oct-01-2020 08:00:46	ACV0PFEINFP6000	Matthew Stephens	<b>Data Entry:</b> <b>Sample I</b> BS6Z7	Initial Entry

090177e196ae2f61\Final\Final On: 01-Apr-2021 03:41 (GMT)

**Header Text:** c4591001

**Visit:** V3\_MONTH1\_POSTVAX2\_L **Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF Audit Trail History

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

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

**Subject No:** 10131165 **Subject Initials:** ---

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

(UTC-05:00) Eastern Time (US & Canada)		(pfe.mstephens)	<b>D:</b> C	
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**5.e Sample ID**

<b>Date</b>	<b>Location</b>	<b>User</b>	<b>Value</b>	<b>Reason</b>
Oct-01-2020 08:00:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe.mstephens)	<b>Data Entry:</b> BS6Z7C	Initial Entry

090177e196ae2f61\Final\Final On: 01-Apr-2021 03:41 (GMT)

**Header Text:** c4591001

**Visit:** V4\_MONTH6\_L

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

**Site No:** 1013

**Subject No:** 10131165

**Generated By:** pfe.lewissc

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

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

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

**Subject Initials:** ---

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

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*1. Date of Visit*

<b>Date</b>	<b>Location</b>	<b>User</b>	<b>Value</b>	<b>Reason</b>
Feb-25-2021 13:39:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Scott Salmon (pfe.ssalmon)	<b>Data Entry:</b> Feb/24/2021	Initial Entry

090177e196ae2f61\Final\Final On: 01-Apr-2021 03:41 (GMT)

**Header Text:** c4591001

**Visit:** V4\_MONTH6\_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:** 10131165

**Subject Initials:** ---

**Generated By:** pfe.lewissc

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

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**1. Data Origin**

Date	Location	User	Value	Reason
Feb-25-2021 13:39:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SITE	Initial Entry

**2. Sample Type**

Date	Location	User	Value	Reason
Feb-25-2021 13:39:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SERUM	Initial Entry

**3. Sample Collected?**

Date	Location	User	Value	Reason
Mar-01-2021 10:38:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Feb-26-2021 06:25:24 (UTC-05:00)	ACV0PFEINFP6000	Roshni Nair (pfe.nairr29)	Query 1: Opened	'Sample Collected?' is Yes, however

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**Header Text:** c4591001**Visit:** V4\_MONTH6\_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:** 10131165**Subject Initials:** ---**Generated By:** pfe.lewissc**Generated Time (GMT):** 29-Mar-2021 04:21

Eastern Time (US & Canada)				no barcodes are entered. Please review and correct as appropriate.
Feb-25-2021 13:39:33 (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.
Feb-25-2021 13:39:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Scott Salmon (pfe.ssalmon)	<b>Data Entry:</b> YES Date of Collection :  Feb/24/2021	Initial Entry

**5.a**

Date	Location	User	Value	Reason
Mar-01-2021 10:38:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe.mstephens)	<b>Data Entry:</b> <b>Sample I</b> BV09X <b>D:</b> 8	Initial Entry

**5.a Sample ID**

Date	Location	User	Value	Reason
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**Header Text:** c4591001

**Visit:** V4\_MONTH6\_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:** 10131165

**Subject Initials:** ---

**Generated By:** pfe.lewissc

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

Mar-01-2021 10:38:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe.mstephens)	<b>Data Entry:</b> BV09X8	Initial Entry
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**5.b**

Date	Location	User	Value	Reason
Mar-01-2021 10:38:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe.mstephens)	<b>Data Entry:</b> <b>Sample I</b> BV09X <b>D:</b> 9	Initial Entry

**5.b Sample ID**

Date	Location	User	Value	Reason
Mar-01-2021 10:38:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe.mstephens)	<b>Data Entry:</b> BV09X9	Initial Entry

**5.c**

Date	Location	User	Value	Reason
Mar-01-2021 10:39:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe.mstephens)	<b>Data Entry:</b> <b>Sample I</b> BV09X <b>D:</b> B	Initial Entry

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**Header Text:** c4591001

**Visit:** V4\_MONTH6\_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:** 10131165

**Subject Initials:** ---

**Generated By:** pfe.lewissc

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

**5.c Sample ID**

Date	Location	User	Value	Reason
Mar-01-2021 10:39:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe.mstephens)	<b>Data Entry:</b> BV09XB	Initial Entry

**5.d**

Date	Location	User	Value	Reason
Mar-01-2021 10:39:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe.mstephens)	<b>Data Entry:</b> <b>Sample I</b> BS49D <b>D:</b> 0	Initial Entry

**5.d Sample ID**

Date	Location	User	Value	Reason
Mar-01-2021 10:39:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe.mstephens)	<b>Data Entry:</b> BS49D0	Initial Entry

**5.e**

Date	Location	User	Value	Reason
Mar-01-2021 10:40:02	ACV0PFEINFP6000	Matthew Stephens	<b>Data Entry:</b> <b>Sample I</b> BS49D	Initial Entry

090177e196ae2f61\Final\Final On: 01-Apr-2021 03:41 (GMT)

**Header Text:** c4591001

**Visit:** V4\_MONTH6\_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:** 10131165

**Subject Initials:** ---

**Generated By:** pfe.lewissc

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

(UTC-05:00) Eastern Time (US & Canada)		(pfe.mstephens)	<b>D:</b> 1	
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**5.e Sample ID**

<b>Date</b>	<b>Location</b>	<b>User</b>	<b>Value</b>	<b>Reason</b>
Mar-01-2021 10:40:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe.mstephens)	<b>Data Entry:</b> BS49D1	Initial Entry

090177e196ae2f61\Final\Final On: 01-Apr-2021 03:41 (GMT)

**Header Text:** c4591001

**Visit:** End of Treatment - Unscheduled **Form:** DISPOSITION - TREATMENT - eCRF Audit Trail History

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

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

**Subject No:** 10131165 **Subject Initials:** ---

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

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

Date	Location	User	Value	Reason
Sep-30-2020 17:12:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Scott Salmon (pfe.ssalmon)	<b>Data Entry:</b> Sep/30/2020	Initial Entry

**2. Phase of Disposition:**

Date	Location	User	Value	Reason
Sep-30-2020 17:12:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> VACCINATION	Initial Entry

**3. Status:**

Date	Location	User	Value	Reason
Sep-30-2020 17:12:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Scott Salmon (pfe.ssalmon)	<b>Data Entry:</b> COMPLETED	Initial Entry

090177e196ae2f61\Final\Final On: 01-Apr-2021 03:41 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

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

**Form Status:**

**Site No:** 1013

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

**Subject No:** 10131165

**Subject Initials:** ---

**Generated By:** pfe.lewissc

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

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Date	Location	User	Value	Reason
Dec-18-2020 14:00:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe.mstephens)	Form Created	

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

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

**Form Status:** Data Complete, Not Complete

**Site No:** 1013

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

**Subject No:** 10131165

**Subject Initials:** ---

**Generated By:** pfe.lewissc

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

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**1. Category:**

Date	Location	User	Value	Reason
Dec-18-2020 14:00:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> ADVERSE EVENT	Initial Entry

**2. AE ID:**

Date	Location	User	Value	Reason
Dec-18-2020 14:00:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 1	Initial Entry

**3. Adverse Event:**

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

Date	Location	User	Value	Reason
Mar-04-2021 11:35:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 2: Closed	Response satisfies query
Mar-02-2021 10:59:33 (UTC-05:00)	ACV0PFEINFP6000	Scott Salmon (pfe.ssalmon)	<b>Data Entry:</b> Pulmonary Embolism Bilateral	New Information

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

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**Subject Initials:** ---

**Generated By:** pfe.lewissc

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Eastern Time (US & Canada)				
Mar-01-2021 16:25:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe.mstephens)	Query 2: Answered	EDC WILL UPDATE TO BILATERAL ONCE INVESTIGATOR UPDATES SAE FORM.
Mar-01-2021 15:07:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 2: Reissued: Opened	Clinical - as the PE event was bilateral; is the event term which needs updating the term HERE on the AE log CRF (which does not include Bilateral)?
Mar-01-2021 12:04:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe.mstephens)	Query 2: Answered	CRC WILL UPDATE SAE REPORT AND UPDATE WHERE APPLICABLE.
Feb-23-2021 13:11:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 2: Opened	Clinical - Followup; Event term on AE CRF remains PE and event term on SAE report

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				(07Jan21 most recent update) remains BILATERAL PE. Please review, harmonize reporting, and update where applicable
Jan-21-2021 16:52:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Kimberly Forbus (pfe.forbuk)	Query 1: Closed	Response satisfies query
Jan-21-2021 15:04:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Scott Salmon (pfe.ssalmon)	Query 1: Answered	CORRECTED
Jan-20-2021 22:05:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 1: Reissued: Opened	Clinical SAE event term is PE; however, SAE event term is Bilateral PE. Please review, harmonize reporting, and update in the applicable location
Jan-20-2021	ACV0PFEINFP6000	auto query	Query 1: Answered	Transcription

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11:36:13 (UTC-05:00) Eastern Time (US & Canada)		(autoquery)	red	Error
Jan-20-2021 11:36:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Scott Salmon (pfe.ssalmon)	<b>Data Entry:</b> Pulmonary Embolism	Transcription Error
Jan-20-2021 08:13:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Kimberly Forbus (pfe.forbuk)	Query 1: Opened	Source does not report bi-lateral. Please review and update if required
Dec-18-2020 14:00:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe.mstephens)	<b>Data Entry:</b> BILATERAL PULMONARY EMBOLISM	Initial Entry

**4. Start Date Time:**

Date	Location	User	Value	Reason
Dec-18-2020 14:00:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe.mstephens)	<b>Data Entry:</b> Dec/14/2020 UNK: UNK	Initial Entry

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

Date	Location	User	Value	Reason
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Jan-27-2021 15:08:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Samuel Dychter (pfe.dychts)	Query 1: Closed	Response satisfies query
Jan-22-2021 09:57:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Scott Salmon (pfe.ssalmon)	Query 1: Answered	STILL ONGOING AT THIS TIME
Jan-21-2021 16:41:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Samuel Dychter (pfe.dychts)	Query 1: Opened	GPD Clin: Please re-confirm if the event is still ongoing since it started in mid-Dec 2020. If ended, please add date.
Dec-18-2020 14:00:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe.mstephens)	<b>Data Entry:</b> YES	Initial Entry

**6. Toxicity Grade:**

Date	Location	User	Value	Reason
Dec-18-2020 14:00:05 (UTC-05:00)	ACV0PFEINFP6000	Matthew Stephens (pfe.mstephens)	<b>Data Entry:</b> 3	Initial Entry

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**7. Is the adverse event serious?**

**If Yes, NOTIFY PFIZER IMMEDIATELY.**

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

Date	Location	User	Value	Reason
Jan-12-2021 14:05:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 3: Closed	COVID test reported as negative on 14DEC20 in SAE update on 07Jan21
Dec-28-2020 09:16:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe.mstephens)	Query 3: Answered	PER CRC NOTHING IN MEDICAL RECORDS IF COVID TEST WAS PEFORMED.
Dec-23-2020 17:07:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 3: Reissued:Opened	Clinical COVID test status (yes/no) during Hosp was not reported in the SAE. Please

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				submit a follow-up SAE form [#2020503549] to document if COVID testing was performed (YES/NO or info not available) and if yes, the date and results.
Dec-23-2020 12:50:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 4: Deleted	Close Auto Query
Dec-23-2020 12:50:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe.mstephens)	<b>Data Entry:</b> YES Is this serious event associated with congenital anomaly or birth defect?  NO  Did this serious event result in death?  NO	Transcription Error

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			<p>Did this serious event require or prolong hospitalization?</p> <p>YES</p> <p>Did this serious event result in persistent or significant disability/incapacity?</p> <p>NO</p> <p>Is this serious event life threatening?</p> <p>NO</p> <p>Other medically important serious event</p> <p>NO</p>	
Dec-23-2020 11:08:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 4: Candidate	For AE BILATERAL PULMONARY EMBOLISM: Response to "Is the adverse event serious?" is 'No' but

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				"Serious Adverse Event Number" is present.
Dec-23-2020 11:08:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 3: Answered	Transcription Error
Dec-23-2020 11:08:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe.mstephens)	<b>Data Entry:</b> NO	Transcription Error
Dec-22-2020 06:44:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Dec-22-2020 01:19:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lina Gaikwad (pfe.gaikwl)	Query 2: Closed	Response satisfies query
Dec-21-2020 16:16:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 3: Opened	Clinical COVID test status (yes/no) during Hosp was not reported in the SAE. Please submit a

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				follow-up SAE form [#2020503549] to document if COVID testing was performed (YES/NO or info not available) and if yes, the date and results.
Dec-18-2020 14:00:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe.mstephens)	Query 2: Answered	Original value is correct
Dec-18-2020 14:00:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Opened	Is this adverse event serious?' is reported 'Yes', but at least one seriousness criteria is missing. Please review and update as appropriate.
Dec-18-2020 14:00:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	For AE BILATERAL PULMONARY EMBOLISM: Response to "Is the adverse

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				event serious?" is 'Yes' but "Serious Adverse Event Number" is blank.
Dec-18-2020 14:00:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe.mstephens)	<p><b>Data Entry:</b> 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>	Initial Entry

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			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
Dec-18-2020 14:00:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe.mstephens)	<b>Data Entry:</b> NO	Initial Entry

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

Date	Location	User	Value	Reason
Feb-15-2021 18:55:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hao Hu (pfe.huh17)	Query 2: Closed	Response satisfies query
Feb-15-2021 10:48:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Scott Salmon (pfe.ssalmon)	Query 2: Answered	Med Hx updated

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**Subject Initials:** ---

**Generated By:** pfe.levisse

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Feb-04-2021 19:12:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hao Hu (pfe.huh17)	Query 2: Reissued:Opened	ClinQuery: please document in the medhx. thank you
Feb-03-2021 14:36:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Scott Salmon (pfe.ssalmon)	Query 2: Answered	DOCUMENTED IN THE DEMOGRAPHIC PAGE
Jan-21-2021 18:57:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hao Hu (pfe.huh17)	Query 2: Opened	ClinQuery: Pulmonary Embolism: the causality states this is related to vaping, however, subject does not have a medhx of vaping. Please review/update as appropriate. Thanks
Jan-20-2021 21:48:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 1: Closed	Response satisfies query
Jan-19-2021 15:24:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	updated per corrected source

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Jan-19-2021 15:24:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Monica Cooper (pfe.mcooper)	<b>Data Entry:</b> NOT RELATED If Not Related to study treatm ent(s), this eve nt is due to:  OTHER  <i>If Other, sp ecify:</i>  Vaping an d sedentar y lifestyle	updated per corrected source
Jan-12-2021 14:07:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 1: Reissu ed:Opened	Clinical SAE report (07Jan21 update) narrative reports "Hospital Physicians felt event was due to vaping and sedentary lifestyle.". Please review & harmonize reporting or report 'UNK', as PE cannot cause PE
Dec-28-2020 09:17:12 (UTC-05:00)	ACV0PFEINFP6000	Matthew Stephens (pfe.mstephens)	Query 1: Answe red	PER CRC NOTHING IN MEDICAL

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Eastern Time (US & Canada)				RECORDS.
Dec-23-2020 17:12:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 1: Reissued:Opened	Clinical Thank you; however please consider what condition or risk might place a 28 yr old at risk for bilateral PE, or unknown
Dec-23-2020 11:08:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe.mstephens)	Query 1: Answered	Original value is correct
Dec-21-2020 11:27:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 1: Opened	Clinical Event of Bilateral PE would not be related in a causal way to itself. If Other cause for event is known please enter that; if currently not known please enter Unknown.

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

Date	Location	User	Value	Reason
Dec-18-2020 14:00:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe.mstephens)	<b>Data Entry:</b> NOT RELATED If Not Related to s tudy treatment(s), this event is due to :  OTHER  <i>If Other, specif y:</i>  BILATERAL PULMONAR Y EMBOLIS M	Initial Entry

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

Date	Location	User	Value	Reason
Dec-18-2020 14:00:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe.mstephens)	<b>Data Entry:</b> NOT APPLICABL E	Initial Entry

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

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Date	Location	User	Value	Reason
Dec-23-2020 17:08:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 1: Closed	Response satisfies query
Dec-23-2020 11:09:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Transcription Error
Dec-23-2020 11:09:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe.mstephens)	<b>Data Entry:</b> YES	Transcription Error
Dec-22-2020 19:33:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 1: Opened	Clinical Con Med given for event of bilateral PE is No; however, SAE report states subject received Eliquis. Please review, and update if applicable.
Dec-18-2020 14:00:05	ACV0PFEINFP6000	Matthew Stephens	<b>Data Entry:</b> NO	Initial Entry

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(UTC-05:00) Eastern Time (US & Canada)		(pfe.mstephens)		
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**12. Was a Non-Drug Treatment given?**

Date	Location	User	Value	Reason
Dec-18-2020 14:00:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe.mstephens)	<b>Data Entry:</b> NO	Initial Entry

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

Date	Location	User	Value	Reason
Dec-18-2020 14:00:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe.mstephens)	<b>Data Entry:</b> RECOVERING/R ESOLVING	Initial Entry

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

Date	Location	User	Value	Reason
Dec-18-2020 14:00:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe.mstephens)	<b>Data Entry:</b> NO	Initial Entry

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**15. Serious Adverse Event Number: For Pfizer Use Only**

<b>Date</b>	<b>Location</b>	<b>User</b>	<b>Value</b>	<b>Reason</b>
Dec-22-2020 06:44:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Ricell Ann Piojo (pfe.quitor)	<b>Data Entry:</b> 2020503549	Initial Entry

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

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

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

**Subject No:** 10131165      **Subject Initials:** ---

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

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*1. Date of Visit*

<b>Date</b>	<b>Location</b>	<b>User</b>	<b>Value</b>	<b>Reason</b>
Jan-25-2021 08:09:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Scott Salmon (pfe.ssalmon)	<b>Data Entry:</b> Jan/20/2021	Initial Entry

090177e196ae2f61\Final\Final On: 01-Apr-2021 03:41 (GMT)

**Header Text:** c4591001

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

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

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

**Subject No:** 10131165 **Subject Initials:** ---

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

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

Date	Location	User	Value	Reason
Jan-25-2021 08:09:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Scott Salmon (pfe.ssalmon)	<b>Data Entry:</b> Participant is willing to return for Vaccinat ion 3 Participant is:  eligible and NOT confirmed to have received only plac ebo at Vaccination 1/2	Initial Entry

090177e196ae2f61\Final\Final On: 01-Apr-2021 03:41 (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:** 10131165

**Subject Initials:** ---

**Generated By:** pfe.lewissc

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

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**1. Date Treatment Unblinded :**

Date	Location	User	Value	Reason
Jan-25-2021 08:09:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Scott Salmon (pfe.ssalmon)	<b>Data Entry:</b> Jan/20/2021	Initial Entry

**2. Primary Reason for Unblinding:**

Date	Location	User	Value	Reason
Jan-25-2021 08:09:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Scott Salmon (pfe.ssalmon)	<b>Data Entry:</b> ASSESS ELIGIBILI TY FOR ADDITION AL VACCINATION	Initial Entry

**Header Text:** c4591001

**Visit:** Subject Status - Unscheduled

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

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

**Form Status:** Data Complete, Verified

**Site No:** 1013

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

**Subject No:** 10131165

**Subject Initials:** ---

**Generated By:** pfe.lewissc

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

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**1. Subject Status**

Date	Location	User	Value	Reason
Sep-30-2020 17:12:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> FOLLOW-UP	Initial Entry
Aug-13-2020 14:27:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> ENROLLED/RANDOMIZED	Initial Entry
Aug-13-2020 14:24:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SCREENED	Initial Entry

**2. Subject Status Date**

Date	Location	User	Value	Reason
Sep-30-2020 17:12:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> Sep/30/2020	Initial Entry
Aug-13-2020 14:27:25	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> Aug/13/2020	Initial Entry

090177e196ae2f61\Final\Final On: 01-Apr-2021 03:41 (GMT)

**Header Text:** c4591001

**Visit:** Subject Status - Unscheduled

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

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

**Form Status:** Data Complete, Verified

**Site No:** 1013

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

**Subject No:** 10131165

**Subject Initials:** ---

**Generated By:** pfe.levisse

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

(UTC-05:00) Eastern Time (US & Canada)				
Aug-13-2020 14:24:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> Aug/13/2020	Initial Entry

**Header Text:** c4591001

**Visit:** Investigator Signature -  
Unscheduled

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

**Site No:** 1013

**Subject No:** 10131165

**Generated By:** pfe.levissc

**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

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*1. Casebook Signature*

Date	Location	User	Value	Reason
Sep-14-2020 16:33:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Matthew Stephens (pfe.mstephens)	<b>Data Entry:</b> Click Here to Enabl e	Initial Entry

090177e196ae2f61\Final\Final On: 01-Apr-2021 03:41 (GMT)