

Header Text: c4591001

Visit: COHORT_SELECTION

Form: COHORT SELECTION

Form Version: 10-Oct-2020 16:01

Form Status: Data Complete, Frozen, Verified

Site No: 1008

Site Name: (1008) Clinical Research Professionals Inc.

Subject No: 10081667

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	06 OCT 2020
2.	Select appropriate response - What cohort does the subject belong to?	STAGE 3 COHORTS

090177e196ae3fd6\Final\Final On: 01-Apr-2021 05:24 (GMT)

Header Text: c4591001

Visit: COHORT_SELECTION

Form: MAIN INFORMED CONSENT

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: 10081667

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 Oct/22/2020
----	--------------	--

090177e196ae3fd6\Final\Final On: 01-Apr-2021 05:24 (GMT)

Header Text: c4591001

Visit: COHORT_SELECTION

Form: DEMOGRAPHY

Form Version: 15-Sep-2020 21:54

Form Status: Data Complete, Frozen, Verified

Site No: 1008

Site Name: (1008) Clinical Research Professionals Inc.

Subject No: 10081667

Subject Initials: ---

Generated By: pfe.levissc

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

[eCRF Audit Trail History](#)

Demography

1.	Subject ID	[10081667]
2.	Birth Date:	(b) (6) 1941
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:	

090177e196ae3fd6\Final\Final On: 01-Apr-2021 05:24 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: DATE OF VISIT

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: 10081667

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	Oct/22/2020
2.	Erroneous Visit	

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 10-Oct-2020 16:00

Site No: 1008

Subject No: 10081667

Generated By: pfe.levissc

Form: INCLUSION/EXCLUSION CRITERIA

Form Status: Data Complete, 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 _____
----	--	-------------------------

090177e196ae3fd6\Final\Final On: 01-Apr-2021 05:24 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 15-Sep-2020 21:52

Site No: 1008

Subject No: 10081667

Generated By: pfe.levissc

Form: DISPOSITION - SCREENING

Form Status: Data Complete, 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	Oct/22/2020
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, Frozen, Verified

Site No: 1008

Site Name: (1008) Clinical Research Professionals Inc.

Subject No: 10081667

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:	[Asthma]
	Start Date:	UNK/UNK/1976
	Ongoing:	YES
1.b	Line/MH Number:	[2]
	Disease/Syndrome /Surgery/Non-Drug Allergies/Drug Allergies:	[Non allergic rhinitis]
	Start Date:	UNK/UNK/1945
	Ongoing:	YES
1.c	Line/MH Number:	[3]
	Disease/Syndrome /Surgery/Non-Drug Allergies/Drug Allergies:	[Gastroesophageal reflux disease]
	Start Date:	UNK/UNK/2005
	Ongoing:	YES

090177e196ae3fd6\Final\Final On: 01-Apr-2021 05:24 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: GENERAL MEDICAL 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: 10081667

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:	[Diabetes type II]
	Start Date:	UNK/UNK/2017
	Ongoing:	YES
1.e	Line/MH Number:	[5]
	Disease/Syndrome /Surgery/Non-Drug Allergies/Drug Allergies:	[Hypertension]
	Start Date:	UNK/UNK/2005
	Ongoing:	YES
1.f	Line/MH Number:	[6]
	Disease/Syndrome /Surgery/Non-Drug Allergies/Drug Allergies:	[Penicillin allergy]
	Start Date:	UNK/UNK/1957
	Ongoing:	YES
1.g	Line/MH Number:	[7]
	Disease/Syndrome /Surgery/Non-Drug Allergies/Drug Allergies:	[Levaquin allergy]
	Start Date:	UNK/UNK/2014
	Ongoing:	YES

090177e196ae3fd6\Final\Final On: 01-Apr-2021 05:24 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 15-Sep-2020 21:57

Site No: 1008

Subject No: 10081667

Generated By: pfe.levissc

Form: HIV STATUS

Form Status: Data Complete, Frozen, Verified

Site Name: (1008) Clinical Research Professionals Inc.

Subject Initials: ---

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

[eCRF Audit Trail History](#)

HIV Status

1.	Select appropriate response - What is the subject HIV status?	The subject is NOT known to be HIV POSITIVE
----	--	---

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 10-Oct-2020 16:04

Site No: 1008

Subject No: 10081667

Generated By: pfe.levissc

Form: VITAL SIGNS - BASELINE

Form Status: Data Complete, 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:	Oct/22/2020
2.	Weight:	[177.6]
3.	Unit:	LB
4.	Height:	[69.0]
5.	Unit:	in
6.	Body Mass Index:	[26.2]

Vital Signs Details

7.a	Record Identifier:	1
	Temperature:	[97.3]
	Unit:	F
	Temperature Location:	FOREHEAD

090177e196ae3fd6\Final\Final On: 01-Apr-2021 05:24 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1008

Subject No: 10081667

Generated By: pfe.levissc

Form: RANDOMIZATION

Form Status: Data Complete, 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 :	Oct/22/2020
2.	Randomization Number:	[272026]
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, Frozen, Verified

Site No: 1008

Site Name: (1008) Clinical Research Professionals Inc.

Subject No: 10081667

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/22/2020
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	[BPZBH6]
5.b	Sample ID	[BRZDBC]
5.c	Sample ID	[BRZDBD]

090177e196ae3fd6\Final\Final On: 01-Apr-2021 05:24 (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, Frozen, Verified

Site No: 1008

Site Name: (1008) Clinical Research Professionals Inc.

Subject No: 10081667

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: Oct/22/2020
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	[BPZBG6]
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090177e196ae3fd6\Final\Final On: 01-Apr-2021 05:24 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:04

Site No: 1008

Subject No: 10081667

Generated By: pfe.lewissc

Form: VACCINATION

Form Status: Data Complete, 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:	Oct/22/2020 11:33
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

090177e196ae3fd6\Final\Final On: 01-Apr-2021 05:24 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 06-Jul-2020 21:53

Site No: 1008

Subject No: 10081667

Generated By: pfe.lewissc

Form: REACTOGENICITY DIARY

Form Status: Data Complete, 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
----	---	---

Header Text: c4591001

Visit: V2_VAX2_L

Form: DATE OF VISIT

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: 10081667

Subject Initials: ---

Generated By: pfe.levissc

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

[eCRF Audit Trail History](#)

Date of Visit

1.	Date of Visit	Nov/12/2020
2.	Erroneous Visit	

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 10-Oct-2020 16:01

Site No: 1008

Subject No: 10081667

Generated By: pfe.levissc

Form: VITAL SIGNS - TEMP

Form Status: Data Complete, 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:	Nov/12/2020
----	-------	-------------

Vital Signs Details

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

090177e196ae3fd6\Final\Final On: 01-Apr-2021 05:24 (GMT)

Header Text: c4591001**Visit:** V2_VAX2_L**Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB**Form Version:** 22-Apr-2020 21:03**Form Status:** Data Complete, Frozen, Verified**Site No:** 1008**Site Name:** (1008) Clinical Research Professionals Inc.**Subject No:** 10081667**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: Nov/12/2020
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	[BRGV3S]
-----	-----------	----------

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1008

Subject No: 10081667

Generated By: pfe.levissc

Form: VACCINATION

Form Status: Data Complete, 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:	Nov/12/2020 09:29
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

090177e196ae3fd6\Final\Final On: 01-Apr-2021 05:24 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L **Form:** DATE OF VISIT

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: 10081667 **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	Dec/10/2020
2.	Erroneous Visit	

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L **Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

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

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

Subject No: 10081667 **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: Dec/10/2020
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[]

Aliquot

Please enter barcode for each aliquot.

5.a	Sample ID	[BRL1RY]
5.b	Sample ID	[BS96NF]
5.c	Sample ID	[BS96NG]

090177e196ae3fd6\Final\Final On: 01-Apr-2021 05:24 (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: 10081667

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: 10081667

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

090177e196ae3fd6\Final\Final On: 01-Apr-2021 05:24 (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:** 10081667**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	[]
----	-----------	-----

Header Text: c4591001

Visit: POT_COVID_ILL - New
Unscheduled Visit

Form: ELECTRONIC SAMPLE TRACKING - NASAL
SWAB

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1008

Site Name: (1008) Clinical Research Professionals Inc.

Subject No: 10081667

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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090177e196ae3fd6\Final\Final On: 01-Apr-2021 05:24 (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: 10081667

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?	
----	--	--

090177e196ae3fd6\Final\Final On: 01-Apr-2021 05:24 (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: 10081667

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: 10081667

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: 10081667

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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090177e196ae3fd6\Final\Final On: 01-Apr-2021 05:24 (GMT)

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: 10081667

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: 10081667 **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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090177e196ae3fd6\Final\Final On: 01-Apr-2021 05:24 (GMT)

Header Text: c4591001

Visit: Logs

Form: ADVERSE EVENT REPORT

Form Version: 22-Apr-2020 21:02

Site No: 1008

Site Name: (1008) Clinical Research Professionals Inc.

Subject No: 10081667

Subject Initials: ---

Generated By: pfe.levissc

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

#	Category	AE Identifier	Adverse Event	Start Date	Is the Adverse Event Still Ongoing	Form Instance
1.	ADVERSE EVENT	1	injection site are soreness	Nov/12/2020 19:30	NO End Date Time: Nov/13/2020 UNK:UNK	Repeating Pages
2.	ADVERSE EVENT	2	liver cancer	Feb/25/2021 UNK:UNK	YES	Repeating Pages

090177e196ae3fd6\Final\Final On: 01-Apr-2021 05:24 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen

Site No: 1008

Site Name: (1008) Clinical Research Professionals Inc.

Subject No: 10081667

Subject Initials: ---

Generated By: pfe.levisse

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

[Back to Form](#)

[eCRF Audit Trail History](#)

[Form Audit Trail](#)

Adverse Event Report

1.	Category:	ADVERSE EVENT
2.	AE ID:	[1]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[injection site are soreness]
4.	Start Date Time:	Nov/12/2020 19:30
5.	Is the adverse event still ongoing?	NO End Date Time: Nov/13/2020 UNK:UNK
6.	Toxicity Grade:	1

090177e196ae3fd6\Final\Final On: 01-Apr-2021 05:24 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen

Site No: 1008

Site Name: (1008) Clinical Research Professionals Inc.

Subject No: 10081667

Subject Initials: ---

Generated By: pfe.lewissc

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

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

090177e196ae3fd6\Final\Final On: 01-Apr-2021 05:24 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen

Site No: 1008

Site Name: (1008) Clinical Research Professionals Inc.

Subject No: 10081667

Subject Initials: ---

Generated By: pfe.levisse

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

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

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete

Site No: 1008

Site Name: (1008) Clinical Research Professionals Inc.

Subject No: 10081667

Subject Initials: ---

Generated By: pfe.levissc

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

[Back to Form](#)

[eCRF Audit Trail History](#)

[Form Audit Trail](#)

Adverse Event Report

1.	Category:	ADVERSE EVENT
2.	AE ID:	[2]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[liver cancer]
4.	Start Date Time:	Feb/25/2021 UNK:UNK
5.	Is the adverse event still ongoing?	YES
6.	Toxicity Grade:	3

Header Text: c4591001**Visit:** Logs - Unscheduled**Form Version:** 22-Apr-2020 21:02**Site No:** 1008**Subject No:** 10081667**Generated By:** pfe.levissc**Form:** ADVERSE EVENT REPORT**Form Status:** Data Complete**Site Name:** (1008) Clinical Research Professionals Inc.**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 04:12

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

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete

Site No: 1008

Site Name: (1008) Clinical Research Professionals Inc.

Subject No: 10081667

Subject Initials: ---

Generated By: pfe.levisse

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

11.	Was a Concomitant Medication given?	NO
12.	Was a Non-Drug Treatment given?	NO
13.	What was the outcome of this adverse event?:	NOT RECOVERED/NOT RESOLVED
14.	Did the adverse event cause the subject to be discontinued from the study?	YES
15.	Serious Adverse Event Number: For Pfizer Use Only	[2021240864]

090177e196ae3fd6\Final\Final On: 01-Apr-2021 05:24 (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: 10081667

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

090177e196ae3fd6\Final\Final On: 01-Apr-2021 05:24 (GMT)

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: 10081667

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	[]

090177e196ae3fd6\Final\Final On: 01-Apr-2021 05:24 (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: 10081667

Subject Initials: ---

Generated By: pfe.lewissc

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

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

090177e196ae3fd6\Final\Final On: 01-Apr-2021 05:24 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - NON STUDY VACCINATIONS

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1008

Site Name: (1008) Clinical Research Professionals Inc.

Subject No: 10081667

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.	Date:	//

090177e196ae3fd6\Final\Final On: 01-Apr-2021 05:24 (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: 10081667

Subject Initials: ---

Generated By: pfe.lewissc

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

090177e196ae3fd6\Final\Final On: 01-Apr-2021 05:24 (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: 10081667

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?	

090177e196ae3fd6\Final\Final On: 01-Apr-2021 05:24 (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: 10081667

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

090177e196ae3fd6\Final\Final On: 01-Apr-2021 05:24 (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: 10081667

Subject Initials: ---

Generated By: pfe.levisse

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

[Back to Form](#)

Radiation Treatment

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

090177e196ae3fd6\Final\Final On: 01-Apr-2021 05:24 (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: 10081667

Subject Initials: ---

Generated By: pfe.levissc

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

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

090177e196ae3fd6\Final\Final On: 01-Apr-2021 05:24 (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: 10081667

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 - 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: 10081667 **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: 10081667 **Subject Initials:** ---

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

Unplanned Assessments

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

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: 10081667

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: 10081667

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:	

090177e196ae3fd6\Final\Final On: 01-Apr-2021 05:24 (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: 10081667

Subject Initials: ---

Generated By: pfe.levisse

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?	

090177e196ae3fd6\Final\Final On: 01-Apr-2021 05:24 (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: 10081667

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: 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: 10081667

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

Form Version: 10-Dec-2020 02:29 **Form Status:** Data Complete, Frozen, Verified

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

Subject No: 10081667 **Subject Initials:** ---

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

[eCRF Audit Trail History](#)

Disposition - Treatment

1.	Date of Completion/Discontinuation/Death :	Dec/10/2020
2.	Phase of Disposition:	VACCINATION
3.	Status:	COMPLETED
4.	Specify Status:	[]

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: 10081667 **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/5/2021
2.	Erroneous Visit	

Header Text: c4591001

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

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

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

Subject No: 10081667 **Subject Initials:** ---

Generated By: pfe.levissc **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 per local/national recommendations and confirmed to have received only placebo at Vaccination 1/2
----	---	--

Header Text: c4591001

Visit: Follow-Up - Unscheduled

Form: DISPOSITION - FOLLOW-UP

Form Version: 15-Sep-2020 21:53

Form Status: Data Complete, Verified

Site No: 1008

Site Name: (1008) Clinical Research Professionals Inc.

Subject No: 10081667

Subject Initials: ---

Generated By: pfe.levissc

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

[eCRF Audit Trail History](#)

Disposition - Follow-Up

1.	Date of Completion/Discontinuation/Death :	Mar/10/2021
2.	Phase of Disposition:	FOLLOW-UP
3.	Status:	WITHDRAWAL BY SUBJECT
4.	Specify Status:	[3/10/21 withdrew consent, refuses study FU/further contact/medical records request]

090177e196ae3fd6\Final\Final On: 01-Apr-2021 05:24 (GMT)

Header Text: c4591001

Visit: V101_VAX3

Form: DATE OF VISIT

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: 10081667

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	Jan/13/2021
2.	Erroneous Visit	

Header Text: c4591001

Visit: V101_VAX3

Form: INFORMED CONSENT - FURTHER VACCINATION

Form Version: 10-Dec-2020 02:31

Form Status: Data Complete, Frozen, Verified

Site No: 1008

Site Name: (1008) Clinical Research Professionals Inc.

Subject No: 10081667

Subject Initials: ---

Generated By: pfe.levissc

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

[eCRF Audit Trail History](#)

Informed Consent - Further Vaccination

1.	Consent Was:	OBTAINED Date Written Consent Obtained Jan/13/2021
----	--------------	--

090177e196ae3fd6\Final\Final On: 01-Apr-2021 05:24 (GMT)

Header Text: c4591001

Visit: V101_VAX3

Form: INCLUSION/EXCLUSION CRITERIA - FURTHER VACCINATION

Form Version: 10-Dec-2020 02:30

Form Status: Data Complete, Frozen, Verified

Site No: 1008

Site Name: (1008) Clinical Research Professionals Inc.

Subject No: 10081667

Subject Initials: ---

Generated By: pfe.lewissc

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

Header Text: c4591001

Visit: V101_VAX3

Form: DISPOSITION - SCREENING FOR FURTHER VACCINATION

Form Version: 10-Dec-2020 02:31

Form Status: Data Complete, Frozen, Verified

Site No: 1008

Site Name: (1008) Clinical Research Professionals Inc.

Subject No: 10081667

Subject Initials: ---

Generated By: pfe.levissc

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

[eCRF Audit Trail History](#)

Disposition - Screening for Further Vaccination

1.	Date of Completion/Discontinuation/Death :	Jan/13/2021
2.	Phase of Disposition:	REPEAT SCREENING 1
3.	Status:	COMPLETED
4.	Specify Status:	[]

090177e196ae3fd6\Final\Final On: 01-Apr-2021 05:24 (GMT)

Header Text: c4591001

Visit: V101_VAX3

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

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: 10081667

Subject Initials: ---

Generated By: pfe.lewissc

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: Jan/13/2021
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[]

Aliquot

Please enter barcode for each aliquot.

5.a	Sample ID	[BRF55N]
5.b	Sample ID	[BSCBDB]
5.c	Sample ID	[BSCBDC]

090177e196ae3fd6\Final\Final On: 01-Apr-2021 05:24 (GMT)

Header Text: c4591001

Visit: V101_VAX3

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB

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: 10081667

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: Jan/13/2021
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[]

Aliquot

Please enter barcode for each aliquot.

5.a	Sample ID	[BRF5DY]
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090177e196ae3fd6\Final\Final On: 01-Apr-2021 05:24 (GMT)

Header Text: c4591001

Visit: V101_VAX3

Form: VACCINATION

Form Version: 10-Dec-2020 02:26

Form Status: Data Complete, Frozen, Verified

Site No: 1008

Site Name: (1008) Clinical Research Professionals Inc.

Subject No: 10081667

Subject Initials: ---

Generated By: pfe.levissc

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	[BNT162b2]
3.	Formulation:	INJECTION
4.	Dose Date Time:	Jan/13/2021 10:46
5.	Anatomical Location:	DELTOID MUSCLE
6.	Body Side:	LEFT
7.	Route:	INTRAMUSCULAR
8.	Actual Dose:	[30.0]
9.	Unit:	ug
10.	Timeframe Subject Was Observed	30 MINUTES
11.	Was the subject observed for at least the protocol specified observation period after investigational product administration?	YES

090177e196ae3fd6\Final\Final On: 01-Apr-2021 05:24 (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: 10081667

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/5/2021
2.	Primary Reason for Unblinding:	ASSESS ELIGIBILITY FOR ADDITIONAL VACCINATION

090177e196ae3fd6\Final\Final On: 01-Apr-2021 05:24 (GMT)

Header Text: c4591001

Visit: Disposition - Unscheduled

Form: WITHDRAWAL OF CONSENT

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Verified

Site No: 1008

Site Name: (1008) Clinical Research Professionals Inc.

Subject No: 10081667

Subject Initials: ---

Generated By: pfe.levissc

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

[eCRF Audit Trail History](#)

Withdrawal Of Consent

1.	Withdrawal of Consent Date :	Mar/10/2021
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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: 10081667

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: V102_VAX4

Form: DATE OF VISIT

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: 10081667

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	Feb/3/2021
2.	Erroneous Visit	

Header Text: c4591001

Visit: V102_VAX4

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB

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: 10081667

Subject Initials: ---

Generated By: pfe.lewissc

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: Feb/3/2021
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[]

Aliquot

Please enter barcode for each aliquot.

5.a	Sample ID	[BRKB0P]
-----	-----------	----------

090177e196ae3fd6\Final\Final On: 01-Apr-2021 05:24 (GMT)

Header Text: c4591001

Visit: V102_VAX4

Form: VACCINATION

Form Version: 10-Dec-2020 02:26

Form Status: Data Complete, Frozen, Verified

Site No: 1008

Site Name: (1008) Clinical Research Professionals Inc.

Subject No: 10081667

Subject Initials: ---

Generated By: pfe.levissc

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	[BNT162b2]
3.	Formulation:	INJECTION
4.	Dose Date Time:	Feb/3/2021 10:32
5.	Anatomical Location:	DELTOID MUSCLE
6.	Body Side:	LEFT
7.	Route:	INTRAMUSCULAR
8.	Actual Dose:	[30.0]
9.	Unit:	ug
10.	Timeframe Subject Was Observed	30 MINUTES
11.	Was the subject observed for at least the protocol specified observation period after investigational product administration?	YES

090177e196ae3fd6\Final\Final On: 01-Apr-2021 05:24 (GMT)

Header Text: c4591001

Visit: V103_MONTH1

Form: DATE OF VISIT

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: 10081667

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	Mar/4/2021
2.	Erroneous Visit	

Header Text: c4591001

Visit: V103_MONTH1

Form Version: 22-Apr-2020 21:04

Site No: 1008

Subject No: 10081667

Generated By: pfe.levissc

Form: CONTACT OUTCOME

Form Status: Data Complete, Frozen, Verified

Site Name: (1008) Clinical Research Professionals Inc.

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Contact Outcome

1.	Contact Type:	TELEPHONE VISIT
2.	Was contact made?	YES Date of Contact: Mar/4/2021
3.	Comments:	[]

Header Text: c4591001

Visit: V104_MONTH6

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: 10081667

Subject Initials: ---

Generated By: pfe.levisse

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

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

Header Text: c4591001

Visit: V104_MONTH6

Form Version: 22-Apr-2020 21:04

Site No: 1008

Subject No: 10081667

Generated By: pfe.levissc

Form: CONTACT OUTCOME

Form Status: Not Started

Site Name: (1008) Clinical Research Professionals Inc.

Subject Initials: ---

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

Contact Outcome

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

Header Text: c4591001

Visit: V105_MONTH18

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: 10081667

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: V105_MONTH18

Form Version: 22-Apr-2020 21:04

Site No: 1008

Subject No: 10081667

Generated By: pfe.levissc

Form: CONTACT OUTCOME

Form Status: Not Started

Site Name: (1008) Clinical Research Professionals Inc.

Subject Initials: ---

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

Contact Outcome

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

Header Text: c4591001

Visit:
FURTHER_VACCINATION_EOT -
Unscheduled

Form: DISPOSITION - TREATMENT

Form Version: 20-Feb-2021 02:26

Form Status: Data Complete, Frozen, Verified

Site No: 1008

Site Name: (1008) Clinical Research Professionals Inc.

Subject No: 10081667

Subject Initials: ---

Generated By: pfe.lewissc

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

[eCRF Audit Trail History](#)

Disposition - Treatment

1.	Date of Completion/Discontinuation/Death :	Mar/4/2021
2.	Phase of Disposition:	OPEN LABEL TREATMENT
3.	Status:	COMPLETED
4.	Specify Status:	[]

090177e196ae3fd6\Final\Final On: 01-Apr-2021 05:24 (GMT)

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: 10081667

Subject Initials: ---

Generated By: pfe.levisse

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

[eCRF Audit Trail History](#)

Subject Status

1.	Subject Status	DISCONTINUED
2.	Subject Status Date	Mar/10/2021

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: 10081667

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
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Header Text: c4591001

Visit: Investigator Signature -
Unscheduled

Form: CASEBOOK SIGNATURE FORM

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Signed, Verified

Site No: 1008

Site Name: (1008) Clinical Research Professionals Inc.

Subject No: 10081667

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	Mar-11-2021 11:18:35 (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.

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: INCLUSION/EXCLUSION CRITERIA -
Comments

Form Version: 10-Oct-2020 16:00

Form Status: Data Complete, Frozen, Verified

Site No: 1008

Site Name: (1008) Clinical Research Professionals Inc.

Subject No: 10081667

Subject Initials: ---

Generated By: pfe.lewissc

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

[Back to Form](#)

Item	Date	User	Comment
Form	Oct-22-2020 11:01:10 (UTC-06:00) Central Time (US & Canada)	Tiffany Baum (pfe.tbaum)	Not Applicable

090177e196ae3fd6\Final\Final On: 01-Apr-2021 05:24 (GMT)

Header Text: c4591001

Visit: V101_VAX3

Form: INCLUSION/EXCLUSION CRITERIA - FURTHER VACCINATION - Comments

Form Version: 10-Dec-2020 02:30

Form Status: Data Complete, Frozen, Verified

Site No: 1008

Site Name: (1008) Clinical Research Professionals Inc.

Subject No: 10081667

Subject Initials: ---

Generated By: pfe.lewissc

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

[Back to Form](#)

Item	Date	User	Comment
Form	Jan-13-2021 10:38:44 (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: 10081667

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	Mar-11-2021 11:18:35 (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.

Ann Patek	N/A	Mar-11-2021 10:16:27 (UTC-06:00) Central Time (US & Canada)		Edit - All signatures invalidated
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Affidavit:

N/A

Timothy Jennings	Approved	Mar-10-2021 21:52:08 (UTC-06:00) Central Time (US & Canada)	BOOK	Signed
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090177e196ae3fd6\Final\Final On: 01-Apr-2021 05:24 (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: 10081667

Subject Initials: ---

Generated By: pfe.lewissc

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

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.

Tiffany Baum	N/A	Mar-05-2021 08:10:26 (UTC-06:00) Central Time (US & Canada)		Edit - All signatures invalidated
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Affidavit:

N/A

Timothy Jennings	Approved	Feb-22-2021 18:09:47 (UTC-06:00) Central Time (US & Canada)	BOOK	Signed
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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.

090177e196ae3fd6\Final\Final On: 01-Apr-2021 05:24 (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: 10081667

Subject Initials: ---

Generated By: pfe.lewissc

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

Tiffany Baum	N/A	Feb-03-2021 11:32:33 (UTC-06:00) Central Time (US & Canada)		Edit - All signatures invalidated
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Affidavit:

N/A

Timothy Jennings	Approved	Jan-22-2021 18:33:34 (UTC-06:00) Central Time (US & Canada)	BOOK	Signed
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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.

090177e196ae3fd6\Final\Final On: 01-Apr-2021 05:24 (GMT)

Header Text: c4591001

Visit: COHORT_SELECTION

Form: COHORT SELECTION - eCRF Audit Trail History

Form Version: 10-Oct-2020 16:01

Form Status: Data Complete, Frozen, Verified

Site No: 1008

Site Name: (1008) Clinical Research Professionals Inc.

Subject No: 10081667

Subject Initials: ---

Generated By: pfe.lewissc

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

[Back to Form](#)

1. Select appropriate response - Protocol version

Date	Location	User	Value	Reason
Oct-22-2020 10:59:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Tiffany Baum (pfe.tbaum)	Data Entry: 06 OCT 2020	Initial Entry

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

Date	Location	User	Value	Reason
Oct-22-2020 10:59:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Tiffany Baum (pfe.tbaum)	Data Entry: STAGE 3 COHORTS	Initial Entry

090177e196ae3fd6\Final\Final On: 01-Apr-2021 05:24 (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, Frozen, Verified

Site No: 1008

Site Name: (1008) Clinical Research Professionals Inc.

Subject No: 10081667

Subject Initials: ---

Generated By: pfe.lewissc

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

[Back to Form](#)

1. Consent Was:

Date	Location	User	Value	Reason
Oct-22-2020 10:59:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Tiffany Baum (pfe.tbaum)	Data Entry: OBTAINED Date Written Consen t Obtained Oct/22/2020	Initial Entry

090177e196ae3fd6\Final\Final On: 01-Apr-2021 05:24 (GMT)

Header Text: c4591001

Visit: COHORT_SELECTION

Form: DEMOGRAPHY - eCRF Audit Trail History

Form Version: 15-Sep-2020 21:54

Form Status: Data Complete, Frozen, Verified

Site No: 1008

Site Name: (1008) Clinical Research Professionals Inc.

Subject No: 10081667

Subject Initials: ---

Generated By: pfe.lewissc

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

[Back to Form](#)

1. Subject ID

Date	Location	User	Value	Reason
Oct-22-2020 10:59:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 10081667	Item copied from previous form

2. Birth Date:

Date	Location	User	Value	Reason
Oct-22-2020 10:59:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: (b) (6) 1941	Enrollment Entry

3. Sex:

Date	Location	User	Value	Reason
Oct-22-2020 10:59:58 (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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090177e196ae3fd6\Final\Final On: 01-Apr-2021 05:24 (GMT)

Header Text: c4591001

Visit: COHORT_SELECTION

Form: DEMOGRAPHY - eCRF Audit Trail History

Form Version: 15-Sep-2020 21:54

Form Status: Data Complete, Frozen, Verified

Site No: 1008

Site Name: (1008) Clinical Research Professionals Inc.

Subject No: 10081667

Subject Initials: ---

Generated By: pfe.levissc

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

Oct-22-2020 10:59:58 (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
Oct-22-2020 10:59:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Tiffany Baum (pfe.tbaum)	Data Entry: WHITE	Initial Entry

090177e196ae3fd6\Final\Final On: 01-Apr-2021 05:24 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:02

Site No: 1008

Subject No: 10081667

Generated By: pfe.levissc

Form: DATE OF VISIT - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1008) Clinical Research Professionals Inc.

Subject Initials: ---

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

[Back to Form](#)

1. Date of Visit

Date	Location	User	Value	Reason
Oct-22-2020 11:00:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Tiffany Baum (pfe.tbaum)	Data Entry: Oct/22/2020	Initial Entry

090177e196ae3fd6\Final\Final On: 01-Apr-2021 05:24 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: DISPOSITION - SCREENING - eCRF Audit Trail History

Form Version: 15-Sep-2020 21:52

Form Status: Data Complete, Frozen, Verified

Site No: 1008

Site Name: (1008) Clinical Research Professionals Inc.

Subject No: 10081667

Subject Initials: ---

Generated By: pfe.levisse

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

[Back to Form](#)

1. Date of Completion/Discontinuation/Death

Date	Location	User	Value	Reason
Oct-22-2020 11:00:16 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Tiffany Baum (pfe.tbaum)	Data Entry: Oct/22/2020	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Oct-22-2020 11:00:16 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SCREENING	Initial Entry

3. Status:

Date	Location	User	Value	Reason
Oct-22-2020 11:00:16 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Tiffany Baum (pfe.tbaum)	Data Entry: COMPLETED	Initial Entry

090177e196ae3fd6\Final\Final On: 01-Apr-2021 05:24 (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, Frozen, Verified**Site No:** 1008**Site Name:** (1008) Clinical Research Professionals Inc.**Subject No:** 10081667**Subject Initials:** ---**Generated By:** pfe.levisse**Generated Time (GMT):** 29-Mar-2021 04:12[Back to Form](#)*1.a*

Date	Location	User	Value	Reason
Oct-22-2020 11:14:54 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH N umber: Medical History Term: Start Date: UNK/UNK/1976 Ongoing: YES	Initial Entry

1.a Line/MH Number:

Date	Location	User	Value	Reason
Oct-22-2020 11:14:54 (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
Oct-22-2020 11:14:54 (UTC-06:00) Central Time (US	ACV0PFEINFP6000	Tiffany Baum (pfe.tbaum)	Data Entry: Asthma	Initial Entry

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, Frozen, Verified

Site No: 1008

Site Name: (1008) Clinical Research Professionals Inc.

Subject No: 10081667

Subject Initials: ---

Generated By: pfe.levisse

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

& Canada)

1.a Start Date:

Date	Location	User	Value	Reason
Oct-22-2020 11:14:54 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Tiffany Baum (pfe.tbaum)	Data Entry: UNK/UNK/1976	Initial Entry

1.a Ongoing:

Date	Location	User	Value	Reason
Oct-22-2020 11:14:54 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Tiffany Baum (pfe.tbaum)	Data Entry: YES	Initial Entry

1.b

Date	Location	User	Value	Reason
Jan-13-2021 15:20:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Tiffany Baum (pfe.tbaum)	Data Entry: Line/MH 2 Number: Medical History Term: Non allergic rhinitis Start Date: UNK/UNK/1945	New Information

090177e196ae3fd6\Final\Final On: 01-Apr-2021 05:24 (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, Frozen, Verified

Site No: 1008

Site Name: (1008) Clinical Research Professionals Inc.

Subject No: 10081667

Subject Initials: ---

Generated By: pfe.lewissc

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

			Ongoing: YES	
Oct-22-2020 11:15:19 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH 2 Number: Medical H Seasona istory Ter 1 allergi m: es Start Date UNK/U : NK/194 5 Ongoing: YES	Initial Entry

090177e196ae3fd6\Final\Final On: 01-Apr-2021 05:24 (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, Frozen, Verified

Site No: 1008

Site Name: (1008) Clinical Research Professionals Inc.

Subject No: 10081667

Subject Initials: ---

Generated By: pfe.lewissc

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

1.b Line/MH Number:

Date	Location	User	Value	Reason
Oct-22-2020 11:15:19 (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
Jan-13-2021 15:20:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Tiffany Baum (pfe.tbaum)	Data Entry: Non allergic rhinitis	New Information
Oct-22-2020 11:15:19 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Tiffany Baum (pfe.tbaum)	Data Entry: Seasonal allergies	Initial Entry

1.b Start Date:

Date	Location	User	Value	Reason
Oct-22-2020 11:15:19 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Tiffany Baum (pfe.tbaum)	Data Entry: UNK/UNK/1945	Initial Entry

090177e196ae3fd6\Final\Final On: 01-Apr-2021 05:24 (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, Frozen, Verified

Site No: 1008

Site Name: (1008) Clinical Research Professionals Inc.

Subject No: 10081667

Subject Initials: ---

Generated By: pfe.lewissc

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

1.b Ongoing:

Date	Location	User	Value	Reason
Oct-22-2020 11:15:19 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Tiffany Baum (pfe.tbaum)	Data Entry: YES	Initial Entry

1.c

Date	Location	User	Value	Reason
Oct-22-2020 11:15:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH 3 Number: Medical Gastroesop History hageal refl Term: x disease Start Dat UNK/UNK/ e: 2005 Ongoing YES :	Initial Entry

090177e196ae3fd6\Final\Final On: 01-Apr-2021 05:24 (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, Frozen, Verified

Site No: 1008

Site Name: (1008) Clinical Research Professionals Inc.

Subject No: 10081667

Subject Initials: ---

Generated By: pfe.lewissc

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

1.c Line/MH Number:

Date	Location	User	Value	Reason
Oct-22-2020 11:15:38 (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
Oct-22-2020 11:15:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Tiffany Baum (pfe.tbaum)	Data Entry: Gastroesophageal refl ux disease	Initial Entry

1.c Start Date:

Date	Location	User	Value	Reason
Oct-22-2020 11:15:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Tiffany Baum (pfe.tbaum)	Data Entry: UNK/UNK/2005	Initial Entry

1.c Ongoing:

Date	Location	User	Value	Reason
Oct-22-2020 11:15:38	ACV0PFEINFP6000	Tiffany Baum	Data Entry: YES	Initial Entry

090177e196ae3fd6\Final\Final On: 01-Apr-2021 05:24 (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, Frozen, Verified

Site No: 1008

Site Name: (1008) Clinical Research Professionals Inc.

Subject No: 10081667

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
Oct-22-2020 11:16:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH N umber: 4 Medical History Term: Diabetes type II Start Date: UNK/UNK/2017 Ongoing: YES	Initial Entry

090177e196ae3fd6\Final\Final On: 01-Apr-2021 05:24 (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, Frozen, Verified

Site No: 1008

Site Name: (1008) Clinical Research Professionals Inc.

Subject No: 10081667

Subject Initials: ---

Generated By: pfe.lewissc

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

1.d Line/MH Number:

Date	Location	User	Value	Reason
Oct-22-2020 11:16:10 (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
Oct-22-2020 11:16:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Tiffany Baum (pfe.tbaum)	Data Entry: Diabetes type II	Initial Entry

1.d Start Date:

Date	Location	User	Value	Reason
Oct-22-2020 11:16:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Tiffany Baum (pfe.tbaum)	Data Entry: UNK/UNK/2017	Initial Entry

1.d Ongoing:

Date	Location	User	Value	Reason
Oct-22-2020 11:16:10	ACV0PFEINFP6000	Tiffany Baum	Data Entry: YES	Initial Entry

090177e196ae3fd6\Final\Final On: 01-Apr-2021 05:24 (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, Frozen, Verified

Site No: 1008

Site Name: (1008) Clinical Research Professionals Inc.

Subject No: 10081667

Subject Initials: ---

Generated By: pfe.lewissc

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

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

(pfe.tbaum)

I.e

Date	Location	User	Value	Reason
Oct-22-2020 11:16:24 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH N umber: 5 Medical History Term: Hypertension Start Date: UNK/UNK/2005 Ongoing: YES	Initial Entry

090177e196ae3fd6\Final\Final On: 01-Apr-2021 05:24 (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, Frozen, Verified

Site No: 1008

Site Name: (1008) Clinical Research Professionals Inc.

Subject No: 10081667

Subject Initials: ---

Generated By: pfe.lewissc

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

1.e Line/MH Number:

Date	Location	User	Value	Reason
Oct-22-2020 11:16:24 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 5	Initial Entry

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

Date	Location	User	Value	Reason
Oct-22-2020 11:16:24 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Tiffany Baum (pfe.tbaum)	Data Entry: Hypertension	Initial Entry

1.e Start Date:

Date	Location	User	Value	Reason
Oct-22-2020 11:16:24 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Tiffany Baum (pfe.tbaum)	Data Entry: UNK/UNK/2005	Initial Entry

1.e Ongoing:

Date	Location	User	Value	Reason
Oct-22-2020 11:16:24	ACV0PFEINFP6000	Tiffany Baum	Data Entry: YES	Initial Entry

090177e196ae3fd6\Final\Final On: 01-Apr-2021 05:24 (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, Frozen, Verified

Site No: 1008

Site Name: (1008) Clinical Research Professionals Inc.

Subject No: 10081667

Subject Initials: ---

Generated By: pfe.lewissc

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

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

(pfe.tbaum)

If

Date	Location	User	Value	Reason
Oct-22-2020 11:16:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH N 6 umber: Medical His Penicilli tory Term: n allergy Start Date: UNK/U NK/195 7 Ongoing: YES	Initial Entry

090177e196ae3fd6\Final\Final On: 01-Apr-2021 05:24 (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, Frozen, Verified

Site No: 1008

Site Name: (1008) Clinical Research Professionals Inc.

Subject No: 10081667

Subject Initials: ---

Generated By: pfe.lewissc

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

1.f Line/MH Number:

Date	Location	User	Value	Reason
Oct-22-2020 11:16:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 6	Initial Entry

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

Date	Location	User	Value	Reason
Oct-22-2020 11:16:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Tiffany Baum (pfe.tbaum)	Data Entry: Penicillin allergy	Initial Entry

1.f Start Date:

Date	Location	User	Value	Reason
Oct-22-2020 11:16:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Tiffany Baum (pfe.tbaum)	Data Entry: UNK/UNK/1957	Initial Entry

1.f Ongoing:

Date	Location	User	Value	Reason
Oct-22-2020 11:16:51	ACV0PFEINFP6000	Tiffany Baum	Data Entry: YES	Initial Entry

090177e196ae3fd6\Final\Final On: 01-Apr-2021 05:24 (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, Frozen, Verified

Site No: 1008

Site Name: (1008) Clinical Research Professionals Inc.

Subject No: 10081667

Subject Initials: ---

Generated By: pfe.lewissc

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

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

(pfe.tbaum)

I.g

Date	Location	User	Value	Reason
Oct-22-2020 11:17:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH N umber: 7 Medical History Term: Levaquin allergy Start Date: UNK/UNK/2014 Ongoing: YES	Initial Entry

090177e196ae3fd6\Final\Final On: 01-Apr-2021 05:24 (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, Frozen, Verified

Site No: 1008

Site Name: (1008) Clinical Research Professionals Inc.

Subject No: 10081667

Subject Initials: ---

Generated By: pfe.lewissc

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

1.g Line/MH Number:

Date	Location	User	Value	Reason
Oct-22-2020 11:17:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 7	Initial Entry

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

Date	Location	User	Value	Reason
Oct-22-2020 11:17:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Tiffany Baum (pfe.tbaum)	Data Entry: Levaquin allergy	Initial Entry

1.g Start Date:

Date	Location	User	Value	Reason
Oct-22-2020 11:17:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Tiffany Baum (pfe.tbaum)	Data Entry: UNK/UNK/2014	Initial Entry

1.g Ongoing:

Date	Location	User	Value	Reason
Oct-22-2020 11:17:05	ACV0PFEINFP6000	Tiffany Baum	Data Entry: YES	Initial Entry

090177e196ae3fd6\Final\Final On: 01-Apr-2021 05:24 (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, Frozen, Verified

Site No: 1008

Site Name: (1008) Clinical Research Professionals Inc.

Subject No: 10081667

Subject Initials: ---

Generated By: pfe.levisse

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: 15-Sep-2020 21:57

Site No: 1008

Subject No: 10081667

Generated By: pfe.lewissc

Form: HIV STATUS - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1008) Clinical Research Professionals Inc.

Subject Initials: ---

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

[Back to Form](#)

1. Select appropriate response - What is the subject HIV status?

Date	Location	User	Value	Reason
Oct-22-2020 11:01:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Tiffany Baum (pfe.tbaum)	Data Entry: The subject is NOT kn own to be HIV POSIT IVE	Initial Entry

090177e196ae3fd6\Final\Final On: 01-Apr-2021 05:24 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 10-Oct-2020 16:04

Site No: 1008

Subject No: 10081667

Generated By: pfe.lewissc

Form: VITAL SIGNS - BASELINE - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1008) Clinical Research Professionals Inc.

Subject Initials: ---

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

[Back to Form](#)

1. Date:

Date	Location	User	Value	Reason
Oct-22-2020 11:14:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Tiffany Baum (pfe.tbaum)	Data Entry: Oct/22/2020	Initial Entry

2. Weight:

Date	Location	User	Value	Reason
Oct-22-2020 11:14:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Tiffany Baum (pfe.tbaum)	Data Entry: 177.6	Initial Entry

3. Unit:

Date	Location	User	Value	Reason
Oct-22-2020 11:14:35 (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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090177e196ae3fd6\Final\Final On: 01-Apr-2021 05:24 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: VITAL SIGNS - BASELINE - eCRF Audit Trail History

Form Version: 10-Oct-2020 16:04

Form Status: Data Complete, Frozen, Verified

Site No: 1008

Site Name: (1008) Clinical Research Professionals Inc.

Subject No: 10081667

Subject Initials: ---

Generated By: pfe.levisse

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

Oct-22-2020 11:14:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Tiffany Baum (pfe.tbaum)	Data Entry: 69.0	Initial Entry
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5. Unit:

Date	Location	User	Value	Reason
Oct-22-2020 11:14:35 (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
Oct-22-2020 11:14:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 26.2	Initial Entry

7.a

Date	Location	User	Value	Reason
Oct-22-2020 11:14:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Tiffany Baum (pfe.tbaum)	Data Entry: Record Identifier: Temperature: 97.3	Initial Entry

090177e196ae3fd6\Final\Final On: 01-Apr-2021 05:24 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: VITAL SIGNS - BASELINE - eCRF Audit Trail History

Form Version: 10-Oct-2020 16:04

Form Status: Data Complete, Frozen, Verified

Site No: 1008

Site Name: (1008) Clinical Research Professionals Inc.

Subject No: 10081667

Subject Initials: ---

Generated By: pfe.levisse

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

			Temperature Unit:	
			Temperature Location: HEAD	

7.a Record Identifier:

Date	Location	User	Value	Reason
Oct-22-2020 11:14:35 (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
Oct-22-2020 11:14:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Tiffany Baum (pfe.tbaum)	Data Entry: 97.3	Initial Entry

7.a Unit:

Date	Location	User	Value	Reason
Oct-22-2020 11:14:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Tiffany Baum (pfe.tbaum)	Data Entry: F	Initial Entry

090177e196ae3fd6\Final\Final On: 01-Apr-2021 05:24 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: VITAL SIGNS - BASELINE - eCRF Audit Trail History

Form Version: 10-Oct-2020 16:04

Form Status: Data Complete, Frozen, Verified

Site No: 1008

Site Name: (1008) Clinical Research Professionals Inc.

Subject No: 10081667

Subject Initials: ---

Generated By: pfe.lewissc

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

7.a Temperature Location:

Date	Location	User	Value	Reason
Oct-22-2020 11:14:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Tiffany Baum (pfe.tbaum)	Data Entry: FOREHEAD	Initial Entry

090177e196ae3fd6\Final\Final On: 01-Apr-2021 05:24 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1008

Subject No: 10081667

Generated By: pfe.levissc

Form: RANDOMIZATION - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1008) Clinical Research Professionals Inc.

Subject Initials: ---

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

[Back to Form](#)

1. Randomization Date :

Date	Location	User	Value	Reason
Oct-22-2020 12:15:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Tiffany Baum (pfe.tbaum)	Data Entry: Oct/22/2020	Initial Entry

2. Randomization Number:

Date	Location	User	Value	Reason
Oct-22-2020 12:15:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Tiffany Baum (pfe.tbaum)	Data Entry: 272026	Initial Entry

090177e196ae3fd6\Final\Final On: 01-Apr-2021 05:24 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1008

Subject No: 10081667

Generated By: pfe.levisse

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

Form Status: Data Complete, Frozen, Verified

Site Name: (1008) Clinical Research Professionals Inc.

Subject Initials: ---

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

[Back to Form](#)

1. Data Origin

Date	Location	User	Value	Reason
Oct-22-2020 11:16:17 (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-22-2020 11:16:17 (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-22-2020 11:16:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Oct-22-2020 11:16:17 (UTC-06:00)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however

090177e196ae3fd6\Final\Final On: 01-Apr-2021 05:24 (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, Frozen, Verified

Site No: 1008

Site Name: (1008) Clinical Research Professionals Inc.

Subject No: 10081667

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.
Oct-22-2020 11:16:17 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Cheyenne Brooks (pfe.cbrooms)	Data Entry: YES Date of Collection: Oct/22/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Oct-22-2020 11:16:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Cheyenne Brooks (pfe.cbrooms)	Data Entry: Sample ID BPZBH : 6	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Oct-22-2020 11:16:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Cheyenne Brooks (pfe.cbrooms)	Data Entry: BPZBH6	Initial Entry

5.b

Date	Location	User	Value	Reason
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090177e196ae3fd6\Final\Final On: 01-Apr-2021 05:24 (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, Frozen, Verified

Site No: 1008

Site Name: (1008) Clinical Research Professionals Inc.

Subject No: 10081667

Subject Initials: ---

Generated By: pfe.levisse

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

Oct-22-2020 11:16:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Cheyenne Brooks (pfe.cbrooks)	Data Entry: Sample I BRZDB D: C	Initial Entry
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5.b Sample ID

Date	Location	User	Value	Reason
Oct-22-2020 11:16:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Cheyenne Brooks (pfe.cbrooks)	Data Entry: BRZDBC	Initial Entry

5.c

Date	Location	User	Value	Reason
Oct-22-2020 11:16:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Cheyenne Brooks (pfe.cbrooks)	Data Entry: Sample I BRZDB D: D	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Oct-22-2020 11:16:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Cheyenne Brooks (pfe.cbrooks)	Data Entry: BRZDBD	Initial Entry

090177e196ae3fd6\Final\Final On: 01-Apr-2021 05:24 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1008

Subject No: 10081667

Generated By: pfe.lewissc

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

Form Status: Data Complete, Frozen, Verified

Site Name: (1008) Clinical Research Professionals Inc.

Subject Initials: ---

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

[Back to Form](#)

1. Data Origin

Date	Location	User	Value	Reason
Oct-22-2020 11:16:47 (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-22-2020 11:16:47 (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
Oct-22-2020 11:16:54 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Oct-22-2020 11:16:47 (UTC-06:00)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however

090177e196ae3fd6\Final\Final On: 01-Apr-2021 05:24 (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, Frozen, Verified

Site No: 1008

Site Name: (1008) Clinical Research Professionals Inc.

Subject No: 10081667

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.
Oct-22-2020 11:16:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Cheyenne Brooks (pfe.cbrooms)	Data Entry: YES Date of Collection: Oct/22/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Oct-22-2020 11:16:54 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Cheyenne Brooks (pfe.cbrooms)	Data Entry: Sample ID BPZBG : 6	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Oct-22-2020 11:16:54 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Cheyenne Brooks (pfe.cbrooms)	Data Entry: BPZBG6	Initial Entry

090177e196ae3fd6\Final\Final On: 01-Apr-2021 05:24 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:04

Site No: 1008

Subject No: 10081667

Generated By: pfe.lewissc

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1008) Clinical Research Professionals Inc.

Subject Initials: ---

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

[Back to Form](#)

1. Was there a temporary delay of vaccination?

Date	Location	User	Value	Reason
Oct-22-2020 12:16:07 (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
Oct-22-2020 12:16:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: BLINDED THERAPY	Initial Entry

3. Formulation:

Date	Location	User	Value	Reason
Oct-22-2020 12:16:07 (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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090177e196ae3fd6\Final\Final On: 01-Apr-2021 05:24 (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, Frozen, Verified

Site No: 1008

Site Name: (1008) Clinical Research Professionals Inc.

Subject No: 10081667

Subject Initials: ---

Generated By: pfe.lewissc

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

Oct-22-2020 12:16:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Tiffany Baum (pfe.tbaum)	Data Entry: Oct/22/2020 11:33	Initial Entry
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5. Anatomical Location:

Date	Location	User	Value	Reason
Oct-22-2020 12:16:07 (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
Oct-22-2020 12:16:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Tiffany Baum (pfe.tbaum)	Data Entry: LEFT	Initial Entry

7. Route:

Date	Location	User	Value	Reason
Oct-22-2020 12:16:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INTRAMUSCULAR	Initial Entry

090177e196ae3fd6\Final\Final On: 01-Apr-2021 05:24 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:04

Site No: 1008

Subject No: 10081667

Generated By: pfe.lewissc

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, 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
Oct-22-2020 12:16:07 (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
Oct-22-2020 12:16:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Tiffany Baum (pfe.tbaum)	Data Entry: YES	Initial Entry

090177e196ae3fd6\Final\Final On: 01-Apr-2021 05:24 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 06-Jul-2020 21:53

Site No: 1008

Subject No: 10081667

Generated By: pfe.lewissc

Form: REACTOGENICITY DIARY - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1008) Clinical Research Professionals Inc.

Subject Initials: ---

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

[Back to Form](#)

1. Select appropriate response - Reactogenicity diary collection

Date	Location	User	Value	Reason
Oct-22-2020 11:00:51 (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

090177e196ae3fd6\Final\Final On: 01-Apr-2021 05:24 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 1008

Subject No: 10081667

Generated By: pfe.levissc

Form: DATE OF VISIT - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1008) Clinical Research Professionals Inc.

Subject Initials: ---

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

[Back to Form](#)

1. Date of Visit

Date	Location	User	Value	Reason
Nov-12-2020 10:09:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Cheyenne Brooks (pfe.cbrooms)	Data Entry: Nov/12/2020	Initial Entry

090177e196ae3fd6\Final\Final On: 01-Apr-2021 05:24 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 10-Oct-2020 16:01

Site No: 1008

Subject No: 10081667

Generated By: pfe.levissc

Form: VITAL SIGNS - TEMP - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1008) Clinical Research Professionals Inc.

Subject Initials: ---

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

[Back to Form](#)

1. Date:

Date	Location	User	Value	Reason
Nov-12-2020 10:09:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Cheyenne Brooks (pfe.cbrooms)	Data Entry: Nov/12/2020	Initial Entry

2.a

Date	Location	User	Value	Reason
Nov-12-2020 10:09:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Cheyenne Brooks (pfe.cbrooms)	Data Entry: Record Identifier:: Temperature: Temperature Unit: Temperature Location::	Initial Entry

2.a Record Identifier:

Date	Location	User	Value	Reason
Nov-12-2020 10:09:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Cheyenne Brooks (pfe.cbrooms)	Data Entry: 1	Initial Entry

090177e196ae3fd6\Final\Final On: 01-Apr-2021 05:24 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form: VITAL SIGNS - TEMP - eCRF Audit Trail History

Form Version: 10-Oct-2020 16:01

Form Status: Data Complete, Frozen, Verified

Site No: 1008

Site Name: (1008) Clinical Research Professionals Inc.

Subject No: 10081667

Subject Initials: ---

Generated By: pfe.lewissc

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

2.a Temperature:

Date	Location	User	Value	Reason
Nov-12-2020 10:09:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Cheyenne Brooks (pfe.cbrooms)	Data Entry: 98.0	Initial Entry

2.a Unit:

Date	Location	User	Value	Reason
Nov-12-2020 10:09:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Cheyenne Brooks (pfe.cbrooms)	Data Entry: F	Initial Entry

2.a Temperature Location:

Date	Location	User	Value	Reason
Nov-12-2020 10:09:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Cheyenne Brooks (pfe.cbrooms)	Data Entry: FOREHEAD	Initial Entry

090177e196ae3fd6\Final\Final On: 01-Apr-2021 05:24 (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, Frozen, Verified

Site No: 1008

Site Name: (1008) Clinical Research Professionals Inc.

Subject No: 10081667

Subject Initials: ---

Generated By: pfe.levisse

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

[Back to Form](#)

1. Data Origin

Date	Location	User	Value	Reason
Nov-12-2020 10:37:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Nov-12-2020 10:37:38 (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
Nov-12-2020 10:37:46 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Nov-12-2020 10:37:38 (UTC-06:00)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however

090177e196ae3fd6\Final\Final On: 01-Apr-2021 05:24 (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, Frozen, Verified

Site No: 1008

Site Name: (1008) Clinical Research Professionals Inc.

Subject No: 10081667

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.
Nov-12-2020 10:37:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Sherri Pangburn (pfe.spangburn)	Data Entry: YES Date of Collection: Nov/12/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Nov-12-2020 10:37:46 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Sherri Pangburn (pfe.spangburn)	Data Entry: Sample I BRGV3 D: S	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Nov-12-2020 10:37:46 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Sherri Pangburn (pfe.spangburn)	Data Entry: BRGV3S	Initial Entry

090177e196ae3fd6\Final\Final On: 01-Apr-2021 05:24 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1008

Subject No: 10081667

Generated By: pfe.lewissc

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1008) Clinical Research Professionals Inc.

Subject Initials: ---

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

[Back to Form](#)

1. Was there a temporary delay of vaccination?

Date	Location	User	Value	Reason
Nov-12-2020 10:10:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Cheyenne Brooks (pfe.cbrooms)	Data Entry: NO	Initial Entry

2. Treatment Name

Date	Location	User	Value	Reason
Nov-12-2020 10:10:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: BLINDED THERAPY	Initial Entry

3. Formulation:

Date	Location	User	Value	Reason
Nov-12-2020 10:10:20 (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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090177e196ae3fd6\Final\Final On: 01-Apr-2021 05:24 (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, Frozen, Verified

Site No: 1008

Site Name: (1008) Clinical Research Professionals Inc.

Subject No: 10081667

Subject Initials: ---

Generated By: pfe.levisse

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

Nov-12-2020 10:10:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Cheyenne Brooks (pfe.cbrooms)	Data Entry: Nov/12/2020 09:29	Initial Entry
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5. Anatomical Location:

Date	Location	User	Value	Reason
Nov-12-2020 10:10:20 (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
Nov-12-2020 10:10:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Cheyenne Brooks (pfe.cbrooms)	Data Entry: LEFT	Initial Entry

7. Route:

Date	Location	User	Value	Reason
Nov-12-2020 10:10:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INTRAMUSCULAR	Initial Entry

090177e196ae3fd6\Final\Final On: 01-Apr-2021 05:24 (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, Frozen, Verified

Site No: 1008

Site Name: (1008) Clinical Research Professionals Inc.

Subject No: 10081667

Subject Initials: ---

Generated By: pfe.levissc

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

10. Timeframe Subject Was Observed

Date	Location	User	Value	Reason
Nov-12-2020 10:10:20 (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
Nov-12-2020 10:10:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Cheyenne Brooks (pfe.cbrooms)	Data Entry: YES	Initial Entry

090177e196ae3fd6\Final\Final On: 01-Apr-2021 05:24 (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, Frozen, Verified

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

Subject No: 10081667 **Subject Initials:** ---

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

[Back to Form](#)

1. Date of Visit

Date	Location	User	Value	Reason
Dec-10-2020 10:27:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Tiffany Baum (pfe.tbaum)	Data Entry: Dec/10/2020	Initial Entry

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, Frozen, Verified

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

Subject No: 10081667 **Subject Initials:** ---

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

[Back to Form](#)

1. Data Origin

Date	Location	User	Value	Reason
Dec-10-2020 11:40:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Dec-10-2020 11:40:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SERUM	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Dec-10-2020 11:40:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Dec-10-2020 11:40:01 (UTC-06:00)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidat e	'Sample Collected?' is Yes, however

090177e196ae3fd6\Final\Final On: 01-Apr-2021 05:24 (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, Frozen, Verified

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

Subject No: 10081667 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.
Dec-10-2020 11:40:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Sherri Pangburn (pfe.spangburn)	Data Entry: YES Date of Collection: Dec/10/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Dec-10-2020 11:40:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Sherri Pangburn (pfe.spangburn)	Data Entry: Sample I BRL1R D: Y	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Dec-10-2020 11:40:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Sherri Pangburn (pfe.spangburn)	Data Entry: BRL1RY	Initial Entry

5.b

090177e196ae3fd6\Final\Final On: 01-Apr-2021 05:24 (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, Frozen, Verified

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

Subject No: 10081667 **Subject Initials:** ---

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

Date	Location	User	Value	Reason
Dec-10-2020 11:40:24 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Sherri Pangburn (pfe.spangburn)	Data Entry: Sample I BS96N D: F	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Dec-10-2020 11:40:24 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Sherri Pangburn (pfe.spangburn)	Data Entry: BS96NF	Initial Entry

5.c

Date	Location	User	Value	Reason
Dec-10-2020 11:40:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Sherri Pangburn (pfe.spangburn)	Data Entry: Sample I BS96N D: G	Initial Entry

090177e196ae3fd6\Final\Final On: 01-Apr-2021 05:24 (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, Frozen, Verified

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

Subject No: 10081667 **Subject Initials:** ---

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

5.c Sample ID

Date	Location	User	Value	Reason
Dec-10-2020 11:40:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Sherri Pangburn (pfe.spangburn)	Data Entry: BS96NG	Initial Entry

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - Audit Trail

Form Version: 22-Apr-2020 21:02

Form Status:

Site No: 1008

Site Name: (1008) Clinical Research Professionals Inc.

Subject No: 10081667

Subject Initials: ---

Generated By: pfe.levisse

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

[Back to Form](#)

Date	Location	User	Value	Reason
Mar-05-2021 08:12:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Tiffany Baum (pfe.tbaum)	Form Created	

090177e196ae3fd6\Final\Final On: 01-Apr-2021 05:24 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - Audit Trail

Form Version: 22-Apr-2020 21:02

Form Status:

Site No: 1008

Site Name: (1008) Clinical Research Professionals Inc.

Subject No: 10081667

Subject Initials: ---

Generated By: pfe.levisse

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

[Back to Form](#)

Date	Location	User	Value	Reason
Mar-05-2021 08:18:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Tiffany Baum (pfe.tbaum)	Form Created	

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen

Site No: 1008

Site Name: (1008) Clinical Research Professionals Inc.

Subject No: 10081667

Subject Initials: ---

Generated By: pfe.levissc

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

[Back to Form](#)

1. Category:

Date	Location	User	Value	Reason
Mar-05-2021 08:12:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: ADVERSE EVENT	Initial Entry

2. AE ID:

Date	Location	User	Value	Reason
Mar-05-2021 08:12:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 1	Initial Entry

3. Adverse Event:

(If possible specify diagnosis, not individual symptoms)

Date	Location	User	Value	Reason
Mar-05-2021 08:12:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Tiffany Baum (pfe.tbaum)	Data Entry: injection site are soren ess	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason
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090177e196ae3fd6\Final\Final On: 01-Apr-2021 05:24 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen

Site No: 1008

Site Name: (1008) Clinical Research Professionals Inc.

Subject No: 10081667

Subject Initials: ---

Generated By: pfe.lewissc

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

Mar-05-2021 08:12:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Tiffany Baum (pfe.tbaum)	Data Entry: Nov/12/2020 19:30	Initial Entry
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5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Mar-05-2021 08:12:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Tiffany Baum (pfe.tbaum)	Data Entry: NO End Date Time: Nov/13/2020 UNK :UNK	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
Mar-05-2021 08:12:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Tiffany Baum (pfe.tbaum)	Data Entry: 1	Initial Entry

7. Is the adverse event serious?

If Yes, NOTIFY PFIZER IMMEDIATELY.

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

090177e196ae3fd6\Final\Final On: 01-Apr-2021 05:24 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen

Site No: 1008

Site Name: (1008) Clinical Research Professionals Inc.

Subject No: 10081667

Subject Initials: ---

Generated By: pfe.lewissc

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

Date	Location	User	Value	Reason
Mar-05-2021 08:12:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Tiffany Baum (pfe.tbaum)	Data Entry: NO	Initial Entry

8. Is this adverse event the result of a study Medication Error?
If Yes, record the type of medication error on the Medication Error Log.

Date	Location	User	Value	Reason
Mar-05-2021 08:12:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Tiffany Baum (pfe.tbaum)	Data Entry: NO	Initial Entry

9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Mar-05-2021 08:12:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Tiffany Baum (pfe.tbaum)	Data Entry: RELATED	Initial Entry

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Mar-05-2021 08:12:14 (UTC-06:00)	ACV0PFEINFP6000	Tiffany Baum (pfe.tbaum)	Data Entry: NOT APPLICABLE	Initial Entry

090177e196ae3fd6\Final\Final On: 01-Apr-2021 05:24 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen

Site No: 1008

Site Name: (1008) Clinical Research Professionals Inc.

Subject No: 10081667

Subject Initials: ---

Generated By: pfe.lewissc

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

Central Time (US & Canada)				
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11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
Mar-05-2021 08:12:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Tiffany Baum (pfe.tbaum)	Data Entry: NO	Initial Entry

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Mar-05-2021 08:12:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Tiffany Baum (pfe.tbaum)	Data Entry: NO	Initial Entry

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

Date	Location	User	Value	Reason
Mar-05-2021 08:12:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Tiffany Baum (pfe.tbaum)	Data Entry: RECOVERED/RESOLVED	Initial Entry

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

090177e196ae3fd6\Final\Final On: 01-Apr-2021 05:24 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen

Site No: 1008

Site Name: (1008) Clinical Research Professionals Inc.

Subject No: 10081667

Subject Initials: ---

Generated By: pfe.lewissc

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

Date	Location	User	Value	Reason
Mar-05-2021 08:12:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Tiffany Baum (pfe.tbaum)	Data Entry: NO	Initial Entry

090177e196ae3fd6\Final\Final On: 01-Apr-2021 05:24 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete

Site No: 1008

Site Name: (1008) Clinical Research Professionals Inc.

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Subject Initials: ---

Generated By: pfe.lewissc

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

[Back to Form](#)

1. Category:

Date	Location	User	Value	Reason
Mar-05-2021 08:18:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: ADVERSE EVENT	Initial Entry

2. AE ID:

Date	Location	User	Value	Reason
Mar-05-2021 08:18:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 2	Initial Entry

3. Adverse Event:

(If possible specify diagnosis, not individual symptoms)

Date	Location	User	Value	Reason
Mar-05-2021 08:18:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Tiffany Baum (pfe.tbaum)	Data Entry: liver cancer	Initial Entry

4. Start Date Time:

090177e196ae3fd6\Final\Final On: 01-Apr-2021 05:24 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete

Site No: 1008

Site Name: (1008) Clinical Research Professionals Inc.

Subject No: 10081667

Subject Initials: ---

Generated By: pfe.lewissc

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

Date	Location	User	Value	Reason
Mar-11-2021 10:22:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Ann Patek (pfe.apatek)	Data Entry: Feb/25/2021 UNK:U NK	New Information
Mar-05-2021 08:18:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Tiffany Baum (pfe.tbaum)	Data Entry: Feb/UNK/2021 UNK :UNK	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Mar-11-2021 12:04:02 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Elizabeth Chatburn (pfe.chatbe)	Query 1: Closed	subject refuses to allow any further follow up
Mar-11-2021 10:22:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Ann Patek (pfe.apatek)	Query 1: Answered	3/10/21 subject withdrew consent, refuses any further FU in study, refuses any further contact, refuses to allow for medical records request by site/sponsor,

090177e196ae3fd6\Final\Final On: 01-Apr-2021 05:24 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete

Site No: 1008

Site Name: (1008) Clinical Research Professionals Inc.

Subject No: 10081667

Subject Initials: ---

Generated By: pfe.lewissc

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

				event is ongoing
Mar-11-2021 10:19:46 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	'Disposition Follow-up form is completed and this Adverse Event is still ongoing. Please review and update as appropriate.
Mar-05-2021 08:18:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Tiffany Baum (pfe.tbaum)	Data Entry: YES	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
Mar-05-2021 08:18:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Tiffany Baum (pfe.tbaum)	Data Entry: 3	Initial Entry

7. Is the adverse event serious?

If Yes, NOTIFY PFIZER IMMEDIATELY.

Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization;

090177e196ae3fd6\Final\Final On: 01-Apr-2021 05:24 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete

Site No: 1008

Site Name: (1008) Clinical Research Professionals Inc.

Subject No: 10081667

Subject Initials: ---

Generated By: pfe.lewissc

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

Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).

Date	Location	User	Value	Reason
Mar-07-2021 23:35:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Mar-05-2021 14:57:02 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Erik Sundgaard (pfe.sundgaardea)	Query 2: Closed	Response satisfies query
Mar-05-2021 09:07:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Tiffany Baum (pfe.tbaum)	Query 2: Answered	Other medically important serious event YES
Mar-05-2021 08:18:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Opened	Is this adverse event serious?' is reported 'Yes', but at least one seriousness criteria is missing. Please review and update as appropriate.

090177e196ae3fd6\Final\Final On: 01-Apr-2021 05:24 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete

Site No: 1008

Site Name: (1008) Clinical Research Professionals Inc.

Subject No: 10081667

Subject Initials: ---

Generated By: pfe.lewissc

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

Mar-05-2021 08:18:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	For AE liver cancer: Response to "Is the adverse event serious?" is 'Yes' but "Serious Adverse Event Number" is blank.
Mar-05-2021 08:18:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Tiffany Baum (pfe.tbaum)	Data Entry: YES Is this serious event associated with congenital anomaly or birth defect? NO Did this serious event result in death? NO Did this serious event result in persistent or significant disability/incapacity?	Initial Entry

090177e196ae3fd6\Final\Final On: 01-Apr-2021 05:24 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete

Site No: 1008

Site Name: (1008) Clinical Research Professionals Inc.

Subject No: 10081667

Subject Initials: ---

Generated By: pfe.lewissc

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

			NO	
			Is this serious event life threatening?	
			NO	
			Other medically important serious event	
			YES	

**8. Is this adverse event the result of a study Medication Error?
If Yes, record the type of medication error on the Medication Error Log.**

Date	Location	User	Value	Reason
Mar-05-2021 08:18:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Tiffany Baum (pfe.tbaum)	Data Entry: NO	Initial Entry

9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Mar-05-2021 08:18:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Tiffany Baum (pfe.tbaum)	Data Entry: NOT RELATED If Not Related to study treatment(s), this event is due to:	Initial Entry

090177e196ae3fd6\Final\Final On: 01-Apr-2021 05:24 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete

Site No: 1008

Site Name: (1008) Clinical Research Professionals Inc.

Subject No: 10081667

Subject Initials: ---

Generated By: pfe.lewissc

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

			OTHER	
			<i>If Other, specify:</i>	
			unknown	

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Mar-05-2021 08:18:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Tiffany Baum (pfe.tbaum)	Data Entry: NOT APPLICABLE	Initial Entry

11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
Mar-09-2021 04:09:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Daria Madar Jacobson (pfe.madard)	Query 1: Closed	Response satisfies query
Mar-08-2021 14:29:04 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Ann Patek (pfe.apatek)	Query 1: Answer ed	initial SAE report narrative states site will update once records/additional info available, not best practice to leave queries open, medical records requests/processing

090177e196ae3fd6\Final\Final On: 01-Apr-2021 05:24 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete

Site No: 1008

Site Name: (1008) Clinical Research Professionals Inc.

Subject No: 10081667

Subject Initials: ---

Generated By: pfe.lewissc

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

				can take up to 90 days, no expected delays, site will update when able
Mar-08-2021 13:40:02 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Daria Madar Jacobson (pfe.madard)	Query 1: Reissued: Opened	GPDCLIN: Per response to query- waiting on records to update therapy. Please clarify when do you expect to have the data available. Please consider keeping the query open and respond only once updates can be made. if a delay is expected, please clarify.
Mar-08-2021 07:54:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Tiffany Baum (pfe.tbaum)	Query 1: Answered	waiting on records to update
Mar-07-2021 15:22:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Daria Madar Jacobson (pfe.madard)	Query 1: Opened	GPDCLIN: Liver Cancer- please clarify if subject was treated (surgery, chemotherapy etc.) and if yes, please update this page

090177e196ae3fd6\Final\Final On: 01-Apr-2021 05:24 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete

Site No: 1008

Site Name: (1008) Clinical Research Professionals Inc.

Subject No: 10081667

Subject Initials: ---

Generated By: pfe.levissc

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

				accordingly. If a per protocol prohibited systemic therapy was given, please also update PROHIB CM page. Else, please clarify.
Mar-05-2021 08:18:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Tiffany Baum (pfe.tbaum)	Data Entry: NO	Initial Entry

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Mar-05-2021 08:18:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Tiffany Baum (pfe.tbaum)	Data Entry: NO	Initial Entry

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

Date	Location	User	Value	Reason
Mar-05-2021 08:18:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Tiffany Baum (pfe.tbaum)	Data Entry: NOT RECOVERED/ NOT RESOLVED	Initial Entry

090177e196ae3fd6\Final\Final On: 01-Apr-2021 05:24 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete

Site No: 1008

Site Name: (1008) Clinical Research Professionals Inc.

Subject No: 10081667

Subject Initials: ---

Generated By: pfe.lewissc

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

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

Date	Location	User	Value	Reason
Mar-12-2021 15:07:32 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Ute Frantz (pfe.frantu)	Query 1: Closed	Response satisfies query
Mar-12-2021 10:49:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Tiffany Baum (pfe.tbaum)	Query 1: Answered	subject chose to withdrawl due to dx, status is not fatal so that is why FUP status is not AE
Mar-12-2021 10:20:04 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Roshni Nair (pfe.nairr29)	Query 1: Opened	DM: "Did the event cause the Subject to be Discontinued from the Study" on AE form is YES and AE outcome is not FATAL and FUP status is not ADVERSE EVENT. Please verify and confirm. Thank you.

090177e196ae3fd6\Final\Final On: 01-Apr-2021 05:24 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete

Site No: 1008

Site Name: (1008) Clinical Research Professionals Inc.

Subject No: 10081667

Subject Initials: ---

Generated By: pfe.lewissc

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

Mar-11-2021 10:16:27 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Ann Patek (pfe.apatek)	Data Entry: YES	3/10/21 subject withdrew consent, refuses any further FU in study, refuses any further contact, refuses to allow for medical records request by site/sponsor.
Mar-05-2021 08:18:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Tiffany Baum (pfe.tbaum)	Data Entry: NO	Initial Entry

15. Serious Adverse Event Number: For Pfizer Use Only

Date	Location	User	Value	Reason
Mar-07-2021 23:35:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Ricell Ann Piojo (pfe.quitor)	Data Entry: 2021240864	Initial Entry

090177e196ae3fd6\Final\Final On: 01-Apr-2021 05:24 (GMT)

Header Text: c4591001

Visit: End of Treatment - Unscheduled **Form:** DISPOSITION - TREATMENT - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:29 **Form Status:** Data Complete, Frozen, Verified

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

Subject No: 10081667 **Subject Initials:** ---

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

[Back to Form](#)

1. Date of Completion/Discontinuation/Death :

Date	Location	User	Value	Reason
Dec-10-2020 10:29:32 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Tiffany Baum (pfe.tbaum)	Data Entry: Dec/10/2020	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Dec-10-2020 10:29:32 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: VACCINATION	Initial Entry

3. Status:

Date	Location	User	Value	Reason
Dec-10-2020 10:29:32 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Tiffany Baum (pfe.tbaum)	Data Entry: COMPLETED	Initial Entry

090177e196ae3fd6\Final\Final On: 01-Apr-2021 05:24 (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: 10081667 **Subject Initials:** ---

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

[Back to Form](#)

1. Date of Visit

Date	Location	User	Value	Reason
Jan-07-2021 13:31:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Tiffany Baum (pfe.tbaum)	Data Entry: Jan/5/2021	Initial Entry

090177e196ae3fd6\Final\Final On: 01-Apr-2021 05:24 (GMT)

Header Text: c4591001

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

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

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

Subject No: 10081667 **Subject Initials:** ---

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

[Back to Form](#)

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

Date	Location	User	Value	Reason
Jan-07-2021 13:32:02 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Tiffany Baum (pfe.tbaum)	Data Entry: Participant is willing to return for Vaccination 3 Participant is: eligible per local/n ational recommend ations and confirm ed to have received only placebo at Vac cination 1/2	Initial Entry

090177e196ae3fd6\Final\Final On: 01-Apr-2021 05:24 (GMT)

Header Text: c4591001

Visit: Follow-Up - Unscheduled

Form: DISPOSITION - FOLLOW-UP - eCRF Audit Trail History

Form Version: 15-Sep-2020 21:53

Form Status: Data Complete, Verified

Site No: 1008

Site Name: (1008) Clinical Research Professionals Inc.

Subject No: 10081667

Subject Initials: ---

Generated By: pfe.lewissc

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

[Back to Form](#)

1. Date of Completion/Discontinuation/Death :

Date	Location	User	Value	Reason
Mar-11-2021 10:19:46 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Ann Patek (pfe.apatek)	Data Entry: Mar/10/2021	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Mar-11-2021 10:19:46 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: FOLLOW-UP	Initial Entry

3. Status:

Date	Location	User	Value	Reason
Mar-11-2021 10:19:46 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Ann Patek (pfe.apatek)	Data Entry: WITHDRAWAL BY SUBJECT	Initial Entry

4. Specify Status:

Date	Location	User	Value	Reason
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Header Text: c4591001

Visit: Follow-Up - Unscheduled

Form: DISPOSITION - FOLLOW-UP - eCRF Audit Trail History

Form Version: 15-Sep-2020 21:53

Form Status: Data Complete, Verified

Site No: 1008

Site Name: (1008) Clinical Research Professionals Inc.

Subject No: 10081667

Subject Initials: ---

Generated By: pfe.lewissc

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

Mar-11-2021 10:19:46 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Ann Patek (pfe.apatek)	Data Entry: 3/10/21 withdrew consent, refuses study FU /further contact/medical records request	Initial Entry
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090177e196ae3fd6\Final\Final On: 01-Apr-2021 05:24 (GMT)

Header Text: c4591001

Visit: V101_VAX3

Form Version: 22-Apr-2020 21:02

Site No: 1008

Subject No: 10081667

Generated By: pfe.levissc

Form: DATE OF VISIT - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1008) Clinical Research Professionals Inc.

Subject Initials: ---

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

[Back to Form](#)

1. Date of Visit

Date	Location	User	Value	Reason
Jan-13-2021 10:38:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Tiffany Baum (pfe.tbaum)	Data Entry: Jan/13/2021	Initial Entry

090177e196ae3fd6\Final\Final On: 01-Apr-2021 05:24 (GMT)

Header Text: c4591001

Visit: V101_VAX3

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

Form Version: 10-Dec-2020 02:31

Form Status: Data Complete, Frozen, Verified

Site No: 1008

Site Name: (1008) Clinical Research Professionals Inc.

Subject No: 10081667

Subject Initials: ---

Generated By: pfe.lewissc

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

[Back to Form](#)

1. Consent Was:

Date	Location	User	Value	Reason
Jan-13-2021 10:38:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Tiffany Baum (pfe.tbaum)	Data Entry: OBTAINED Date Written Consent Obtained Jan/13/2021	Initial Entry

090177e196ae3fd6\Final\Final On: 01-Apr-2021 05:24 (GMT)

Header Text: c4591001

Visit: V101_VAX3

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

Form Version: 10-Dec-2020 02:31

Form Status: Data Complete, Frozen, Verified

Site No: 1008

Site Name: (1008) Clinical Research Professionals Inc.

Subject No: 10081667

Subject Initials: ---

Generated By: pfe.lewissc

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

[Back to Form](#)

1. Date of Completion/Discontinuation/Death :

Date	Location	User	Value	Reason
Jan-13-2021 10:38:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Tiffany Baum (pfe.tbaum)	Data Entry: Jan/13/2021	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Jan-13-2021 10:38:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: REPEAT SCREENING 1	Initial Entry

3. Status:

Date	Location	User	Value	Reason
Jan-13-2021 10:38:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Tiffany Baum (pfe.tbaum)	Data Entry: COMPLETED	Initial Entry

090177e196ae3fd6\Final\Final On: 01-Apr-2021 05:24 (GMT)

Header Text: c4591001

Visit: V101_VAX3

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1008

Site Name: (1008) Clinical Research Professionals Inc.

Subject No: 10081667

Subject Initials: ---

Generated By: pfe.levisse

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

[Back to Form](#)

1. Data Origin

Date	Location	User	Value	Reason
Jan-13-2021 14:45:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Jan-13-2021 14:45:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SERUM	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Jan-13-2021 14:45:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Jan-13-2021 14:45:13 (UTC-06:00)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however

090177e196ae3fd6\Final\Final On: 01-Apr-2021 05:24 (GMT)

Header Text: c4591001

Visit: V101_VAX3

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1008

Site Name: (1008) Clinical Research Professionals Inc.

Subject No: 10081667

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.
Jan-13-2021 14:45:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Megan Felty (pfe.mfelty)	Data Entry: YES Date of Collection: Jan/13/2021	Initial Entry

5.a

Date	Location	User	Value	Reason
Jan-13-2021 14:45:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Megan Felty (pfe.mfelty)	Data Entry: Sample ID BRF55 : N	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Jan-13-2021 14:45:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Megan Felty (pfe.mfelty)	Data Entry: BRF55N	Initial Entry

5.b

Date	Location	User	Value	Reason
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090177e196ae3fd6\Final\Final On: 01-Apr-2021 05:24 (GMT)

Header Text: c4591001

Visit: V101_VAX3

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1008

Site Name: (1008) Clinical Research Professionals Inc.

Subject No: 10081667

Subject Initials: ---

Generated By: pfe.levisse

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

Jan-13-2021 14:45:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Megan Felty (pfe.mfelty)	Data Entry: Sample ID BSCBD : B	Initial Entry
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5.b Sample ID

Date	Location	User	Value	Reason
Jan-13-2021 14:45:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Megan Felty (pfe.mfelty)	Data Entry: BSCBDB	Initial Entry

5.c

Date	Location	User	Value	Reason
Jan-13-2021 14:46:04 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Megan Felty (pfe.mfelty)	Data Entry: Sample ID BSCBD : C	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Jan-13-2021 14:46:04 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Megan Felty (pfe.mfelty)	Data Entry: BSCBDC	Initial Entry

090177e196ae3fd6\Final\Final On: 01-Apr-2021 05:24 (GMT)

Header Text: c4591001

Visit: V101_VAX3

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1008

Site Name: (1008) Clinical Research Professionals Inc.

Subject No: 10081667

Subject Initials: ---

Generated By: pfe.levisse

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

[Back to Form](#)

1. Data Origin

Date	Location	User	Value	Reason
Jan-13-2021 14:11:32 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Jan-13-2021 14:11:32 (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
Jan-13-2021 14:11:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Jan-13-2021 14:11:32 (UTC-06:00)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however

090177e196ae3fd6\Final\Final On: 01-Apr-2021 05:24 (GMT)

Header Text: c4591001

Visit: V101_VAX3

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1008

Site Name: (1008) Clinical Research Professionals Inc.

Subject No: 10081667

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.
Jan-13-2021 14:11:32 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Megan Felty (pfe.mfelty)	Data Entry: YES Date of Collection: Jan/13/2021	Initial Entry

5.a

Date	Location	User	Value	Reason
Jan-13-2021 14:11:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Megan Felty (pfe.mfelty)	Data Entry: Sample ID BRF5D : Y	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Jan-13-2021 14:11:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Megan Felty (pfe.mfelty)	Data Entry: BRF5DY	Initial Entry

090177e196ae3fd6\Final\Final On: 01-Apr-2021 05:24 (GMT)

Header Text: c4591001

Visit: V101_VAX3

Form Version: 10-Dec-2020 02:26

Site No: 1008

Subject No: 10081667

Generated By: pfe.lewissc

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1008) Clinical Research Professionals Inc.

Subject Initials: ---

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

[Back to Form](#)

1. Was there a temporary delay of vaccination?

Date	Location	User	Value	Reason
Jan-13-2021 11:30:41 (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
Jan-13-2021 11:30:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: BNT162b2	Initial Entry

3. Formulation:

Date	Location	User	Value	Reason
Jan-13-2021 11:30:41 (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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090177e196ae3fd6\Final\Final On: 01-Apr-2021 05:24 (GMT)

Header Text: c4591001

Visit: V101_VAX3

Form: VACCINATION - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:26

Form Status: Data Complete, Frozen, Verified

Site No: 1008

Site Name: (1008) Clinical Research Professionals Inc.

Subject No: 10081667

Subject Initials: ---

Generated By: pfe.levissc

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

Jan-13-2021 11:30:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Tiffany Baum (pfe.tbaum)	Data Entry: Jan/13/2021 10:46	Initial Entry
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5. Anatomical Location:

Date	Location	User	Value	Reason
Jan-13-2021 11:30:41 (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
Jan-13-2021 11:30:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Tiffany Baum (pfe.tbaum)	Data Entry: LEFT	Initial Entry

7. Route:

Date	Location	User	Value	Reason
Jan-13-2021 11:30:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INTRAMUSCULAR	Initial Entry

090177e196ae3fd6\Final\Final On: 01-Apr-2021 05:24 (GMT)

Header Text: c4591001

Visit: V101_VAX3

Form: VACCINATION - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:26

Form Status: Data Complete, Frozen, Verified

Site No: 1008

Site Name: (1008) Clinical Research Professionals Inc.

Subject No: 10081667

Subject Initials: ---

Generated By: pfe.levisse

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

8. Actual Dose:

Date	Location	User	Value	Reason
Jan-13-2021 11:30:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 30.0	Initial Entry

9. Unit:

Date	Location	User	Value	Reason
Jan-13-2021 11:30:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: ug	Initial Entry

10. Timeframe Subject Was Observed

Date	Location	User	Value	Reason
Jan-13-2021 11:30:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 30 MINUTES	Initial Entry

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

Date	Location	User	Value	Reason
Jan-13-2021 11:30:41	ACV0PFEINFP6000	Tiffany Baum	Data Entry: YES	Initial Entry

090177e196ae3fd6\Final\Final On: 01-Apr-2021 05:24 (GMT)

Header Text: c4591001

Visit: V101_VAX3

Form: VACCINATION - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:26

Form Status: Data Complete, Frozen, Verified

Site No: 1008

Site Name: (1008) Clinical Research Professionals Inc.

Subject No: 10081667

Subject Initials: ---

Generated By: pfe.levissc

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

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

(pfe.tbaum)

090177e196ae3fd6\Final\Final On: 01-Apr-2021 05:24 (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: 10081667

Subject Initials: ---

Generated By: pfe.lewissc

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

[Back to Form](#)

1. Date Treatment Unblinded :

Date	Location	User	Value	Reason
Jan-07-2021 13:31:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Tiffany Baum (pfe.tbaum)	Data Entry: Jan/5/2021	Initial Entry

2. Primary Reason for Unblinding:

Date	Location	User	Value	Reason
Jan-07-2021 13:31:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Tiffany Baum (pfe.tbaum)	Data Entry: ASSESS ELIGIBILIT Y FOR ADDITIONA L VACCINATION	Initial Entry

090177e196ae3fd6\Final\Final On: 01-Apr-2021 05:24 (GMT)

Header Text: c4591001

Visit: Disposition - Unscheduled

Form: WITHDRAWAL OF CONSENT - 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: 10081667

Subject Initials: ---

Generated By: pfe.levissc

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

[Back to Form](#)

1. Withdrawal of Consent Date :

Date	Location	User	Value	Reason
Mar-11-2021 10:16:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Ann Patek (pfe.apatek)	Data Entry: Mar/10/2021	Initial Entry

090177e196ae3fd6\Final\Final On: 01-Apr-2021 05:24 (GMT)

Header Text: c4591001

Visit: V102_VAX4

Form Version: 22-Apr-2020 21:02

Site No: 1008

Subject No: 10081667

Generated By: pfe.lewissc

Form: DATE OF VISIT - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1008) Clinical Research Professionals Inc.

Subject Initials: ---

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

[Back to Form](#)

1. Date of Visit

Date	Location	User	Value	Reason
Feb-03-2021 11:32:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Tiffany Baum (pfe.tbaum)	Data Entry: Feb/3/2021	Initial Entry

090177e196ae3fd6\Final\Final On: 01-Apr-2021 05:24 (GMT)

Header Text: c4591001

Visit: V102_VAX4

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1008

Site Name: (1008) Clinical Research Professionals Inc.

Subject No: 10081667

Subject Initials: ---

Generated By: pfe.levisse

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

[Back to Form](#)

1. Data Origin

Date	Location	User	Value	Reason
Feb-03-2021 12:25:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Feb-03-2021 12:25:10 (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
Feb-03-2021 12:25:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Feb-03-2021 12:25:10 (UTC-06:00)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however

090177e196ae3fd6\Final\Final On: 01-Apr-2021 05:24 (GMT)

Header Text: c4591001

Visit: V102_VAX4

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1008

Site Name: (1008) Clinical Research Professionals Inc.

Subject No: 10081667

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.
Feb-03-2021 12:25:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Megan Felty (pfe.mfelty)	Data Entry: YES Date of Collection: Feb/3/2021	Initial Entry

5.a

Date	Location	User	Value	Reason
Feb-03-2021 12:25:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Megan Felty (pfe.mfelty)	Data Entry: Sample ID BRKB0 : P	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Feb-03-2021 12:25:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Megan Felty (pfe.mfelty)	Data Entry: BRKB0P	Initial Entry

090177e196ae3fd6\Final\Final On: 01-Apr-2021 05:24 (GMT)

Header Text: c4591001

Visit: V102_VAX4

Form Version: 10-Dec-2020 02:26

Site No: 1008

Subject No: 10081667

Generated By: pfe.lewissc

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1008) Clinical Research Professionals Inc.

Subject Initials: ---

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

[Back to Form](#)

1. Was there a temporary delay of vaccination?

Date	Location	User	Value	Reason
Feb-03-2021 11:32:53 (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
Feb-03-2021 11:32:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: BNT162b2	Initial Entry

3. Formulation:

Date	Location	User	Value	Reason
Feb-03-2021 11:32:53 (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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090177e196ae3fd6\Final\Final On: 01-Apr-2021 05:24 (GMT)

Header Text: c4591001

Visit: V102_VAX4

Form: VACCINATION - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:26

Form Status: Data Complete, Frozen, Verified

Site No: 1008

Site Name: (1008) Clinical Research Professionals Inc.

Subject No: 10081667

Subject Initials: ---

Generated By: pfe.levissc

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

Feb-03-2021 11:32:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Tiffany Baum (pfe.tbaum)	Data Entry: Feb/3/2021 10:32	Initial Entry
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5. Anatomical Location:

Date	Location	User	Value	Reason
Feb-03-2021 11:32:53 (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
Feb-03-2021 11:32:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Tiffany Baum (pfe.tbaum)	Data Entry: LEFT	Initial Entry

7. Route:

Date	Location	User	Value	Reason
Feb-03-2021 11:32:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INTRAMUSCULAR	Initial Entry

090177e196ae3fd6\Final\Final On: 01-Apr-2021 05:24 (GMT)

Header Text: c4591001

Visit: V102_VAX4

Form: VACCINATION - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:26

Form Status: Data Complete, Frozen, Verified

Site No: 1008

Site Name: (1008) Clinical Research Professionals Inc.

Subject No: 10081667

Subject Initials: ---

Generated By: pfe.levisse

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

8. Actual Dose:

Date	Location	User	Value	Reason
Feb-03-2021 11:32:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 30.0	Initial Entry

9. Unit:

Date	Location	User	Value	Reason
Feb-03-2021 11:32:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: ug	Initial Entry

10. Timeframe Subject Was Observed

Date	Location	User	Value	Reason
Feb-03-2021 11:32:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 30 MINUTES	Initial Entry

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

Date	Location	User	Value	Reason
Feb-03-2021 11:32:53	ACV0PFEINFP6000	Tiffany Baum	Data Entry: YES	Initial Entry

090177e196ae3fd6\Final\Final On: 01-Apr-2021 05:24 (GMT)

Header Text: c4591001

Visit: V102_VAX4

Form: VACCINATION - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:26

Form Status: Data Complete, Frozen, Verified

Site No: 1008

Site Name: (1008) Clinical Research Professionals Inc.

Subject No: 10081667

Subject Initials: ---

Generated By: pfe.levissc

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

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

(pfe.tbaum)

Header Text: c4591001

Visit: V103_MONTH1

Form Version: 22-Apr-2020 21:02

Site No: 1008

Subject No: 10081667

Generated By: pfe.levissc

Form: DATE OF VISIT - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1008) Clinical Research Professionals Inc.

Subject Initials: ---

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

[Back to Form](#)

1. Date of Visit

Date	Location	User	Value	Reason
Mar-05-2021 08:10:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Tiffany Baum (pfe.tbaum)	Data Entry: Mar/4/2021	Initial Entry

090177e196ae3fd6\Final\Final On: 01-Apr-2021 05:24 (GMT)

Header Text: c4591001

Visit: V103_MONTH1

Form: CONTACT OUTCOME - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Frozen, Verified

Site No: 1008

Site Name: (1008) Clinical Research Professionals Inc.

Subject No: 10081667

Subject Initials: ---

Generated By: pfe.levissc

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

[Back to Form](#)

1. Contact Type:

Date	Location	User	Value	Reason
Mar-05-2021 08:10:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: TELEPHONE VISIT	Initial Entry

2. Was contact made?

Date	Location	User	Value	Reason
Mar-05-2021 08:10:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Tiffany Baum (pfe.tbaum)	Data Entry: YES Date of Contact: Mar/4/2021	Initial Entry

090177e196ae3fd6\Final\Final On: 01-Apr-2021 05:24 (GMT)

Header Text: c4591001

Visit:
FURTHER_VACCINATION_EOT -
Unscheduled

Form: DISPOSITION - TREATMENT - eCRF Audit
Trail History

Form Version: 20-Feb-2021 02:26

Form Status: Data Complete, Frozen, Verified

Site No: 1008

Site Name: (1008) Clinical Research Professionals Inc.

Subject No: 10081667

Subject Initials: ---

Generated By: pfe.lewissc

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

[Back to Form](#)

1. Date of Completion/Discontinuation/Death :

Date	Location	User	Value	Reason
Mar-05-2021 09:06:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Tiffany Baum (pfe.tbaum)	Data Entry: Mar/4/2021	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Mar-05-2021 09:06:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: OPEN LABEL TREAT MENT	Initial Entry

3. Status:

Date	Location	User	Value	Reason
Mar-05-2021 09:06:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Tiffany Baum (pfe.tbaum)	Data Entry: COMPLETED	Initial Entry

090177e196ae3fd6\Final\Final On: 01-Apr-2021 05:24 (GMT)

Header Text: c4591001

Visit: Subject Status - Unscheduled

Form: SUBJECT STATUS - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Verified

Site No: 1008

Site Name: (1008) Clinical Research Professionals Inc.

Subject No: 10081667

Subject Initials: ---

Generated By: pfe.levisse

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

[Back to Form](#)

1. Subject Status

Date	Location	User	Value	Reason
Mar-11-2021 10:19:46 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: DISCONTINUED	Initial Entry
Dec-10-2020 10:29:32 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: FOLLOW-UP	Initial Entry
Oct-22-2020 12:15:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: ENROLLED/RANDO MIZED	Initial Entry
Oct-22-2020 11:00:16 (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
Mar-11-2021 10:19:46	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Mar/10/2021	Initial Entry

090177e196ae3fd6\Final\Final On: 01-Apr-2021 05:24 (GMT)

Header Text: c4591001

Visit: Subject Status - Unscheduled

Form: SUBJECT STATUS - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Verified

Site No: 1008

Site Name: (1008) Clinical Research Professionals Inc.

Subject No: 10081667

Subject Initials: ---

Generated By: pfe.levisse

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

(UTC-06:00) Central Time (US & Canada)				
Dec-10-2020 10:29:32 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Dec/10/2020	Initial Entry
Oct-22-2020 12:15:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Oct/22/2020	Initial Entry
Oct-22-2020 11:00:16 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Oct/22/2020	Initial Entry

090177e196ae3fd6\Final\Final On: 01-Apr-2021 05:24 (GMT)

Header Text: c4591001

Visit: Investigator Signature -
Unscheduled

Form Version: 22-Apr-2020 21:04

Site No: 1008

Subject No: 10081667

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

[Back to Form](#)

1. Casebook Signature

Date	Location	User	Value	Reason
Dec-10-2020 10:29:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Tiffany Baum (pfe.tbaum)	Data Entry: Click Here to Enable	Initial Entry