

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: 1008

Site Name: (1008) Clinical Research Professionals Inc.

Subject No: 10081152

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:12

[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

090177e196ae3fd3\Final\Final On: 01-Apr-2021 05:23 (GMT)

Header Text: c4591001

Visit: COHORT_SELECTION

Form: MAIN INFORMED CONSENT

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1008

Site Name: (1008) Clinical Research Professionals Inc.

Subject No: 10081152

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:12

[eCRF Audit Trail History](#)

Informed Consent

1.	Consent Was:	OBTAINED Date Written Consent Obtained Aug/31/2020
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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: 1008

Site Name: (1008) Clinical Research Professionals Inc.

Subject No: 10081152

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:12

[eCRF Audit Trail History](#)

Demography

1.	Subject ID	[10081152]
2.	Birth Date:	(b) (6) 1979
3.	Sex:	MALE
4.	Ethnicity:	NOT HISPANIC OR LATINO(A) OR OF SPANISH ORIGIN
5.	Race: (Check X all that apply):	WHITE
6.	Racial Designation:	

090177e196ae3fd3\Final\Final On: 01-Apr-2021 05:23 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:02

Site No: 1008

Subject No: 10081152

Generated By: pfe.lewissc

Form: DATE OF VISIT

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1008) Clinical Research Professionals Inc.

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:12

[eCRF Audit Trail History](#)

Date of Visit

1.	Date of Visit	Aug/31/2020
2.	Erroneous Visit	

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 30-Jul-2020 21:29

Site No: 1008

Subject No: 10081152

Generated By: pfe.levissc

Form: INCLUSION/EXCLUSION CRITERIA

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1008) Clinical Research Professionals Inc.

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:12

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

090177e196ae3fd3\Final\Final On: 01-Apr-2021 05:23 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1008

Subject No: 10081152

Generated By: pfe.levissc

Form: DISPOSITION - SCREENING

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1008) Clinical Research Professionals Inc.

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:12

[eCRF Audit Trail History](#)

Disposition - Screening

1.	Date of Completion/Discontinuation /Death	Aug/31/2020
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: 1008

Site Name: (1008) Clinical Research Professionals Inc.

Subject No: 10081152

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:12

[eCRF Audit Trail History](#)

Medical History Details

1.a	Line/MH Number:	[1]
	Disease/Syndrome /Surgery/Non-Drug Allergies/Drug Allergies:	[Seasonal allergies]
	Start Date:	UNK/UNK/2010
	Ongoing:	YES
1.b	Line/MH Number:	[2]
	Disease/Syndrome /Surgery/Non-Drug Allergies/Drug Allergies:	[Hypertension]
	Start Date:	UNK/UNK/2018
	Ongoing:	YES
1.c	Line/MH Number:	[3]
	Disease/Syndrome /Surgery/Non-Drug Allergies/Drug Allergies:	[Percocet allergy]
	Start Date:	UNK/UNK/1998
	Ongoing:	YES

090177e196ae3fd3\Final\Final On: 01-Apr-2021 05:23 (GMT)

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: 1008

Site Name: (1008) Clinical Research Professionals Inc.

Subject No: 10081152

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:12

1.d	Line/MH Number:	[4]
	Disease/Syndrome /Surgery/Non-Drug Allergies/Drug Allergies:	[Tinea Versicolor]
	Start Date:	May/UNK/2020
	Ongoing:	YES

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 21-Aug-2020 02:51

Site No: 1008

Subject No: 10081152

Generated By: pfe.levissc

Form: VITAL SIGNS - BASELINE

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1008) Clinical Research Professionals Inc.

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:12

eCRF Audit Trail History

Vital Signs

1.	Date:	Aug/31/2020
2.	Weight:	[228.2]
3.	Unit:	LB
4.	Height:	[74.5]
5.	Unit:	in
6.	Body Mass Index:	[28.9]

Vital Signs Details

7.a	Record Identifier:	1
	Temperature:	[98.0]
	Unit:	F
	Temperature Location:	FOREHEAD

090177e196ae3fd3\Final\Final On: 01-Apr-2021 05:23 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1008

Subject No: 10081152

Generated By: pfe.levisse

Form: RANDOMIZATION

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1008) Clinical Research Professionals Inc.

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:12

[eCRF Audit Trail History](#)

Disposition

1.	Randomization Date :	Aug/31/2020
2.	Randomization Number:	[75850]
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: 1008

Site Name: (1008) Clinical Research Professionals Inc.

Subject No: 10081152

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:12

[eCRF Audit Trail History](#)

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	SERUM
3.	Sample Collected?	YES Date of Collection: Aug/31/2020
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	[BTPN0]
5.b	Sample ID	[BTPN1]
5.c	Sample ID	[BTPN2]
5.d	Sample ID	[BPRL7M]
5.e	Sample ID	[BPRL7N]

090177e196ae3fd3\Final\Final On: 01-Apr-2021 05:23 (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: 1008

Site Name: (1008) Clinical Research Professionals Inc.

Subject No: 10081152

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:12

[eCRF Audit Trail History](#)

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Aug/31/2020
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	[BP51LF]
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090177e196ae3fd3\Final\Final On: 01-Apr-2021 05:23 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:04

Site No: 1008

Subject No: 10081152

Generated By: pfe.levissc

Form: VACCINATION

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1008) Clinical Research Professionals Inc.

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:12

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/31/2020 15:31
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

090177e196ae3fd3\Final\Final On: 01-Apr-2021 05:23 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 06-Jul-2020 21:53

Site No: 1008

Subject No: 10081152

Generated By: pfe.levissc

Form: REACTOGENICITY DIARY

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1008) Clinical Research Professionals Inc.

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:12

[eCRF Audit Trail History](#)

Reactogenicity Diary

1.	Select appropriate response - Reactogenicity diary collection	NO - REACTOGENICITY E-DIARY NOT COLLECTED FOR THIS SUBJECT
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Header Text: c4591001

Visit: V2_VAX2_L

Form: DATE OF VISIT

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1008

Site Name: (1008) Clinical Research Professionals Inc.

Subject No: 10081152

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:12

[eCRF Audit Trail History](#)

Date of Visit

1.	Date of Visit	Sep/21/2020
2.	Erroneous Visit	

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 15-Sep-2020 21:54

Site No: 1008

Subject No: 10081152

Generated By: pfe.levissc

Form: VITAL SIGNS - TEMP

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1008) Clinical Research Professionals Inc.

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:12

[eCRF Audit Trail History](#)

Vital Signs

1.	Date:	Sep/21/2020
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Vital Signs Details

2.a	Record Identifier:	1
	Temperature:	[98.2]
	Unit:	F
	Temperature Location:	FOREHEAD

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: 1008

Site Name: (1008) Clinical Research Professionals Inc.

Subject No: 10081152

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:12

[eCRF Audit Trail History](#)

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Sep/21/2020
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	[BGK0Y3]
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090177e196ae3fd3\Final\Final On: 01-Apr-2021 05:23 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1008

Subject No: 10081152

Generated By: pfe.levissc

Form: VACCINATION

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1008) Clinical Research Professionals Inc.

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:12

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/21/2020 14:54
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

090177e196ae3fd3\Final\Final On: 01-Apr-2021 05:23 (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: 1008 **Site Name:** (1008) Clinical Research Professionals Inc.

Subject No: 10081152 **Subject Initials:** ---

Generated By: pfe.levisse **Generated Time (GMT):** 29-Mar-2021 04:12

[eCRF Audit Trail History](#)

Date of Visit

1.	Date of Visit	Oct/19/2020
2.	Erroneous Visit	

090177e196ae3fd3\Final\Final On: 01-Apr-2021 05:23 (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: 1008 **Site Name:** (1008) Clinical Research Professionals Inc.

Subject No: 10081152 **Subject Initials:** ---

Generated By: pfe.levisse **Generated Time (GMT):** 29-Mar-2021 04:12

[eCRF Audit Trail History](#)

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	SERUM
3.	Sample Collected?	YES Date of Collection: Oct/19/2020
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[]

Aliquot

Please enter barcode for each aliquot.

5.a	Sample ID	[BGL5BM]
5.b	Sample ID	[BRZDBV]
5.c	Sample ID	[BRZDBW]

090177e196ae3fd3\Final\Final On: 01-Apr-2021 05:23 (GMT)

Header Text: c4591001

Visit: V4_MONTH6_L

Form Version: 22-Apr-2020 21:02

Site No: 1008

Subject No: 10081152

Generated By: pfe.lewissc

Form: DATE OF VISIT

Form Status: Not Started

Site Name: (1008) Clinical Research Professionals Inc.

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:12

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

Header Text: c4591001

Visit: V4_MONTH6_L

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1008

Site Name: (1008) Clinical Research Professionals Inc.

Subject No: 10081152

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:12

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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090177e196ae3fd3\Final\Final On: 01-Apr-2021 05:23 (GMT)

Header Text: c4591001

Visit: V5_MONTH12_L

Form Version: 22-Apr-2020 21:02

Site No: 1008

Subject No: 10081152

Generated By: pfe.levissc

Form: DATE OF VISIT

Form Status: Not Started

Site Name: (1008) Clinical Research Professionals Inc.

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:12

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

Header Text: c4591001

Visit: V5_MONTH12_L

Form Version: 22-Apr-2020 21:03

Site No: 1008

Subject No: 10081152

Generated By: pfe.levissc

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Status: Not Started

Site Name: (1008) Clinical Research Professionals Inc.

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:12

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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090177e196ae3fd3\Final\Final On: 01-Apr-2021 05:23 (GMT)

Header Text: c4591001

Visit: V6_MONTH24_L

Form Version: 22-Apr-2020 21:02

Site No: 1008

Subject No: 10081152

Generated By: pfe.levissc

Form: DATE OF VISIT

Form Status: Not Started

Site Name: (1008) Clinical Research Professionals Inc.

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:12

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: 1008

Site Name: (1008) Clinical Research Professionals Inc.

Subject No: 10081152

Subject Initials: ---

Generated By: pfe.lewissc

Generated Time (GMT): 29-Mar-2021 04:12

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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090177e196ae3fd3\Final\Final On: 01-Apr-2021 05:23 (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: 1008

Site Name: (1008) Clinical Research Professionals Inc.

Subject No: 10081152

Subject Initials: ---

Generated By: pfe.lewissc

Generated Time (GMT): 29-Mar-2021 04:12

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: 1008

Subject No: 10081152

Generated By: pfe.lewissc

Form: SIGNS AND SYMPTOMS OF POTENTIAL
COVID-19

Form Status: Not Started

Site Name: (1008) Clinical Research Professionals Inc.

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:12

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

090177e196ae3fd3\Final\Final On: 01-Apr-2021 05:23 (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: 1008

Site Name: (1008) Clinical Research Professionals Inc.

Subject No: 10081152

Subject Initials: ---

Generated By: pfe.lewissc

Generated Time (GMT): 29-Mar-2021 04:12

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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090177e196ae3fd3\Final\Final On: 01-Apr-2021 05:23 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL - New
Unscheduled Visit

Form Version: 22-Apr-2020 21:03

Site No: 1008

Subject No: 10081152

Generated By: pfe.levissc

Form: ELECTRONIC SAMPLE TRACKING - NASAL
SWAB

Form Status: Not Started

Site Name: (1008) Clinical Research Professionals Inc.

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:12

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

090177e196ae3fd3\Final\Final On: 01-Apr-2021 05:23 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL - New
Unscheduled Visit

Form: HEALTH CARE UTILIZATION

Form Version: 20-Feb-2021 02:19

Form Status: Not Started

Site No: 1008

Site Name: (1008) Clinical Research Professionals Inc.

Subject No: 10081152

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:12

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?	
----	--	--

090177e196ae3fd3\Final\Final On: 01-Apr-2021 05:23 (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: 1008

Site Name: (1008) Clinical Research Professionals Inc.

Subject No: 10081152

Subject Initials: ---

Generated By: pfe.lewissc

Generated Time (GMT): 29-Mar-2021 04:12

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: 1008

Site Name: (1008) Clinical Research Professionals Inc.

Subject No: 10081152

Subject Initials: ---

Generated By: pfe.lewissc

Generated Time (GMT): 29-Mar-2021 04:12

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: 1008

Site Name: (1008) Clinical Research Professionals Inc.

Subject No: 10081152

Subject Initials: ---

Generated By: pfe.lewissc

Generated Time (GMT): 29-Mar-2021 04:12

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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090177e196ae3fd3\Final\Final On: 01-Apr-2021 05:23 (GMT)

Header Text: c4591001

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

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

Site No: 1008

Site Name: (1008) Clinical Research Professionals Inc.

Subject No: 10081152

Subject Initials: ---

Generated By: pfe.lewissc

Generated Time (GMT): 29-Mar-2021 04:12

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: 1008 **Site Name:** (1008) Clinical Research Professionals Inc.

Subject No: 10081152 **Subject Initials:** ---

Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 04:12

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: 1008

Site Name: (1008) Clinical Research Professionals Inc.

Subject No: 10081152

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:12

[eCRF Audit Trail History](#)

Disposition - Treatment

1.	Date of Completion/Discontinuation/Death :	Oct/19/2020
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: 1008

Site Name: (1008) Clinical Research Professionals Inc.

Subject No: 10081152

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:12

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: 1008

Site Name: (1008) Clinical Research Professionals Inc.

Subject No: 10081152

Subject Initials: ---

Generated By: pfe.lewissc

Generated Time (GMT): 29-Mar-2021 04:12

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

COVID-19 Repeat Swab

3.	COVID-19 Repeat Swab:	
----	-----------------------	--

Header Text: c4591001

Visit: POT_COVID_REPEAT_SWAB - New Unscheduled Visit **Form:** ELECTRONIC SAMPLE TRACKING - REPEAT SWAB

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

Site No: 1008 **Site Name:** (1008) Clinical Research Professionals Inc.

Subject No: 10081152 **Subject Initials:** ---

Generated By: pfe.levisse **Generated Time (GMT):** 29-Mar-2021 04:12

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

090177e196ae3fd3\Final\Final On: 01-Apr-2021 05:23 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1008

Subject No: 10081152

Generated By: pfe.levissc

Form: ADVERSE EVENT REPORT

Form Status: Not Started

Site Name: (1008) Clinical Research Professionals Inc.

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:12

Adverse Event Report

1.	Category:	
2.	AE ID:	[]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[]
4.	Start Date Time:	//
5.	Is the adverse event still ongoing?	
6.	Toxicity Grade:	
7.	Is the adverse event serious? If Yes, NOTIFY PFIZER IMMEDIATELY. Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).	

090177e196ae3fd3\Final\Final On: 01-Apr-2021 05:23 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT

Form Version: 22-Apr-2020 21:02

Form Status: Not Started

Site No: 1008

Site Name: (1008) Clinical Research Professionals Inc.

Subject No: 10081152

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:12

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

090177e196ae3fd3\Final\Final On: 01-Apr-2021 05:23 (GMT)

Header Text: c4591001

Visit: Logs

Form: MEDICATION ERROR

Form Version: 17-Jul-2020 21:54

Site No: 1008

Site Name: (1008) Clinical Research Professionals Inc.

Subject No: 10081152

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:12

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

Header Text: c4591001

Visit: Logs - Unscheduled

Form: MEDICATION ERROR

Form Version: 17-Jul-2020 21:54

Form Status: Not Started

Site No: 1008

Site Name: (1008) Clinical Research Professionals Inc.

Subject No: 10081152

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:12

[Back to Form](#)

Medication Error

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

090177e196ae3fd3\Final\Final On: 01-Apr-2021 05:23 (GMT)

Header Text: c4591001

Visit: Logs

Form: CONCOMITANT MEDICATIONS - NON STUDY VACCINATIONS

Form Version: 22-Apr-2020 21:03

Site No: 1008

Site Name: (1008) Clinical Research Professionals Inc.

Subject No: 10081152

Subject Initials: ---

Generated By: pfe.lewissc

Generated Time (GMT): 29-Mar-2021 04:12

#	Sponsor-Defined Identifier	Category of Medication	Concomitant Medications Pre-specified	Name of Medication	Start Date	Form Instance
1.	1	VACCINATIONS	NO	Quadrivalent flu prophylaxis intramuscular vaccine 0.5 ml once	Oct/8/2020	Repeating Pages

090177e196ae3fd3\Final\Final On: 01-Apr-2021 05:23 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - NON STUDY VACCINATIONS

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1008

Site Name: (1008) Clinical Research Professionals Inc.

Subject No: 10081152

Subject Initials: ---

Generated By: pfe.lewissc

Generated Time (GMT): 29-Mar-2021 04:12

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[eCRF Audit Trail History](#)

[Form Audit Trail](#)

Concomitant Medications

1.	What is the medication identifier?	[1]
2.	Category:	VACCINATIONS
3.	Concomitant Medications Pre-specified:	NO
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).	[Quadrivalent flu prophylaxis intramuscular vaccine 0.5 ml once]
5.	Date:	Oct/8/2020

090177e196ae3fd3\Final\Final On: 01-Apr-2021 05:23 (GMT)

Header Text: c4591001

Visit: Logs

Form: CONCOMITANT MEDICATIONS - PROHIBITED

Form Version: 22-Apr-2020 21:03

Site No: 1008

Site Name: (1008) Clinical Research Professionals Inc.

Subject No: 10081152

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:12

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

090177e196ae3fd3\Final\Final On: 01-Apr-2021 05:23 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - PROHIBITED

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1008

Site Name: (1008) Clinical Research Professionals Inc.

Subject No: 10081152

Subject Initials: ---

Generated By: pfe.lewissc

Generated Time (GMT): 29-Mar-2021 04:12

[Back to Form](#)

Concomitant Medications

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

090177e196ae3fd3\Final\Final On: 01-Apr-2021 05:23 (GMT)

Header Text: c4591001

Visit: Logs

Form: RADIATION TREATMENT

Form Version: 22-Apr-2020 21:02

Site No: 1008

Site Name: (1008) Clinical Research Professionals Inc.

Subject No: 10081152

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:12

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

090177e196ae3fd3\Final\Final On: 01-Apr-2021 05:23 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: RADIATION TREATMENT

Form Version: 22-Apr-2020 21:02

Form Status: Not Started

Site No: 1008

Site Name: (1008) Clinical Research Professionals Inc.

Subject No: 10081152

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:12

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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?	

090177e196ae3fd3\Final\Final On: 01-Apr-2021 05:23 (GMT)

Header Text: c4591001

Visit: Logs

Form: TRANSFUSIONS

Form Version: 22-Apr-2020 21:03

Site No: 1008

Site Name: (1008) Clinical Research Professionals Inc.

Subject No: 10081152

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:12

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

090177e196ae3fd3\Final\Final On: 01-Apr-2021 05:23 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: TRANSFUSIONS

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1008

Site Name: (1008) Clinical Research Professionals Inc.

Subject No: 10081152

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:12

[Back to Form](#)

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

Header Text: c4591001

Visit: Unplanned Vaccination -
Unscheduled

Form: DATE OF VISIT

Form Version: 22-Apr-2020 21:02

Form Status: Not Started

Site No: 1008

Site Name: (1008) Clinical Research Professionals Inc.

Subject No: 10081152

Subject Initials: ---

Generated By: pfe.lewissc

Generated Time (GMT): 29-Mar-2021 04:12

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: 1008

Site Name: (1008) Clinical Research Professionals Inc.

Subject No: 10081152

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:12

Vital Signs

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

Vital Signs Details

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

090177e196ae3fd3\Final\Final On: 01-Apr-2021 05:23 (GMT)

Header Text: c4591001

Visit: Unplanned Vaccination -
Unscheduled

Form: VACCINATION

Form Version: 10-Dec-2020 02:26

Form Status: Not Started

Site No: 1008

Site Name: (1008) Clinical Research Professionals Inc.

Subject No: 10081152

Subject Initials: ---

Generated By: pfe.lewissc

Generated Time (GMT): 29-Mar-2021 04:12

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?	

090177e196ae3fd3\Final\Final On: 01-Apr-2021 05:23 (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: 1008

Site Name: (1008) Clinical Research Professionals Inc.

Subject No: 10081152

Subject Initials: ---

Generated By: pfe.lewissc

Generated Time (GMT): 29-Mar-2021 04:12

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: 1008

Site Name: (1008) Clinical Research Professionals Inc.

Subject No: 10081152

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:12

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: 1008 **Site Name:** (1008) Clinical Research Professionals Inc.

Subject No: 10081152 **Subject Initials:** ---

Generated By: pfe.lewissc **Generated Time (GMT):** 29-Mar-2021 04:12

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: 1008

Site Name: (1008) Clinical Research Professionals Inc.

Subject No: 10081152

Subject Initials: ---

Generated By: pfe.lewissc

Generated Time (GMT): 29-Mar-2021 04:12

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:** 1008**Site Name:** (1008) Clinical Research Professionals Inc.**Subject No:** 10081152**Subject Initials:** ---**Generated By:** pfe.levissc**Generated Time (GMT):** 29-Mar-2021 04:12**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: 1008

Site Name: (1008) Clinical Research Professionals Inc.

Subject No: 10081152

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:12

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

090177e196ae3fd3\Final\Final On: 01-Apr-2021 05:23 (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: 1008 **Site Name:** (1008) Clinical Research Professionals Inc.

Subject No: 10081152 **Subject Initials:** ---

Generated By: pfe.lewissc **Generated Time (GMT):** 29-Mar-2021 04:12

[eCRF Audit Trail History](#)

Date of Visit		
1.	Date of Visit	Jan/7/2021
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: 1008 **Site Name:** (1008) Clinical Research Professionals Inc.

Subject No: 10081152 **Subject Initials:** ---

Generated By: pfe.lewissc **Generated Time (GMT):** 29-Mar-2021 04:12

[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
----	---	---

090177e196ae3fd3\Final\Final On: 01-Apr-2021 05:23 (GMT)

Header Text: c4591001

Visit: Disposition - Unscheduled

Form: TREATMENT UNBLINDED

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1008

Site Name: (1008) Clinical Research Professionals Inc.

Subject No: 10081152

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:12

[eCRF Audit Trail History](#)

Treatment Unblinded

1.	Date Treatment Unblinded :	Jan/7/2021
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: 1008

Site Name: (1008) Clinical Research Professionals Inc.

Subject No: 10081152

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:12

Withdrawal Of Consent

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

090177e196ae3fd3\Final\Final On: 01-Apr-2021 05:23 (GMT)

Header Text: c4591001

Visit: Disposition - Unscheduled

Form: DEATH DETAILS CODED

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1008

Site Name: (1008) Clinical Research Professionals Inc.

Subject No: 10081152

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:12

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: 1008

Site Name: (1008) Clinical Research Professionals Inc.

Subject No: 10081152

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:12

[eCRF Audit Trail History](#)

Subject Status

1.	Subject Status	FOLLOW-UP
2.	Subject Status Date	Oct/19/2020

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: 1008

Site Name: (1008) Clinical Research Professionals Inc.

Subject No: 10081152

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:12

[eCRF Audit Trail History](#)

Casebook Signature Form

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

Header Text: c4591001

Visit: Investigator Signature -
Unscheduled

Form: CASEBOOK SIGNATURE FORM

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Signed, Verified

Site No: 1008

Site Name: (1008) Clinical Research Professionals Inc.

Subject No: 10081152

Subject Initials: ---

Generated By: pfe.lewissc

Generated Time (GMT): 29-Mar-2021 04:12

[Audit Trail](#)

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

- CRF_Sign

Name	Signature Meaning	Date	Type	Action
Timothy Jennings	Approved	Jan-21-2021 16:49:56 (UTC-06:00) Central Time (US & Canada)	BOOK	Signed

Affidavit:

By my dated signature below, I, TimothyJennings, 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.

090177e196ae3fd3\Final\Final On: 01-Apr-2021 05:23 (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: 1008

Site Name: (1008) Clinical Research Professionals Inc.

Subject No: 10081152

Subject Initials: ---

Generated By: pfe.lewissc

Generated Time (GMT): 29-Mar-2021 04:12

[Back to Form](#)

Item	Date	User	Comment
Form	Aug-31-2020 15:01:26 (UTC-06:00) Central Time (US & Canada)	Tiffany Baum (pfe.tbaum)	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: 1008

Site Name: (1008) Clinical Research Professionals Inc.

Subject No: 10081152

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:12

[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
Timothy Jennings	Approved	Jan-21-2021 16:49:56 (UTC-06:00) Central Time (US & Canada)	BOOK	Signed

Affidavit:

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

Tonya Clausen	N/A	Jan-08-2021 15:49:40 (UTC-06:00) Central Time (US & Canada)		Edit - All signatures invalidated
---------------	-----	--	--	-----------------------------------

Affidavit:

N/A

Timothy Jennings	Approved	Oct-29-2020 15:53:47 (UTC-06:00) Central Time (US & Canada)	BOOK	Signed
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090177e196ae3fd3\Final\Final On: 01-Apr-2021 05:23 (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: 1008

Site Name: (1008) Clinical Research Professionals Inc.

Subject No: 10081152

Subject Initials: ---

Generated By: pfe.lewissc

Generated Time (GMT): 29-Mar-2021 04:12

Affidavit:

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

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

090177e196ae3fd3\Final\Final On: 01-Apr-2021 05:23 (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: 1008

Site Name: (1008) Clinical Research Professionals Inc.

Subject No: 10081152

Subject Initials: ---

Generated By: pfe.lewissc

Generated Time (GMT): 29-Mar-2021 04:12

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1. Select appropriate response - Protocol version

Date	Location	User	Value	Reason
Aug-31-2020 15:00:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Tiffany Baum (pfe.tbaum)	Data Entry: 24 JUL 2020	Initial Entry

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

Date	Location	User	Value	Reason
Aug-31-2020 15:00:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Tiffany Baum (pfe.tbaum)	Data Entry: STAGE 3 COHORTS	Initial Entry

090177e196ae3fd3\Final\Final On: 01-Apr-2021 05:23 (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: 1008

Site Name: (1008) Clinical Research Professionals Inc.

Subject No: 10081152

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:12

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1. Consent Was:

Date	Location	User	Value	Reason
Aug-31-2020 15:01:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Tiffany Baum (pfe.tbaum)	Data Entry: OBTAINED Date Written Consen t Obtained Aug/31/2020	Initial Entry

Header Text: c4591001

Visit: COHORT_SELECTION

Form Version: 06-Jul-2020 21:55

Site No: 1008

Subject No: 10081152

Generated By: pfe.lewissc

Form: DEMOGRAPHY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1008) Clinical Research Professionals Inc.

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:12

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1. Subject ID

Date	Location	User	Value	Reason
Aug-31-2020 15:00:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 10081152	Item copied from previous form

2. Birth Date:

Date	Location	User	Value	Reason
Aug-31-2020 15:00:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: (b) (6) 1979	Enrollment Entry

3. Sex:

Date	Location	User	Value	Reason
Aug-31-2020 15:01:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Tiffany Baum (pfe.tbaum)	Data Entry: MALE	Initial Entry

4. Ethnicity:

Date	Location	User	Value	Reason
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090177e196ae3fd3\Final\Final On: 01-Apr-2021 05:23 (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: 1008

Site Name: (1008) Clinical Research Professionals Inc.

Subject No: 10081152

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:12

Aug-31-2020 15:01:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Tiffany Baum (pfe.tbaum)	Data Entry: NOT HISPANIC OR LATINO(A) OR OF S PANISH ORIGIN	Initial Entry
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5. Race: (Check X all that apply):

Date	Location	User	Value	Reason
Aug-31-2020 15:01:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Tiffany Baum (pfe.tbaum)	Data Entry: WHITE	Initial Entry

090177e196ae3fd3\Final\Final On: 01-Apr-2021 05:23 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:02

Site No: 1008

Subject No: 10081152

Generated By: pfe.levissc

Form: DATE OF VISIT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1008) Clinical Research Professionals Inc.

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:12

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1. Date of Visit

Date	Location	User	Value	Reason
Aug-31-2020 15:01:19 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Tiffany Baum (pfe.tbaum)	Data Entry: Aug/31/2020	Initial Entry

090177e196ae3fd3\Final\Final On: 01-Apr-2021 05:23 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1008

Subject No: 10081152

Generated By: pfe.lewissc

Form: DISPOSITION - SCREENING - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1008) Clinical Research Professionals Inc.

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:12

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1. Date of Completion/Discontinuation/Death

Date	Location	User	Value	Reason
Aug-31-2020 15:01:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Tiffany Baum (pfe.tbaum)	Data Entry: Aug/31/2020	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Aug-31-2020 15:01:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SCREENING	Initial Entry

3. Status:

Date	Location	User	Value	Reason
Aug-31-2020 15:01:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Tiffany Baum (pfe.tbaum)	Data Entry: COMPLETED	Initial Entry

090177e196ae3fd3\Final\Final On: 01-Apr-2021 05:23 (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: 1008

Site Name: (1008) Clinical Research Professionals Inc.

Subject No: 10081152

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:12

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1.a

Date	Location	User	Value	Reason
Aug-31-2020 15:01:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH N umber: Medical Hi story Term: Seasonal allergies Start Date: UNK/U NK/2010 Ongoing: YES	Initial Entry

1.a Line/MH Number:

Date	Location	User	Value	Reason
Aug-31-2020 15:01:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 1	Initial Entry

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

Date	Location	User	Value	Reason
Aug-31-2020 15:01:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Tiffany Baum (pfe.tbaum)	Data Entry: Seasonal allergies	Initial Entry

090177e196ae3fd3\Final\Final On: 01-Apr-2021 05:23 (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: 1008

Site Name: (1008) Clinical Research Professionals Inc.

Subject No: 10081152

Subject Initials: ---

Generated By: pfe.lewissc

Generated Time (GMT): 29-Mar-2021 04:12

1.a Start Date:

Date	Location	User	Value	Reason
Aug-31-2020 15:01:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Tiffany Baum (pfe.tbaum)	Data Entry: UNK/UNK/2010	Initial Entry

1.a Ongoing:

Date	Location	User	Value	Reason
Aug-31-2020 15:01:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Tiffany Baum (pfe.tbaum)	Data Entry: YES	Initial Entry

1.b

Date	Location	User	Value	Reason
Aug-31-2020 15:02:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH N umber: 2 Medical History Term: Hypertension Start Date: UNK/UNK/2018 Ongoing: YES	Initial Entry

090177e196ae3fd3\Final\Final On: 01-Apr-2021 05:23 (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: 1008

Site Name: (1008) Clinical Research Professionals Inc.

Subject No: 10081152

Subject Initials: ---

Generated By: pfe.lewissc

Generated Time (GMT): 29-Mar-2021 04:12

1.b Line/MH Number:

Date	Location	User	Value	Reason
Aug-31-2020 15:02:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 2	Initial Entry

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

Date	Location	User	Value	Reason
Aug-31-2020 15:02:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Tiffany Baum (pfe.tbaum)	Data Entry: Hypertension	Initial Entry

1.b Start Date:

Date	Location	User	Value	Reason
Aug-31-2020 15:02:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Tiffany Baum (pfe.tbaum)	Data Entry: UNK/UNK/2018	Initial Entry

1.b Ongoing:

Date	Location	User	Value	Reason
Aug-31-2020 15:02:26	ACV0PFEINFP6000	Tiffany Baum	Data Entry: YES	Initial Entry

090177e196ae3fd3\Final\Final On: 01-Apr-2021 05:23 (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: 1008

Site Name: (1008) Clinical Research Professionals Inc.

Subject No: 10081152

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:12

(UTC-06:00)
Central Time (US
& Canada)

(pfe.tbaum)

I.c

Date	Location	User	Value	Reason
Aug-31-2020 15:03:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH N umber: 3 Medical History Term: Percocet allergy Start Date: UNK/UNK/1998 Ongoing: YES	Initial Entry

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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: 1008

Site Name: (1008) Clinical Research Professionals Inc.

Subject No: 10081152

Subject Initials: ---

Generated By: pfe.lewissc

Generated Time (GMT): 29-Mar-2021 04:12

1.c Line/MH Number:

Date	Location	User	Value	Reason
Aug-31-2020 15:03:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 3	Initial Entry

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

Date	Location	User	Value	Reason
Aug-31-2020 15:03:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Tiffany Baum (pfe.tbaum)	Data Entry: Percocet allergy	Initial Entry

1.c Start Date:

Date	Location	User	Value	Reason
Aug-31-2020 15:03:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Tiffany Baum (pfe.tbaum)	Data Entry: UNK/UNK/1998	Initial Entry

1.c Ongoing:

Date	Location	User	Value	Reason
Aug-31-2020 15:03:15	ACV0PFEINFP6000	Tiffany Baum	Data Entry: YES	Initial Entry

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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: 1008

Site Name: (1008) Clinical Research Professionals Inc.

Subject No: 10081152

Subject Initials: ---

Generated By: pfe.lewissc

Generated Time (GMT): 29-Mar-2021 04:12

(UTC-06:00)
Central Time (US
& Canada)

(pfe.tbaum)

1.d

Date	Location	User	Value	Reason
Aug-31-2020 16:10:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH N umber: 4 Medical History Term: Tinea Versicolor Start Date: May/UNK/2020 Ongoing: YES	Initial Entry

090177e196ae3fd3\Final\Final On: 01-Apr-2021 05:23 (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: 1008

Site Name: (1008) Clinical Research Professionals Inc.

Subject No: 10081152

Subject Initials: ---

Generated By: pfe.lewissc

Generated Time (GMT): 29-Mar-2021 04:12

1.d Line/MH Number:

Date	Location	User	Value	Reason
Aug-31-2020 16:10:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 4	Initial Entry

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

Date	Location	User	Value	Reason
Aug-31-2020 16:10:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Tiffany Baum (pfe.tbaum)	Data Entry: Tinea Versicolor	Initial Entry

1.d Start Date:

Date	Location	User	Value	Reason
Aug-31-2020 16:10:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Tiffany Baum (pfe.tbaum)	Data Entry: May/UNK/2020	Initial Entry

1.d Ongoing:

Date	Location	User	Value	Reason
Aug-31-2020 16:10:22	ACV0PFEINFP6000	Tiffany Baum	Data Entry: YES	Initial Entry

090177e196ae3fd3\Final\Final On: 01-Apr-2021 05:23 (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: 1008

Site Name: (1008) Clinical Research Professionals Inc.

Subject No: 10081152

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:12

(UTC-06:00) Central Time (US & Canada)		(pfe.tbaum)		
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Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 21-Aug-2020 02:51

Site No: 1008

Subject No: 10081152

Generated By: pfe.lewissc

Form: VITAL SIGNS - BASELINE - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1008) Clinical Research Professionals Inc.

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:12

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1. Date:

Date	Location	User	Value	Reason
Aug-31-2020 15:04:24 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Tiffany Baum (pfe.tbaum)	Data Entry: Aug/31/2020	Initial Entry

2. Weight:

Date	Location	User	Value	Reason
Aug-31-2020 15:04:24 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Tiffany Baum (pfe.tbaum)	Data Entry: 228.2	Initial Entry

3. Unit:

Date	Location	User	Value	Reason
Aug-31-2020 15:04:24 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Tiffany Baum (pfe.tbaum)	Data Entry: LB	Initial Entry

4. Height:

Date	Location	User	Value	Reason
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090177e196ae3fd3\Final\Final On: 01-Apr-2021 05:23 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: VITAL SIGNS - BASELINE - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1008

Site Name: (1008) Clinical Research Professionals Inc.

Subject No: 10081152

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:12

Aug-31-2020 15:04:24 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Tiffany Baum (pfe.tbaum)	Data Entry: 74.5	Initial Entry
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5. Unit:

Date	Location	User	Value	Reason
Aug-31-2020 15:04:24 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Tiffany Baum (pfe.tbaum)	Data Entry: in	Initial Entry

6. Body Mass Index:

Date	Location	User	Value	Reason
Aug-31-2020 15:04:24 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 28.9	Initial Entry

7.a

Date	Location	User	Value	Reason
Aug-31-2020 15:04:24 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Tiffany Baum (pfe.tbaum)	Data Entry: Record Identifier: Temperature: 98.0	Initial Entry

090177e196ae3fd3\Final\Final On: 01-Apr-2021 05:23 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: VITAL SIGNS - BASELINE - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1008

Site Name: (1008) Clinical Research Professionals Inc.

Subject No: 10081152

Subject Initials: ---

Generated By: pfe.lewissc

Generated Time (GMT): 29-Mar-2021 04:12

			Temperature Unit: Temperature Location: HEAD	
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7.a Record Identifier:

Date	Location	User	Value	Reason
Aug-31-2020 15:04:24 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Tiffany Baum (pfe.tbaum)	Data Entry: 1	Initial Entry

7.a Temperature:

Date	Location	User	Value	Reason
Aug-31-2020 15:04:24 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Tiffany Baum (pfe.tbaum)	Data Entry: 98.0	Initial Entry

7.a Unit:

Date	Location	User	Value	Reason
Aug-31-2020 15:04:24 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Tiffany Baum (pfe.tbaum)	Data Entry: F	Initial Entry

090177e196ae3fd3\Final\Final On: 01-Apr-2021 05:23 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: VITAL SIGNS - BASELINE - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1008

Site Name: (1008) Clinical Research Professionals Inc.

Subject No: 10081152

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:12

7.a Temperature Location:

Date	Location	User	Value	Reason
Aug-31-2020 15:04:24 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Tiffany Baum (pfe.tbaum)	Data Entry: FOREHEAD	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1008

Subject No: 10081152

Generated By: pfe.levissc

Form: RANDOMIZATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1008) Clinical Research Professionals Inc.

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:12

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1. Randomization Date :

Date	Location	User	Value	Reason
Aug-31-2020 16:08:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Tiffany Baum (pfe.tbaum)	Data Entry: Aug/31/2020	Initial Entry

2. Randomization Number:

Date	Location	User	Value	Reason
Aug-31-2020 16:08:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Tiffany Baum (pfe.tbaum)	Data Entry: 75850	Initial Entry

090177e196ae3fd3\Final\Final On: 01-Apr-2021 05:23 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1008

Subject No: 10081152

Generated By: pfe.lewissc

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

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1008) Clinical Research Professionals Inc.

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:12

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1. Data Origin

Date	Location	User	Value	Reason
Aug-31-2020 15:04:32 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Aug-31-2020 15:04:32 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SERUM	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Aug-31-2020 15:22:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Aug-31-2020 15:04:32 (UTC-06:00)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however

090177e196ae3fd3\Final\Final On: 01-Apr-2021 05:23 (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: 1008

Site Name: (1008) Clinical Research Professionals Inc.

Subject No: 10081152

Subject Initials: ---

Generated By: pfe.lewissc

Generated Time (GMT): 29-Mar-2021 04:12

Central Time (US & Canada)				no barcodes are entered. Please review and correct as appropriate.
Aug-31-2020 15:04:32 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Tiffany Baum (pfe.tbaum)	Data Entry: YES Date of Collection: Aug/31/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Aug-31-2020 15:22:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Cheyenne Brooks (pfe.cbrooms)	Data Entry: Sample ID BTPN : 0	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Aug-31-2020 15:22:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Cheyenne Brooks (pfe.cbrooms)	Data Entry: BTPN0	Initial Entry

5.b

Date	Location	User	Value	Reason
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090177e196ae3fd3\Final\Final On: 01-Apr-2021 05:23 (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: 1008

Site Name: (1008) Clinical Research Professionals Inc.

Subject No: 10081152

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:12

Aug-31-2020 15:22:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Cheyenne Brooks (pfe.cbrooms)	Data Entry: Sample ID BTPN : 1	Initial Entry
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5.b Sample ID

Date	Location	User	Value	Reason
Aug-31-2020 15:22:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Cheyenne Brooks (pfe.cbrooms)	Data Entry: BTPN1	Initial Entry

5.c

Date	Location	User	Value	Reason
Aug-31-2020 15:22:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Cheyenne Brooks (pfe.cbrooms)	Data Entry: Sample ID BTPN : 2	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Aug-31-2020 15:22:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Cheyenne Brooks (pfe.cbrooms)	Data Entry: BTPN2	Initial Entry

090177e196ae3fd3\Final\Final On: 01-Apr-2021 05:23 (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: 1008

Site Name: (1008) Clinical Research Professionals Inc.

Subject No: 10081152

Subject Initials: ---

Generated By: pfe.lewissc

Generated Time (GMT): 29-Mar-2021 04:12

5.d

Date	Location	User	Value	Reason
Aug-31-2020 15:22:46 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Cheyenne Brooks (pfe.cbrooks)	Data Entry: Sample I BPRL7 D: M	Initial Entry

5.d Sample ID

Date	Location	User	Value	Reason
Aug-31-2020 15:22:46 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Cheyenne Brooks (pfe.cbrooks)	Data Entry: BPRL7M	Initial Entry

5.e

Date	Location	User	Value	Reason
Aug-31-2020 15:22:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Cheyenne Brooks (pfe.cbrooks)	Data Entry: Sample ID BPRL7 : N	Initial Entry

090177e196ae3fd3\Final\Final On: 01-Apr-2021 05:23 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1008

Subject No: 10081152

Generated By: pfe.lewissc

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

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1008) Clinical Research Professionals Inc.

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:12

5.e Sample ID

Date	Location	User	Value	Reason
Aug-31-2020 15:22:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Cheyenne Brooks (pfe.cbrooms)	<u>Data Entry:</u> BPRL7N	Initial Entry

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: 1008

Site Name: (1008) Clinical Research Professionals Inc.

Subject No: 10081152

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:12

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1. Data Origin

Date	Location	User	Value	Reason
Aug-31-2020 15:04:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Aug-31-2020 15:04:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: NASAL_SWAB	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Aug-31-2020 15:23:04 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Aug-31-2020 15:04:39 (UTC-06:00)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however

090177e196ae3fd3\Final\Final On: 01-Apr-2021 05:23 (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: 1008

Site Name: (1008) Clinical Research Professionals Inc.

Subject No: 10081152

Subject Initials: ---

Generated By: pfe.lewissc

Generated Time (GMT): 29-Mar-2021 04:12

Central Time (US & Canada)				no barcodes are entered. Please review and correct as appropriate.
Aug-31-2020 15:04:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Tiffany Baum (pfe.tbaum)	Data Entry: YES Date of Collection: Aug/31/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Aug-31-2020 15:23:04 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Cheyenne Brooks (pfe.cbrooms)	Data Entry: Sample ID BP51L : F	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Aug-31-2020 15:23:04 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Cheyenne Brooks (pfe.cbrooms)	Data Entry: BP51LF	Initial Entry

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Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:04

Site No: 1008

Subject No: 10081152

Generated By: pfe.levissc

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1008) Clinical Research Professionals Inc.

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:12

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1. Was there a temporary delay of vaccination?

Date	Location	User	Value	Reason
Aug-31-2020 16:09:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Tiffany Baum (pfe.tbaum)	Data Entry: NO	Initial Entry

2. Treatment Name

Date	Location	User	Value	Reason
Aug-31-2020 16:09:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: BLINDED THERAPY	Initial Entry

3. Formulation:

Date	Location	User	Value	Reason
Aug-31-2020 16:09:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INJECTION	Initial Entry

4. Dose Date Time:

Date	Location	User	Value	Reason
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090177e196ae3fd3\Final\Final On: 01-Apr-2021 05:23 (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: 1008

Site Name: (1008) Clinical Research Professionals Inc.

Subject No: 10081152

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:12

Aug-31-2020 16:09:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Tiffany Baum (pfe.tbaum)	Data Entry: Aug/31/2020 15:31	Initial Entry
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5. Anatomical Location:

Date	Location	User	Value	Reason
Aug-31-2020 16:09:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: DELTOID MUSCLE	Initial Entry

6. Body Side:

Date	Location	User	Value	Reason
Aug-31-2020 16:09:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Tiffany Baum (pfe.tbaum)	Data Entry: LEFT	Initial Entry

7. Route:

Date	Location	User	Value	Reason
Aug-31-2020 16:09:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INTRAMUSCULAR	Initial Entry

090177e196ae3fd3\Final\Final On: 01-Apr-2021 05:23 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:04

Site No: 1008

Subject No: 10081152

Generated By: pfe.lewissc

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1008) Clinical Research Professionals Inc.

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:12

10. Timeframe Subject Was Observed

Date	Location	User	Value	Reason
Aug-31-2020 16:09:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: THE PROTOCOL SPE CIFIED OBSERVATIO N PERIOD	Initial Entry

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

Date	Location	User	Value	Reason
Aug-31-2020 16:09:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Tiffany Baum (pfe.tbaum)	Data Entry: YES	Initial Entry

090177e196ae3fd3\Final\Final On: 01-Apr-2021 05:23 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 06-Jul-2020 21:53

Site No: 1008

Subject No: 10081152

Generated By: pfe.levissc

Form: REACTOGENICITY DIARY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1008) Clinical Research Professionals Inc.

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:12

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1. Select appropriate response - Reactogenicity diary collection

Date	Location	User	Value	Reason
Aug-31-2020 15:04:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Tiffany Baum (pfe.tbaum)	Data Entry: NO - REACTOGENI CITY E-DIARY NOT COLLECTED FOR T HIS SUBJECT	Initial Entry

090177e196ae3fd3\Final\Final On: 01-Apr-2021 05:23 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 1008

Subject No: 10081152

Generated By: pfe.levissc

Form: DATE OF VISIT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1008) Clinical Research Professionals Inc.

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:12

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1. Date of Visit

Date	Location	User	Value	Reason
Sep-21-2020 15:05:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Tiffany Baum (pfe.tbaum)	Data Entry: Sep/21/2020	Initial Entry

090177e196ae3fd3\Final\Final On: 01-Apr-2021 05:23 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 15-Sep-2020 21:54

Site No: 1008

Subject No: 10081152

Generated By: pfe.lewissc

Form: VITAL SIGNS - TEMP - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1008) Clinical Research Professionals Inc.

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:12

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1. Date:

Date	Location	User	Value	Reason
Sep-21-2020 15:05:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Tiffany Baum (pfe.tbaum)	Data Entry: Sep/21/2020	Initial Entry

2.a

Date	Location	User	Value	Reason
Sep-21-2020 15:05:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Tiffany Baum (pfe.tbaum)	Data Entry: Record Identifier:: Temperature: 98.2 Temperature Unit: Temperature Location:: HEAD	Initial Entry

2.a Record Identifier:

Date	Location	User	Value	Reason
Sep-21-2020 15:05:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Tiffany Baum (pfe.tbaum)	Data Entry: 1	Initial Entry

090177e196ae3fd3\Final\Final On: 01-Apr-2021 05:23 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form: VITAL SIGNS - TEMP - eCRF Audit Trail History

Form Version: 15-Sep-2020 21:54

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1008

Site Name: (1008) Clinical Research Professionals Inc.

Subject No: 10081152

Subject Initials: ---

Generated By: pfe.lewissc

Generated Time (GMT): 29-Mar-2021 04:12

2.a Temperature:

Date	Location	User	Value	Reason
Sep-21-2020 15:05:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Tiffany Baum (pfe.tbaum)	Data Entry: 98.2	Initial Entry

2.a Unit:

Date	Location	User	Value	Reason
Sep-21-2020 15:05:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Tiffany Baum (pfe.tbaum)	Data Entry: F	Initial Entry

2.a Temperature Location:

Date	Location	User	Value	Reason
Sep-21-2020 15:05:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Tiffany Baum (pfe.tbaum)	Data Entry: FOREHEAD	Initial Entry

090177e196ae3fd3\Final\Final On: 01-Apr-2021 05:23 (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: 1008

Site Name: (1008) Clinical Research Professionals Inc.

Subject No: 10081152

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:12

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1. Data Origin

Date	Location	User	Value	Reason
Sep-21-2020 14:38:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Sep-21-2020 14:38:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: NASAL_SWAB	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Sep-21-2020 14:38:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Sep-21-2020 14:38:35 (UTC-06:00)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however

090177e196ae3fd3\Final\Final On: 01-Apr-2021 05:23 (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: 1008

Site Name: (1008) Clinical Research Professionals Inc.

Subject No: 10081152

Subject Initials: ---

Generated By: pfe.lewissc

Generated Time (GMT): 29-Mar-2021 04:12

Central Time (US & Canada)				no barcodes are entered. Please review and correct as appropriate.
Sep-21-2020 14:38:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Cheyenne Brooks (pfe.cbrooms)	Data Entry: YES Date of Collection: Sep/21/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Sep-21-2020 14:38:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Cheyenne Brooks (pfe.cbrooms)	Data Entry: Sample ID BGK0Y : 3	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Sep-21-2020 14:38:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Cheyenne Brooks (pfe.cbrooms)	Data Entry: BGK0Y3	Initial Entry

090177e196ae3fd3\Final\Final On: 01-Apr-2021 05:23 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1008

Subject No: 10081152

Generated By: pfe.lewissc

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1008) Clinical Research Professionals Inc.

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:12

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1. Was there a temporary delay of vaccination?

Date	Location	User	Value	Reason
Sep-21-2020 15:05:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Tiffany Baum (pfe.tbaum)	Data Entry: NO	Initial Entry

2. Treatment Name

Date	Location	User	Value	Reason
Sep-21-2020 15:05:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: BLINDED THERAPY	Initial Entry

3. Formulation:

Date	Location	User	Value	Reason
Sep-21-2020 15:05:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INJECTION	Initial Entry

4. Dose Date Time:

Date	Location	User	Value	Reason
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090177e196ae3fd3\Final\Final On: 01-Apr-2021 05:23 (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: 1008

Site Name: (1008) Clinical Research Professionals Inc.

Subject No: 10081152

Subject Initials: ---

Generated By: pfe.lewissc

Generated Time (GMT): 29-Mar-2021 04:12

Sep-21-2020 15:05:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Tiffany Baum (pfe.tbaum)	Data Entry: Sep/21/2020 14:54	Initial Entry
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5. Anatomical Location:

Date	Location	User	Value	Reason
Sep-21-2020 15:05:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: DELTOID MUSCLE	Initial Entry

6. Body Side:

Date	Location	User	Value	Reason
Sep-21-2020 15:05:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Tiffany Baum (pfe.tbaum)	Data Entry: LEFT	Initial Entry

7. Route:

Date	Location	User	Value	Reason
Sep-21-2020 15:05:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INTRAMUSCULAR	Initial Entry

090177e196ae3fd3\Final\Final On: 01-Apr-2021 05:23 (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: 1008

Site Name: (1008) Clinical Research Professionals Inc.

Subject No: 10081152

Subject Initials: ---

Generated By: pfe.lewissc

Generated Time (GMT): 29-Mar-2021 04:12

10. Timeframe Subject Was Observed

Date	Location	User	Value	Reason
Sep-21-2020 15:05:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: THE PROTOCOL SPE CIFIED OBSERVATIO N PERIOD	Initial Entry

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

Date	Location	User	Value	Reason
Sep-21-2020 15:05:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Tiffany Baum (pfe.tbaum)	Data Entry: YES	Initial Entry

090177e196ae3fd3\Final\Final On: 01-Apr-2021 05:23 (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: 1008 **Site Name:** (1008) Clinical Research Professionals Inc.

Subject No: 10081152 **Subject Initials:** ---

Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 04:12

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1. Date of Visit

Date	Location	User	Value	Reason
Oct-19-2020 15:02:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Tiffany Baum (pfe.tbaum)	Data Entry: Oct/19/2020	Initial Entry

090177e196ae3fd3\Final\Final On: 01-Apr-2021 05:23 (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: 1008 **Site Name:** (1008) Clinical Research Professionals Inc.

Subject No: 10081152 **Subject Initials:** ---

Generated By: pfe.levisse **Generated Time (GMT):** 29-Mar-2021 04:12

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1. Data Origin

Date	Location	User	Value	Reason
Oct-19-2020 15:36:54 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Oct-19-2020 15:36:54 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SERUM	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Oct-19-2020 15:37:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Oct-19-2020 15:36:54 (UTC-06:00)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however

090177e196ae3fd3\Final\Final On: 01-Apr-2021 05:23 (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: 1008 **Site Name:** (1008) Clinical Research Professionals Inc.

Subject No: 10081152 **Subject Initials:** ---

Generated By: pfe.levisse **Generated Time (GMT):** 29-Mar-2021 04:12

Central Time (US & Canada)				no barcodes are entered. Please review and correct as appropriate.
Oct-19-2020 15:36:54 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Cheyenne Brooks (pfe.cbrooms)	Data Entry: YES Date of Collection: Oct/19/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Oct-19-2020 15:37:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Cheyenne Brooks (pfe.cbrooms)	Data Entry: Sample I BGL5B D: M	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Oct-19-2020 15:37:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Cheyenne Brooks (pfe.cbrooms)	Data Entry: BGL5BM	Initial Entry

5.b

Date	Location	User	Value	Reason
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090177e196ae3fd3\Final\Final On: 01-Apr-2021 05:23 (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: 1008 **Site Name:** (1008) Clinical Research Professionals Inc.

Subject No: 10081152 **Subject Initials:** ---

Generated By: pfe.levisse **Generated Time (GMT):** 29-Mar-2021 04:12

Oct-19-2020 15:37:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Cheyenne Brooks (pfe.cbrooms)	Data Entry: Sample I BRZDB D: V	Initial Entry
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5.b Sample ID

Date	Location	User	Value	Reason
Oct-19-2020 15:37:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Cheyenne Brooks (pfe.cbrooms)	Data Entry: BRZDBV	Initial Entry

5.c

Date	Location	User	Value	Reason
Oct-19-2020 15:37:18 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Cheyenne Brooks (pfe.cbrooms)	Data Entry: Sample I BRZDB D: W	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Oct-19-2020 15:37:18 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Cheyenne Brooks (pfe.cbrooms)	Data Entry: BRZDBW	Initial Entry

090177e196ae3fd3\Final\Final On: 01-Apr-2021 05:23 (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: 1008 **Site Name:** (1008) Clinical Research Professionals Inc.

Subject No: 10081152 **Subject Initials:** ---

Generated By: pfe.lewissc **Generated Time (GMT):** 29-Mar-2021 04:12

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1. Date of Completion/Discontinuation/Death :

Date	Location	User	Value	Reason
Oct-19-2020 15:02:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Tiffany Baum (pfe.tbaum)	Data Entry: Oct/19/2020	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Oct-19-2020 15:02:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: VACCINATION	Initial Entry

3. Status:

Date	Location	User	Value	Reason
Oct-19-2020 15:02:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Tiffany Baum (pfe.tbaum)	Data Entry: COMPLETED	Initial Entry

090177e196ae3fd3\Final\Final On: 01-Apr-2021 05:23 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - NON
STUDY VACCINATIONS - Audit Trail

Form Version: 22-Apr-2020 21:03

Form Status:

Site No: 1008

Site Name: (1008) Clinical Research Professionals Inc.

Subject No: 10081152

Subject Initials: ---

Generated By: pfe.lewissc

Generated Time (GMT): 29-Mar-2021 04:12

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Date	Location	User	Value	Reason
Oct-19-2020 15:03:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Tiffany Baum (pfe.tbaum)	Form Created	

Header Text: c4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - NON STUDY VACCINATIONS - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1008

Site Name: (1008) Clinical Research Professionals Inc.

Subject No: 10081152

Subject Initials: ---

Generated By: pfe.lewissc

Generated Time (GMT): 29-Mar-2021 04:12

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1. What is the medication identifier?

Date	Location	User	Value	Reason
Oct-19-2020 15:03:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 1	Initial Entry

2. Category:

Date	Location	User	Value	Reason
Oct-19-2020 15:03:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: VACCINATIONS	Initial Entry

3. Concomitant Medications Pre-specified:

Date	Location	User	Value	Reason
Oct-19-2020 15:03:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: NO	Initial Entry

4. Medication:

Provide the complete generic drug name (including salt form, where applicable). Where generic name is unknown, enter the full trade or proprietary name. Include clarifying information in

090177e196ae3fd3\Final\Final On: 01-Apr-2021 05:23 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - NON STUDY VACCINATIONS - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1008

Site Name: (1008) Clinical Research Professionals Inc.

Subject No: 10081152

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Generated By: pfe.lewissc

Generated Time (GMT): 29-Mar-2021 04:12

the Medication text (e.g., Ingredient(s), route, use, formulation).

Date	Location	User	Value	Reason
Oct-19-2020 15:03:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Tiffany Baum (pfe.tbaum)	Data Entry: Quadrivalent flu prop hylaxis intramuscular vaccine 0.5 ml once	Initial Entry

5. Date:

Date	Location	User	Value	Reason
Oct-19-2020 15:03:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Tiffany Baum (pfe.tbaum)	Data Entry: Oct/8/2020	Initial Entry

090177e196ae3fd3\Final\Final On: 01-Apr-2021 05:23 (GMT)

Header Text: c4591001

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

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen, Verified

Site No: 1008

Site Name: (1008) Clinical Research Professionals Inc.

Subject No: 10081152

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:12

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1. Date of Visit

Date	Location	User	Value	Reason
Jan-08-2021 15:49:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Tonya Clausen (pfe.tclausen)	Data Entry: Jan/7/2021	Initial Entry

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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: 1008 **Site Name:** (1008) Clinical Research Professionals Inc.

Subject No: 10081152 **Subject Initials:** ---

Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 04:12

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

Date	Location	User	Value	Reason
Jan-08-2021 15:50:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Tonya Clausen (pfe.tclausen)	Data Entry: 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

090177e196ae3fd3\Final\Final On: 01-Apr-2021 05:23 (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: 1008

Site Name: (1008) Clinical Research Professionals Inc.

Subject No: 10081152

Subject Initials: ---

Generated By: pfe.lewissc

Generated Time (GMT): 29-Mar-2021 04:12

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1. Date Treatment Unblinded :

Date	Location	User	Value	Reason
Jan-08-2021 15:49:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Tonya Clausen (pfe.tclausen)	Data Entry: Jan/7/2021	Initial Entry

2. Primary Reason for Unblinding:

Date	Location	User	Value	Reason
Jan-08-2021 15:49:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Tonya Clausen (pfe.tclausen)	Data Entry: ASSESS ELIGIBILI TY FOR ADDITION AL VACCINATION	Initial Entry

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Header Text: c4591001

Visit: Subject Status - Unscheduled

Form: SUBJECT STATUS - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Verified

Site No: 1008

Site Name: (1008) Clinical Research Professionals Inc.

Subject No: 10081152

Subject Initials: ---

Generated By: pfe.lewissc

Generated Time (GMT): 29-Mar-2021 04:12

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1. Subject Status

Date	Location	User	Value	Reason
Oct-19-2020 15:02:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: FOLLOW-UP	Initial Entry
Aug-31-2020 16:08:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: ENROLLED/RANDOMIZED	Initial Entry
Aug-31-2020 15:01:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SCREENED	Initial Entry

2. Subject Status Date

Date	Location	User	Value	Reason
Oct-19-2020 15:02:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Oct/19/2020	Initial Entry
Aug-31-2020 16:08:51	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Aug/31/2020	Initial Entry

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Header Text: c4591001

Visit: Subject Status - Unscheduled

Form: SUBJECT STATUS - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Verified

Site No: 1008

Site Name: (1008) Clinical Research Professionals Inc.

Subject No: 10081152

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:12

(UTC-06:00) Central Time (US & Canada)				
Aug-31-2020 15:01:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Aug/31/2020	Initial Entry

090177e196ae3fd3\Final\Final On: 01-Apr-2021 05:23 (GMT)

Header Text: c4591001

Visit: Investigator Signature -
Unscheduled

Form Version: 22-Apr-2020 21:04

Site No: 1008

Subject No: 10081152

Generated By: pfe.lewissc

Form: CASEBOOK SIGNATURE FORM - eCRF Audit
Trail History

Form Status: Data Complete, Signed, Verified

Site Name: (1008) Clinical Research Professionals Inc.

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:12

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1. Casebook Signature

Date	Location	User	Value	Reason
Oct-19-2020 15:02:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Tiffany Baum (pfe.tbaum)	Data Entry: Click Here to Enable	Initial Entry

090177e196ae3fd3\Final\Final On: 01-Apr-2021 05:23 (GMT)