

Header Text: c4591001

Visit: COHORT_SELECTION

Form: COHORT SELECTION

Form Version: 10-Oct-2020 16:01

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1008

Site Name: (1008) Clinical Research Professionals Inc.

Subject No: 10081603

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

Header Text: c4591001

Visit: COHORT_SELECTION

Form Version: 22-Apr-2020 21:02

Site No: 1008

Subject No: 10081603

Generated By: pfe.levisse

Form: MAIN INFORMED CONSENT

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1008) Clinical Research Professionals Inc.

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Informed Consent

1.	Consent Was:	OBTAINED Date Written Consent Obtained Oct/14/2020
----	--------------	--

Header Text: c4591001

Visit: COHORT_SELECTION

Form: DEMOGRAPHY

Form Version: 15-Sep-2020 21:54

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1008

Site Name: (1008) Clinical Research Professionals Inc.

Subject No: 10081603

Subject Initials: ---

Generated By: pfe.levisse

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

[eCRF Audit Trail History](#)

Demography

1.	Subject ID	[10081603]
2.	Birth Date:	(b) (6)1955
3.	Sex:	MALE
4.	Ethnicity:	NOT HISPANIC OR LATINO(A) OR OF SPANISH ORIGIN
5.	Race: (Check X all that apply):	BLACK OR AFRICAN AMERICAN
6.	Racial Designation:	

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:02

Site No: 1008

Subject No: 10081603

Generated By: pfe.levisse

Form: DATE OF VISIT

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1008) Clinical Research Professionals Inc.

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Date of Visit

1.	Date of Visit	Oct/14/2020
2.	Erroneous Visit	

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 10-Oct-2020 16:00

Site No: 1008

Subject No: 10081603

Generated By: pfe.levisse

Form: INCLUSION/EXCLUSION CRITERIA

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1008) Clinical Research Professionals Inc.

Subject Initials: ---

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

[Form Comments](#)

Inclusion Criteria Not Met

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

Exclusion Criteria Met

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

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 15-Sep-2020 21:52

Site No: 1008

Subject No: 10081603

Generated By: pfe.levisse

Form: DISPOSITION - SCREENING

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1008) Clinical Research Professionals Inc.

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Disposition - Screening

1.	Date of Completion/Discontinuation /Death	Oct/14/2020
2.	Phase of Disposition:	SCREENING
3.	Status:	COMPLETED
4.	Specify Status:	[]

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1008

Subject No: 10081603

Generated By: pfe.levisse

Form: GENERAL MEDICAL HISTORY

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1008) Clinical Research Professionals Inc.

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Medical History Details

1.a	Line/MH Number:	[1]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Sebaceous cyst of scalp]
	Start Date:	Sep/UNK/2020
	Ongoing:	YES
1.b	Line/MH Number:	[2]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Diabetes type II]
	Start Date:	UNK/UNK/2000
	Ongoing:	YES
1.c	Line/MH Number:	[3]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Coronary artery disease]
	Start Date:	UNK/UNK/2015
	Ongoing:	YES
1.d	Line/MH Number:	[4]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Hypertension]
	Start Date:	UNK/UNK/1980
	Ongoing:	YES

090177e196ae3fd1\Final\Final On: 01-Apr-2021 05:23 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1008

Subject No: 10081603

Generated By: pfe.levisse

Form: GENERAL MEDICAL HISTORY

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1008) Clinical Research Professionals Inc.

Subject Initials: ---

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

1.e	Line/MH Number:	[5]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[High cholesterol]
	Start Date:	UNK/UNK/2014
	Ongoing:	YES

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 15-Sep-2020 21:57

Site No: 1008

Subject No: 10081603

Generated By: pfe.levisse

Form: HIV STATUS

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1008) Clinical Research Professionals Inc.

Subject Initials: ---

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

[eCRF Audit Trail History](#)

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: 10081603

Generated By: pfe.levisse

Form: VITAL SIGNS - BASELINE

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1008) Clinical Research Professionals Inc.

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Vital Signs

1.	Date:	Oct/14/2020
2.	Weight:	[202.6]
3.	Unit:	LB
4.	Height:	[68.5]
5.	Unit:	in
6.	Body Mass Index:	[30.4]

Vital Signs Details

7.a	Record Identifier:	1
	Temperature:	[97.5]
	Unit:	F
	Temperature Location:	FOREHEAD

090177e196ae3fd1\Final\Final On: 01-Apr-2021 05:23 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1008

Subject No: 10081603

Generated By: pfe.levisse

Form: RANDOMIZATION

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1008) Clinical Research Professionals Inc.

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Disposition

1.	Randomization Date :	Oct/14/2020
2.	Randomization Number:	[269278]
3.	Randomization Group:	[]

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1008

Subject No: 10081603

Generated By: pfe.levisse

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1008) Clinical Research Professionals Inc.

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	SERUM
3.	Sample Collected?	YES Date of Collection: Oct/14/2020
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[]

Aliquot

Please enter barcode for each aliquot.

5.a	Sample ID	[BGL5DZ]
5.b	Sample ID	[BPCV02]
5.c	Sample ID	[BPCV03]

090177e196ae3fd1\Final\Final On: 01-Apr-2021 05:23 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1008

Subject No: 10081603

Generated By: pfe.levisse

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1008) Clinical Research Professionals Inc.

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Oct/14/2020
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[]

Aliquot

Please enter barcode for each aliquot.

5.a	Sample ID	[BGL5BH]
-----	-----------	----------

090177e196ae3fd1\Final\Final On: 01-Apr-2021 05:23 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:04

Site No: 1008

Subject No: 10081603

Generated By: pfe.levisse

Form: VACCINATION

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1008) Clinical Research Professionals Inc.

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Vaccination

1.	Was there a temporary delay of vaccination?	NO
2.	Treatment Name	[BLINDED THERAPY]
3.	Formulation:	INJECTION
4.	Dose Date Time:	Oct/14/2020 11:44
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

090177e196ae3fd1\Final\Final On: 01-Apr-2021 05:23 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 06-Jul-2020 21:53

Site No: 1008

Subject No: 10081603

Generated By: pfe.levisse

Form: REACTOGENICITY DIARY

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1008) Clinical Research Professionals Inc.

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Reactogenicity Diary

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

090177e196ae3fd1\Final\Final On: 01-Apr-2021 05:23 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 1008

Subject No: 10081603

Generated By: pfe.levisse

Form: DATE OF VISIT

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1008) Clinical Research Professionals Inc.

Subject Initials: ---

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

eCRF Audit Trail History

Date of Visit

1.	Date of Visit	Nov/5/2020
2.	Erroneous Visit	

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 10-Oct-2020 16:01

Site No: 1008

Subject No: 10081603

Generated By: pfe.levisse

Form: VITAL SIGNS - TEMP

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1008) Clinical Research Professionals Inc.

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Vital Signs

1.	Date:	Nov/5/2020
----	-------	------------

Vital Signs Details

2.a	Record Identifier:	1
	Temperature:	[97.6]
	Unit:	F
	Temperature Location:	FOREHEAD

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:03

Site No: 1008

Subject No: 10081603

Generated By: pfe.levisse

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1008) Clinical Research Professionals Inc.

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Nov/5/2020
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	[BRGV1M]
-----	-----------	----------

090177e196ae3fd1\Final\Final On: 01-Apr-2021 05:23 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1008

Subject No: 10081603

Generated By: pfe.levisse

Form: VACCINATION

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1008) Clinical Research Professionals Inc.

Subject Initials: ---

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

eCRF Audit Trail History

Vaccination

1.	Was there a temporary delay of vaccination?	NO
2.	Treatment Name	[BLINDED THERAPY]
3.	Formulation:	INJECTION
4.	Dose Date Time:	Nov/5/2020 15:06
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

090177e196ae3fd1\Final\Final On: 01-Apr-2021 05:23 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 1008

Subject No: 10081603

Generated By: pfe.levisse

Form: DATE OF VISIT

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1008) Clinical Research Professionals Inc.

Subject Initials: ---

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

eCRF Audit Trail History

Date of Visit

1.	Date of Visit	Dec/3/2020
2.	Erroneous Visit	

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1008

Site Name: (1008) Clinical Research Professionals Inc.

Subject No: 10081603

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/3/2020
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	[BRD9J6]
5.b	Sample ID	[BRT3NS]
5.c	Sample ID	[BRT3NT]

090177e196ae3fd1\Final\Final On: 01-Apr-2021 05:23 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL - New Unscheduled Visit **Form:** DATE OF VISIT - ILLNESS ONSET

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1008

Site Name: (1008) Clinical Research Professionals Inc.

Subject No: 10081603

Subject Initials: ---

Generated By: pfe.levisse

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:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19

Form Version: 20-Feb-2021 02:17

Form Status: Not Started

Site No: 1008

Site Name: (1008) Clinical Research Professionals Inc.

Subject No: 10081603

Subject Initials: ---

Generated By: pfe.levisse

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

090177e196ae3fd1\Final\Final On: 01-Apr-2021 05:23 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL - New Unscheduled **Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB SELF Visit

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1008

Site Name: (1008) Clinical Research Professionals Inc.

Subject No: 10081603

Subject Initials: ---

Generated By: pfe.levisse

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

Electronic Sample Tracking

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

Aliquot

Please enter barcode for each aliquot.

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

090177e196ae3fd1\Final\Final On: 01-Apr-2021 05:23 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL - New Unscheduled **Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB Visit

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1008

Site Name: (1008) Clinical Research Professionals Inc.

Subject No: 10081603

Subject Initials: ---

Generated By: pfe.levisse

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

Electronic Sample Tracking

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

Aliquot

Please enter barcode for each aliquot.

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

090177e196ae3fd1\Final\Final On: 01-Apr-2021 05:23 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL - New Unscheduled Visit **Form:** HEALTH CARE UTILIZATION

Form Version: 20-Feb-2021 02:19

Form Status: Not Started

Site No: 1008

Site Name: (1008) Clinical Research Professionals Inc.

Subject No: 10081603

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?	
----	--	--

090177e196ae3fd1\Final\Final On: 01-Apr-2021 05:23 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL - New Unscheduled Visit **Form:** ILLNESS DETAILS

Form Version: 06-Jul-2020 21:52

Form Status: Not Started

Site No: 1008

Site Name: (1008) Clinical Research Professionals Inc.

Subject No: 10081603

Subject Initials: ---

Generated By: pfe.levisse

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:	

090177e196ae3fd1\Final\Final On: 01-Apr-2021 05:23 (GMT)

Header Text: c4591001

Visit: POT_COVID_CONVA - New
Unscheduled Visit

Form: DATE OF VISIT - ILLNESS CONVALESCENT

Form Version: 22-Apr-2020 21:04

Form Status: Not Started

Site No: 1008

Site Name: (1008) Clinical Research Professionals Inc.

Subject No: 10081603

Subject Initials: ---

Generated By: pfe.levisse

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: 10081603

Subject Initials: ---

Generated By: pfe.levisse

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

Electronic Sample Tracking

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

Aliquot

Please enter barcode for each aliquot.

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

090177e196ae3fd1\Final\Final On: 01-Apr-2021 05:23 (GMT)

Header Text: c4591001

Visit: POT_COVID_REPEAT_SWAB - New **Form:** DATE OF VISIT - REPEAT SWAB
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: 10081603

Subject Initials: ---

Generated By: pfe.levisse

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 **Form:** ELECTRONIC SAMPLE TRACKING - REPEAT SWAB
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: 10081603

Subject Initials: ---

Generated By: pfe.levisse

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

Electronic Sample Tracking

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

Aliquot

Please enter barcode for each aliquot.

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

090177e196ae3fd1\Final\Final On: 01-Apr-2021 05:23 (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: 10081603

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	SCALP ABCCESS	Oct/26/2020 U NK:UNK	NO End Date Time: Oct/27/2020 UNK: UNK	Repeating Pages
2. DELETED	ADVERSE EVENT	2	SEPSIS	Oct/26/2020 U NK:UNK	NO End Date Time: Nov/2/2020 UNK: UNK	Repeating Pages
3.	ADVERSE EVENT	3	CELLULITIS UP PER BACK	Oct/26/2020 U NK:UNK	NO End Date Time: Nov/2/2020 UNK: UNK	Repeating Pages
4.	ADVERSE EVENT	4	Surgical wound sc alp	Oct/27/2020 U NK:UNK	NO End Date Time: Jan/21/2021 UNK: UNK	Repeating Pages

090177e196ae3fd1\Final\Final On: 01-Apr-2021 05:23 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1008

Subject No: 10081603

Generated By: pfe.levisse

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Frozen

Site Name: (1008) Clinical Research Professionals Inc.

Subject Initials: ---

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)	[SCALP ABCCESS]
4.	Start Date Time:	Oct/26/2020 UNK:UNK
5.	Is the adverse event still ongoing?	NO End Date Time: Oct/27/2020 UNK:UNK
6.	Toxicity Grade:	3
7.	Is the adverse event serious? If Yes, NOTIFY PFIZER IMMEDIATELY. Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).	YES Is this serious event associated with congenital anomaly or birth defect? NO Did this serious event result in death? NO Did this serious event require or prolong hospitalization? YES Did this serious event result in persistent or significant disability/incapacity? NO Is this serious event life threatening? NO Other medically important serious event NO
8.	Is this adverse event the result of a study Medication Error? If Yes, record the type of medication error on the Medication Error Log.	NO

090177e196ae3fd1\Final\Final On: 01-Apr-2021 05:23 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1008

Subject No: 10081603

Generated By: pfe.levisse

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Frozen

Site Name: (1008) Clinical Research Professionals Inc.

Subject Initials: ---

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

9.	Is this event related to study treatment:	NOT RELATED If Not Related to study treatment(s), this event is due to: OTHER If Other, specify: [HISTORY SCALP CYST]
10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE
11.	Was a Concomitant Medication given?	YES
12.	Was a Non-Drug Treatment given?	YES
13.	What was the outcome of this adverse event?:	RECOVERED/RESOLVED
14.	Did the adverse event cause the subject to be discontinued from the study?	NO
15.	Serious Adverse Event Number: For Pfizer Use Only	[2020437863]

090177e196ae3fd1\Final\Final On: 01-Apr-2021 05:23 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1008

Subject No: 10081603

Generated By: pfe.levissc

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Deleted

Site Name: (1008) Clinical Research Professionals Inc.

Subject Initials: ---

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

***** THIS REPEATING FORM HAS BEEN DELETED *****

[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)	[SEPSIS]
4.	Start Date Time:	Oct/26/2020 UNK:UNK
5.	Is the adverse event still ongoing?	NO End Date Time: Nov/2/2020 UNK:UNK
6.	Toxicity Grade:	3
7.	Is the adverse event serious? If Yes, NOTIFY PFIZER IMMEDIATELY. Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).	YES Is this serious event associated with congenital anomaly or birth defect? NO Did this serious event result in death? NO Did this serious event require or prolong hospitalization? YES Did this serious event result in persistent or significant disability/incapacity? NO Is this serious event life threatening? NO Other medically important serious event NO

090177e196ae3fd1\Final\Final On: 01-Apr-2021 05:23 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1008

Subject No: 10081603

Generated By: pfe.levisse

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Deleted

Site Name: (1008) Clinical Research Professionals Inc.

Subject Initials: ---

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

***** THIS REPEATING FORM HAS BEEN DELETED *****

8.	Is this adverse event the result of a study Medication Error? If Yes, record the type of medication error on the Medication Error Log.	NO
9.	Is this event related to study treatment:	NOT RELATED If Not Related to study treatment(s), this event is due to: OTHER If Other, specify: [SCALP ABCESS]
10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE
11.	Was a Concomitant Medication given?	YES
12.	Was a Non-Drug Treatment given?	NO
13.	What was the outcome of this adverse event?:	RECOVERED/RESOLVED
14.	Did the adverse event cause the subject to be discontinued from the study?	NO
15.	Serious Adverse Event Number: For Pfizer Use Only	[2020437863]

090177e196ae3fd1\Final\Final On: 01-Apr-2021 05:23 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1008

Subject No: 10081603

Generated By: pfe.levissc

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Frozen

Site Name: (1008) Clinical Research Professionals Inc.

Subject Initials: ---

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:	[3]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[CELLULITIS UPPER BACK]
4.	Start Date Time:	Oct/26/2020 UNK:UNK
5.	Is the adverse event still ongoing?	NO End Date Time: Nov/2/2020 UNK:UNK
6.	Toxicity Grade:	3
7.	Is the adverse event serious? If Yes, NOTIFY PFIZER IMMEDIATELY. Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).	YES Is this serious event associated with congenital anomaly or birth defect? NO Did this serious event result in death? NO Did this serious event require or prolong hospitalization? YES Did this serious event result in persistent or significant disability/incapacity? NO Is this serious event life threatening? NO Other medically important serious event NO

090177e196ae3fd1\Final\Final On: 01-Apr-2021 05:23 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1008

Subject No: 10081603

Generated By: pfe.levisse

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Frozen

Site Name: (1008) Clinical Research Professionals Inc.

Subject Initials: ---

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

8.	Is this adverse event the result of a study Medication Error? If Yes, record the type of medication error on the Medication Error Log.	NO
9.	Is this event related to study treatment:	NOT RELATED If Not Related to study treatment(s), this event is due to: OTHER If Other, specify: [SCALP ABCESS]
10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE
11.	Was a Concomitant Medication given?	YES
12.	Was a Non-Drug Treatment given?	NO
13.	What was the outcome of this adverse event?:	RECOVERED/RESOLVED
14.	Did the adverse event cause the subject to be discontinued from the study?	NO
15.	Serious Adverse Event Number: For Pfizer Use Only	[2020437863]

090177e196ae3fd1\Final\Final On: 01-Apr-2021 05:23 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1008

Subject No: 10081603

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

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

Adverse Event Report

1.	Category:	ADVERSE EVENT
2.	AE ID:	[4]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[Surgical wound scalp]
4.	Start Date Time:	Oct/27/2020 UNK:UNK
5.	Is the adverse event still ongoing?	NO End Date Time: Jan/21/2021 UNK:UNK
6.	Toxicity Grade:	2
7.	Is the adverse event serious? If Yes, NOTIFY PFIZER IMMEDIATELY. Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).	NO
8.	Is this adverse event the result of a study Medication Error? If Yes, record the type of medication error on the Medication Error Log.	NO

090177e196ae3fd1\Final\Final On: 01-Apr-2021 05:23 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1008

Subject No: 10081603

Generated By: pfe.levisse

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

9.	Is this event related to study treatment:	NOT RELATED If Not Related to study treatment(s), this event is due to: OTHER If Other, specify: [Post I&D scalp abcess]
10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE
11.	Was a Concomitant Medication given?	YES
12.	Was a Non-Drug Treatment given?	YES
13.	What was the outcome of this adverse event?:	RECOVERED/RESOLVED
14.	Did the adverse event cause the subject to be discontinued from the study?	NO
15.	Serious Adverse Event Number: For Pfizer Use Only	[]

090177e196ae3fd1\Final\Final On: 01-Apr-2021 05:23 (GMT)

Header Text: c4591001

Visit: Logs

Form: MEDICATION ERROR

Form Version: 17-Jul-2020 21:54

Site No: 1008

Site Name: (1008) Clinical Research Professionals Inc.

Subject No: 10081603

Subject Initials: ---

Generated By: pfe.levisse

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

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

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 17-Jul-2020 21:54

Site No: 1008

Subject No: 10081603

Generated By: pfe.levissc

Form: MEDICATION ERROR

Form Status: Not Started

Site Name: (1008) Clinical Research Professionals Inc.

Subject Initials: ---

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	[]

090177e196ae3fd1\Final\Final On: 01-Apr-2021 05:23 (GMT)

Header Text: c4591001

Visit: Logs

Form: CONCOMITANT MEDICATIONS - NON STUDY
VACCINATIONS

Form Version: 22-Apr-2020 21:03

Site No: 1008

Site Name: (1008) Clinical Research Professionals Inc.

Subject No: 10081603

Subject Initials: ---

Generated By: pfe.levisse

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

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: 10081603

Subject Initials: ---

Generated By: pfe.levisse

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:	//

090177e196ae3fd1\Final\Final On: 01-Apr-2021 05:23 (GMT)

Header Text: c4591001

Visit: Logs

Form: CONCOMITANT MEDICATIONS - PROHIBITED

Form Version: 22-Apr-2020 21:03

Site No: 1008

Site Name: (1008) Clinical Research Professionals Inc.

Subject No: 10081603

Subject Initials: ---

Generated By: pfe.levisse

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

090177e196ae3fd1\Final\Final On: 01-Apr-2021 05:23 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1008

Subject No: 10081603

Generated By: pfe.levisse

Form: CONCOMITANT MEDICATIONS - PROHIBITED

Form Status: Not Started

Site Name: (1008) Clinical Research Professionals Inc.

Subject Initials: ---

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?	

090177e196ae3fd1\Final\Final On: 01-Apr-2021 05:23 (GMT)

Header Text: c4591001

Visit: Logs

Form: RADIATION TREATMENT

Form Version: 22-Apr-2020 21:02

Site No: 1008

Site Name: (1008) Clinical Research Professionals Inc.

Subject No: 10081603

Subject Initials: ---

Generated By: pfe.levisse

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

090177e196ae3fd1\Final\Final On: 01-Apr-2021 05:23 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1008

Subject No: 10081603

Generated By: pfe.levissc

Form: RADIATION TREATMENT

Form Status: Not Started

Site Name: (1008) Clinical Research Professionals Inc.

Subject Initials: ---

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?	

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: 10081603

Subject Initials: ---

Generated By: pfe.levisse

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

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

090177e196ae3fd1\Final\Final On: 01-Apr-2021 05:23 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1008

Subject No: 10081603

Generated By: pfe.levissc

Form: TRANSFUSIONS

Form Status: Not Started

Site Name: (1008) Clinical Research Professionals Inc.

Subject Initials: ---

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 Visit

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: 10081603

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: 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: 10081603

Subject Initials: ---

Generated By: pfe.levisse

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: 10081603

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: 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: 10081603

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:	

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: 10081603

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?	

090177e196ae3fd1\Final\Final On: 01-Apr-2021 05:23 (GMT)

Header Text: c4591001

Visit: Unplanned Vaccination - Unscheduled

Form: CONTACT OUTCOME - MONTH 1

Form Version: 10-Oct-2020 15:57

Form Status: Not Started

Site No: 1008

Site Name: (1008) Clinical Research Professionals Inc.

Subject No: 10081603

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: 10081603

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: 15-Sep-2020 21:55

Form Status: Data Complete, Frozen, Verified

Site No: 1008

Site Name: (1008) Clinical Research Professionals Inc.

Subject No: 10081603

Subject Initials: ---

Generated By: pfe.levisse

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

[eCRF Audit Trail History](#)

Disposition - Treatment

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

Header Text: c4591001

Visit: Potential ReVax Initial Contact -
Unscheduled

Form: DATE OF VISIT

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen, Verified

Site No: 1008

Site Name: (1008) Clinical Research Professionals Inc.

Subject No: 10081603

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/15/2021
2.	Erroneous Visit	

Header Text: c4591001

Visit: Potential ReVax Initial Contact -
Unscheduled

Form: FURTHER VACCINATION CONFIRMATION

Form Version: 10-Dec-2020 02:25

Form Status: Data Complete, Frozen

Site No: 1008

Site Name: (1008) Clinical Research Professionals Inc.

Subject No: 10081603

Subject Initials: ---

Generated By: pfe.levisse

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: Not Started

Site No: 1008

Site Name: (1008) Clinical Research Professionals Inc.

Subject No: 10081603

Subject Initials: ---

Generated By: pfe.levisse

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

Disposition - Follow-Up

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

Header Text: c4591001

Visit: Disposition - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1008

Subject No: 10081603

Generated By: pfe.levisse

Form: TREATMENT UNBLINDED

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](#)

Treatment Unblinded

1.	Date Treatment Unblinded :	Jan/15/2021
2.	Primary Reason for Unblinding:	ASSESS ELIGIBILITY FOR ADDITIONAL VACCINATION

Header Text: c4591001

Visit: Disposition - Unscheduled

Form: WITHDRAWAL OF CONSENT

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1008

Site Name: (1008) Clinical Research Professionals Inc.

Subject No: 10081603

Subject Initials: ---

Generated By: pfe.levisse

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

Withdrawal Of Consent

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

090177e196ae3fd1\Final\Final On: 01-Apr-2021 05:23 (GMT)

Header Text: c4591001

Visit: Disposition - Unscheduled

Form: DEATH DETAILS CODED

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1008

Site Name: (1008) Clinical Research Professionals Inc.

Subject No: 10081603

Subject Initials: ---

Generated By: pfe.levisse

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: V101_VAX3

Form Version: 22-Apr-2020 21:02

Site No: 1008

Subject No: 10081603

Generated By: pfe.levisse

Form: DATE OF VISIT

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1008) Clinical Research Professionals Inc.

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Date of Visit

1.	Date of Visit	Jan/21/2021
2.	Erroneous Visit	

Header Text: c4591001

Visit: V101_VAX3

Form Version: 10-Dec-2020 02:31

Site No: 1008

Subject No: 10081603

Generated By: pfe.levisse

Form: INFORMED CONSENT - FURTHER VACCINATION

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1008) Clinical Research Professionals Inc.

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Informed Consent - Further Vaccination

1.	Consent Was:	OBTAINED Date Written Consent Obtained Jan/21/2021
----	--------------	--

Header Text: c4591001

Visit: V101_VAX3

Form: INCLUSION/EXCLUSION CRITERIA - FURTHER VACCINATION

Form Version: 10-Dec-2020 02:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1008

Site Name: (1008) Clinical Research Professionals Inc.

Subject No: 10081603

Subject Initials: ---

Generated By: pfe.levisse

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, Locked, Frozen, Verified

Site No: 1008

Site Name: (1008) Clinical Research Professionals Inc.

Subject No: 10081603

Subject Initials: ---

Generated By: pfe.levisse

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

[eCRF Audit Trail History](#)

Disposition - Screening for Further Vaccination

1.	Date of Completion/Discontinuation /Death :	Jan/21/2021
2.	Phase of Disposition:	REPEAT SCREENING 1
3.	Status:	COMPLETED
4.	Specify Status:	[]

Header Text: c4591001

Visit: V101_VAX3

Form Version: 22-Apr-2020 21:03

Site No: 1008

Subject No: 10081603

Generated By: pfe.levisse

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1008) Clinical Research Professionals Inc.

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	SERUM
3.	Sample Collected?	YES Date of Collection: Jan/21/2021
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	[BRF0PW]
5.b	Sample ID	[BSJSG0]
5.c	Sample ID	[BSJSG1]

090177e196ae3fd1\Final\Final On: 01-Apr-2021 05:23 (GMT)

Header Text: c4591001

Visit: V101_VAX3

Form Version: 22-Apr-2020 21:03

Site No: 1008

Subject No: 10081603

Generated By: pfe.levisse

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1008) Clinical Research Professionals Inc.

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Jan/21/2021
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	[BRK9R7]
-----	-----------	----------

090177e196ae3fd1\Final\Final On: 01-Apr-2021 05:23 (GMT)

Header Text: c4591001

Visit: V101_VAX3

Form Version: 10-Dec-2020 02:26

Site No: 1008

Subject No: 10081603

Generated By: pfe.levisse

Form: VACCINATION

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1008) Clinical Research Professionals Inc.

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Vaccination

1.	Was there a temporary delay of vaccination?	NO
2.	Treatment Name	[BNT162b2]
3.	Formulation:	INJECTION
4.	Dose Date Time:	Jan/21/2021 13:58
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

090177e196ae3fd1\Final\Final On: 01-Apr-2021 05:23 (GMT)

Header Text: c4591001

Visit: V102_VAX4

Form Version: 22-Apr-2020 21:02

Site No: 1008

Subject No: 10081603

Generated By: pfe.levisse

Form: DATE OF VISIT

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1008) Clinical Research Professionals Inc.

Subject Initials: ---

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

eCRF Audit Trail History

Date of Visit

1.	Date of Visit	Feb/11/2021
2.	Erroneous Visit	

Header Text: c4591001

Visit: V102_VAX4

Form Version: 22-Apr-2020 21:03

Site No: 1008

Subject No: 10081603

Generated By: pfe.levisse

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1008) Clinical Research Professionals Inc.

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Feb/11/2021
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	[BRG1VV]
-----	-----------	----------

090177e196ae3fd1\Final\Final On: 01-Apr-2021 05:23 (GMT)

Header Text: c4591001

Visit: V102_VAX4

Form Version: 10-Dec-2020 02:26

Site No: 1008

Subject No: 10081603

Generated By: pfe.levisse

Form: VACCINATION

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1008) Clinical Research Professionals Inc.

Subject Initials: ---

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

eCRF Audit Trail History

Vaccination

1.	Was there a temporary delay of vaccination?	NO
2.	Treatment Name	[BNT162b2]
3.	Formulation:	INJECTION
4.	Dose Date Time:	Feb/11/2021 12:20
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

090177e196ae3fd1\Final\Final On: 01-Apr-2021 05:23 (GMT)

Header Text: c4591001

Visit: V103_MONTH1

Form Version: 22-Apr-2020 21:02

Site No: 1008

Subject No: 10081603

Generated By: pfe.levisse

Form: DATE OF VISIT

Form Status: Data Complete, Verified

Site Name: (1008) Clinical Research Professionals Inc.

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Date of Visit

1.	Date of Visit	Mar/11/2021
2.	Erroneous Visit	

Header Text: c4591001

Visit: V103_MONTH1

Form Version: 22-Apr-2020 21:04

Site No: 1008

Subject No: 10081603

Generated By: pfe.levisse

Form: CONTACT OUTCOME

Form Status: Data Complete, 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/11/2021
3.	Comments:	[]

Header Text: c4591001

Visit: V104_MONTH6

Form Version: 22-Apr-2020 21:02

Site No: 1008

Subject No: 10081603

Generated By: pfe.levisse

Form: DATE OF VISIT

Form Status: Not Started

Site Name: (1008) Clinical Research Professionals Inc.

Subject Initials: ---

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

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

Header Text: c4591001

Visit: V104_MONTH6

Form Version: 22-Apr-2020 21:04

Site No: 1008

Subject No: 10081603

Generated By: pfe.levisse

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 Version: 22-Apr-2020 21:02

Site No: 1008

Subject No: 10081603

Generated By: pfe.levisse

Form: DATE OF VISIT

Form Status: Not Started

Site Name: (1008) Clinical Research Professionals Inc.

Subject Initials: ---

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

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

Header Text: c4591001

Visit: V105_MONTH18

Form Version: 22-Apr-2020 21:04

Site No: 1008

Subject No: 10081603

Generated By: pfe.levisse

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, Verified

Site No: 1008

Site Name: (1008) Clinical Research Professionals Inc.

Subject No: 10081603

Subject Initials: ---

Generated By: pfe.levisse

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

[eCRF Audit Trail History](#)

Disposition - Treatment

1.	Date of Completion/Discontinuation/Death :	Mar/11/2021
2.	Phase of Disposition:	OPEN LABEL TREATMENT
3.	Status:	COMPLETED
4.	Specify Status:	[]

Header Text: c4591001

Visit: Subject Status - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1008

Subject No: 10081603

Generated By: pfe.levisse

Form: SUBJECT STATUS

Form Status: Data Complete, Verified

Site Name: (1008) Clinical Research Professionals Inc.

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Subject Status

1.	Subject Status	FOLLOW-UP
2.	Subject Status Date	Dec/3/2020

Header Text: c4591001

Visit: Investigator Signature - Unscheduled

Form: CASEBOOK SIGNATURE FORM

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Verified

Site No: 1008

Site Name: (1008) Clinical Research Professionals Inc.

Subject No: 10081603

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
----	--------------------	----------------------

090177e196ae3fd1\Final\Final On: 01-Apr-2021 05:23 (GMT)

Header Text: c4591001

Visit: Investigator Signature - Unscheduled

Form: CASEBOOK SIGNATURE FORM

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Verified

Site No: 1008

Site Name: (1008) Clinical Research Professionals Inc.

Subject No: 10081603

Subject Initials: ---

Generated By: pfe.levissc

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
- CRF_Sign_1

Name	Signature Meaning	Date	Type	Action
------	-------------------	------	------	--------

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 10-Oct-2020 16:00

Site No: 1008

Subject No: 10081603

Generated By: pfe.levissc

Form: INCLUSION/EXCLUSION CRITERIA - Comments

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1008) Clinical Research Professionals Inc.

Subject Initials: ---

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

[Back to Form](#)

Item	Date	User	Comment
Form	Oct-14-2020 13:56:58 (UTC-06:00) Central Time (US & Canada)	Tiffany Baum (pfe.tbaum)	Not Applicable

Header Text: c4591001

Visit: V101_VAX3

Form Version: 10-Dec-2020 02:30

Site No: 1008

Subject No: 10081603

Generated By: pfe.levisse

Form: INCLUSION/EXCLUSION CRITERIA - FURTHER
VACCINATION - Comments

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1008) Clinical Research Professionals Inc.

Subject Initials: ---

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

[Back to Form](#)

Item	Date	User	Comment
Form	Jan-21-2021 15:12:39 (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, Verified

Site No: 1008

Site Name: (1008) Clinical Research Professionals Inc.

Subject No: 10081603

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
- CRF_Sign_1

Name	Signature Meaning	Date	Type	Action
Sherri Pangburn	N/A	Mar-11-2021 13:41:27 (UTC-06:00) Central Time (US & Canada)		Edit - All signatures invalidated

Affidavit:

N/A

Timothy Jennings	Approved	Feb-22-2021 11:25:20 (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.

Megan Felty	N/A	Feb-11-2021 12:05:22 (UTC-06:00) Central Time (US & Canada)		Edit - All signatures invalidated
-------------	-----	---	--	-----------------------------------

Affidavit:

N/A

Timothy Jennings	Approved	Jan-22-2021 17:53:56 (UTC-06:00) Central Time (US & Canada)	BOOK	Signed
------------------	----------	---	------	--------

090177e196ae3fd1\Final\Final On: 01-Apr-2021 05:23 (GMT)

Header Text: c4591001

Visit: Investigator Signature - Unscheduled

Form: CASEBOOK SIGNATURE FORM - Signature History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Verified

Site No: 1008

Site Name: (1008) Clinical Research Professionals Inc.

Subject No: 10081603

Subject Initials: ---

Generated By: pfe.levissc

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.

Header Text: c4591001

Visit: COHORT_SELECTION

Form Version: 10-Oct-2020 16:01

Site No: 1008

Subject No: 10081603

Generated By: pfe.levisse

Form: COHORT SELECTION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1008) Clinical Research Professionals Inc.

Subject Initials: ---

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

[Back to Form](#)

1. Select appropriate response - Protocol version

Date	Location	User	Value	Reason
Oct-14-2020 10:52:45 (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-14-2020 10:52:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Tiffany Baum (pfe.tbaum)	Data Entry: STAGE 3 COHORTS	Initial Entry

090177e196ae3fd1\Final\Final On: 01-Apr-2021 05:23 (GMT)

Header Text: c4591001

Visit: COHORT_SELECTION

Form Version: 22-Apr-2020 21:02

Site No: 1008

Subject No: 10081603

Generated By: pfe.levisse

Form: MAIN INFORMED CONSENT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1008) Clinical Research Professionals Inc.

Subject Initials: ---

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

[Back to Form](#)

1. Consent Was:

Date	Location	User	Value	Reason
Oct-14-2020 10:52:54 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Tiffany Baum (pfe.tbaum)	<u>Data Entry:</u> OBTAINED Date Written Consent Obtained Oct/14/2020	Initial Entry

Header Text: c4591001

Visit: COHORT_SELECTION

Form Version: 15-Sep-2020 21:54

Site No: 1008

Subject No: 10081603

Generated By: pfe.levisse

Form: DEMOGRAPHY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1008) Clinical Research Professionals Inc.

Subject Initials: ---

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

[Back to Form](#)

1. Subject ID

Date	Location	User	Value	Reason
Oct-14-2020 10:52:37 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 10081603	Item copied from previous form

2. Birth Date:

Date	Location	User	Value	Reason
Oct-14-2020 10:52:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: (b) (6)/1955	Enrollment Entry

3. Sex:

Date	Location	User	Value	Reason
Oct-14-2020 10:53:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Tiffany Baum (pfe.tbaum)	Data Entry: MALE	Initial Entry

4. Ethnicity:

Date	Location	User	Value	Reason
Oct-14-2020 10:53:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Tiffany Baum (pfe.tbaum)	Data Entry: NOT HISPANIC OR LATINO(A) OR OF SPANISH ORIGIN	Initial Entry

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

Date	Location	User	Value	Reason
Oct-14-2020 10:53:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Tiffany Baum (pfe.tbaum)	Data Entry: BLACK OR AFRICAN AMERI CAN	Initial Entry

090177e196ae3fd1\Final\Final On: 01-Apr-2021 05:23 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:02

Site No: 1008

Subject No: 10081603

Generated By: pfe.levisse

Form: DATE OF VISIT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1008) Clinical Research Professionals Inc.

Subject Initials: ---

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

[Back to Form](#)

1. Date of Visit

Date	Location	User	Value	Reason
Oct-14-2020 10:53:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Tiffany Baum (pfe.tbaum)	Data Entry: Oct/14/2020	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 15-Sep-2020 21:52

Site No: 1008

Subject No: 10081603

Generated By: pfe.levisse

Form: DISPOSITION - SCREENING - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1008) Clinical Research Professionals Inc.

Subject Initials: ---

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

[Back to Form](#)

1. Date of Completion/Discontinuation/Death

Date	Location	User	Value	Reason
Oct-14-2020 10:53:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Tiffany Baum (pfe.tbaum)	Data Entry: Oct/14/2020	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Oct-14-2020 10:53:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SCREENING	Initial Entry

3. Status:

Date	Location	User	Value	Reason
Oct-14-2020 10:53:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Tiffany Baum (pfe.tbaum)	Data Entry: COMPLETED	Initial Entry

090177e196ae3fd1\Final\Final On: 01-Apr-2021 05:23 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1008

Subject No: 10081603

Generated By: pfe.levisse

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1008) Clinical Research Professionals Inc.

Subject Initials: ---

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

[Back to Form](#)

1.a

Date	Location	User	Value	Reason
Oct-16-2020 08:53:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Tiffany Baum (pfe.tbaum)	Data Entry: Line/MH Number: Medical History Term: Sebaceous cyst of scalp Start Date: Sep/UNK/2020 Ongoing: YES	unknown cause, term updated, on antibiotic
Oct-14-2020 11:31:02 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: Medical History Term: Cyst of scalp Start Date: Sep/UNK/2020 Ongoing: YES	Initial Entry

1.a Line/MH Number:

Date	Location	User	Value	Reason
Oct-14-2020 11:31:02 (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 06:07:32 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Daria Madar Jacobson (pfe.madard)	Query 1: Closed	Response satisfies query
Oct-16-2020 08:53:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	unknown cause, term updated, on antibiotic

090177e196ae3fd1\Final\Final On: 01-Apr-2021 05:23 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1008

Subject No: 10081603

Generated By: pfe.levisse

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1008) Clinical Research Professionals Inc.

Subject Initials: ---

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

Oct-16-2020 08:53:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Tiffany Baum (pfe.tbaum)	Data Entry: Sebaceous cyst of scalp	unknown cause,term updated, on antibiotic
Oct-15-2020 15:45:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Daria Madar Jacobson (pfe.madard)	Query 1: Opened	GPDCLIN: Please further clarify the medical history term: type of cyst, cause, required treatment.
Oct-14-2020 11:31:02 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Tiffany Baum (pfe.tbaum)	Data Entry: Cyst of scalp	Initial Entry

1.a Start Date:

Date	Location	User	Value	Reason
Oct-14-2020 11:31:02 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Tiffany Baum (pfe.tbaum)	Data Entry: Sep/UNK/2020	Initial Entry

1.a Ongoing:

Date	Location	User	Value	Reason
Oct-14-2020 11:31:02 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Tiffany Baum (pfe.tbaum)	Data Entry: YES	Initial Entry

1.b

Date	Location	User	Value	Reason
Oct-14-2020 11:31:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Numbe 2 r: Medical History Diabetes typ e II Term: Start Date: UNK/UNK/ 2000 Ongoing: YES	Initial Entry

090177e196ae3fd1\Final\Final On: 01-Apr-2021 05:23 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1008

Subject No: 10081603

Generated By: pfe.levisse

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1008) Clinical Research Professionals Inc.

Subject Initials: ---

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

1.b Line/MH Number:

Date	Location	User	Value	Reason
Oct-14-2020 11:31:29 (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
Oct-14-2020 11:31:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Tiffany Baum (pfe.tbaum)	Data Entry: Diabetes type II	Initial Entry

1.b Start Date:

Date	Location	User	Value	Reason
Oct-14-2020 11:31:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Tiffany Baum (pfe.tbaum)	Data Entry: UNK/UNK/2000	Initial Entry

1.b Ongoing:

Date	Location	User	Value	Reason
Oct-14-2020 11:31:29 (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-14-2020 11:31:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Num 3 ber: Medical Histor Coronary arter y Term: y disease Start Date: UNK/UNK/20 15 Ongoing: YES	Initial Entry

090177e196ae3fd1\Final\Final On: 01-Apr-2021 05:23 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1008

Subject No: 10081603

Generated By: pfe.levisse

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1008) Clinical Research Professionals Inc.

Subject Initials: ---

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

I.c Line/MH Number:

Date	Location	User	Value	Reason
Oct-14-2020 11:31:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 3	Initial Entry

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

Date	Location	User	Value	Reason
Oct-14-2020 11:31:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Tiffany Baum (pfe.tbaum)	Data Entry: Coronary artery disease	Initial Entry

I.c Start Date:

Date	Location	User	Value	Reason
Oct-14-2020 11:31:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Tiffany Baum (pfe.tbaum)	Data Entry: UNK/UNK/2015	Initial Entry

I.c Ongoing:

Date	Location	User	Value	Reason
Oct-14-2020 11:31:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Tiffany Baum (pfe.tbaum)	Data Entry: YES	Initial Entry

I.d

Date	Location	User	Value	Reason
Oct-14-2020 11:32:06 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 4 Medical History Term: Hypertension Start Date: UNK/UNK/ 1980 Ongoing: YES	Initial Entry

090177e196ae3fd1\Final\Final On: 01-Apr-2021 05:23 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1008

Subject No: 10081603

Generated By: pfe.levisse

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1008) Clinical Research Professionals Inc.

Subject Initials: ---

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

1.d Line/MH Number:

Date	Location	User	Value	Reason
Oct-14-2020 11:32:06 (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-14-2020 11:32:06 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Tiffany Baum (pfe.tbaum)	Data Entry: Hypertension	Initial Entry

1.d Start Date:

Date	Location	User	Value	Reason
Oct-14-2020 11:32:06 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Tiffany Baum (pfe.tbaum)	Data Entry: UNK/UNK/1980	Initial Entry

1.d Ongoing:

Date	Location	User	Value	Reason
Oct-14-2020 11:32:06 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Tiffany Baum (pfe.tbaum)	Data Entry: YES	Initial Entry

1.e

Date	Location	User	Value	Reason
Oct-14-2020 11:32:23 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 5 r: Medical History Term: High cholesterol Start Date: UNK/UNK/ 2014 Ongoing: YES	Initial Entry

090177e196ae3fd1\Final\Final On: 01-Apr-2021 05:23 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1008

Subject No: 10081603

Generated By: pfe.levisse

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1008) Clinical Research Professionals Inc.

Subject Initials: ---

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

I.e Line/MH Number:

Date	Location	User	Value	Reason
Oct-14-2020 11:32:23 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 5	Initial Entry

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

Date	Location	User	Value	Reason
Oct-14-2020 11:32:23 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Tiffany Baum (pfe.tbaum)	Data Entry: High cholesterol	Initial Entry

I.e Start Date:

Date	Location	User	Value	Reason
Oct-14-2020 11:32:23 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Tiffany Baum (pfe.tbaum)	Data Entry: UNK/UNK/2014	Initial Entry

I.e Ongoing:

Date	Location	User	Value	Reason
Oct-14-2020 11:32:23 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Tiffany Baum (pfe.tbaum)	Data Entry: YES	Initial Entry

090177e196ae3fd1\Final\Final On: 01-Apr-2021 05:23 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 15-Sep-2020 21:57

Site No: 1008

Subject No: 10081603

Generated By: pfe.levisse

Form: HIV STATUS - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1008) Clinical Research Professionals Inc.

Subject Initials: ---

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

[Back to Form](#)

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

Date	Location	User	Value	Reason
Oct-14-2020 11:34:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Tiffany Baum (pfe.tbaum)	Data Entry: The subject is NOT known to be HIV POSITIVE	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 10-Oct-2020 16:04

Site No: 1008

Subject No: 10081603

Generated By: pfe.levisse

Form: VITAL SIGNS - BASELINE - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1008) Clinical Research Professionals Inc.

Subject Initials: ---

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

[Back to Form](#)

1. Date:

Date	Location	User	Value	Reason
Oct-14-2020 11:30:32 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Tiffany Baum (pfe.tbaum)	Data Entry: Oct/14/2020	Initial Entry

2. Weight:

Date	Location	User	Value	Reason
Oct-14-2020 11:30:32 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Tiffany Baum (pfe.tbaum)	Data Entry: 202.6	Initial Entry

3. Unit:

Date	Location	User	Value	Reason
Oct-14-2020 11:30:32 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Tiffany Baum (pfe.tbaum)	Data Entry: LB	Initial Entry

4. Height:

Date	Location	User	Value	Reason
Oct-14-2020 11:30:32 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Tiffany Baum (pfe.tbaum)	Data Entry: 68.5	Initial Entry

5. Unit:

Date	Location	User	Value	Reason
Oct-14-2020 11:30:32 (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
------	----------	------	-------	--------

090177e196ae3fd1\Final\Final On: 01-Apr-2021 05:23 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 10-Oct-2020 16:04

Site No: 1008

Subject No: 10081603

Generated By: pfe.levisse

Form: VITAL SIGNS - BASELINE - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1008) Clinical Research Professionals Inc.

Subject Initials: ---

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

Oct-14-2020 11:30:32 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 30.4	Initial Entry
---	-----------------	-------------------------	----------------------------	---------------

7.a

Date	Location	User	Value	Reason
Oct-14-2020 11:30:32 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Tiffany Baum (pfe.tbaum)	Data Entry: Record Identifier:: 1 Temperature: 97.5 Temperature Unit: F Temperature Loca tion:: FOREHE AD	Initial Entry

7.a Record Identifier:

Date	Location	User	Value	Reason
Oct-14-2020 11:30:32 (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-14-2020 11:30:32 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Tiffany Baum (pfe.tbaum)	Data Entry: 97.5	Initial Entry

7.a Unit:

Date	Location	User	Value	Reason
Oct-14-2020 11:30:32 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Tiffany Baum (pfe.tbaum)	Data Entry: F	Initial Entry

7.a Temperature Location:

Date	Location	User	Value	Reason
Oct-14-2020 11:30:32 (UTC-06:00) Central	ACV0PFEINFP6000	Tiffany Baum	Data Entry: FOREHEAD	Initial Entry

090177e196ae3fd1\Final\Final On: 01-Apr-2021 05:23 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 10-Oct-2020 16:04

Site No: 1008

Subject No: 10081603

Generated By: pfe.levissc

Form: VITAL SIGNS - BASELINE - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1008) Clinical Research Professionals Inc.

Subject Initials: ---

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

Time (US & Canada)

(pfe.tbaum)

090177e196ae3fd1\Final\Final On: 01-Apr-2021 05:23 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1008

Subject No: 10081603

Generated By: pfe.levisse

Form: RANDOMIZATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1008) Clinical Research Professionals Inc.

Subject Initials: ---

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

[Back to Form](#)

1. Randomization Date :

Date	Location	User	Value	Reason
Oct-14-2020 13:55:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Tiffany Baum (pfe.tbaum)	Data Entry: Oct/14/2020	Initial Entry

2. Randomization Number:

Date	Location	User	Value	Reason
Oct-14-2020 13:55:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Tiffany Baum (pfe.tbaum)	Data Entry: 269278	Initial Entry

090177e196ae3fd1\Final\Final On: 01-Apr-2021 05:23 (GMT)

Header Text: c4591001**Visit:** V1_DAY1_VAX1_L**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY
- eCRF Audit Trail History**Form Version:** 22-Apr-2020 21:03**Form Status:** Data Complete, Locked, Frozen, Verified**Site No:** 1008**Site Name:** (1008) Clinical Research Professionals Inc.**Subject No:** 10081603**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
Oct-14-2020 11:54:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Oct-14-2020 11:54:39 (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-14-2020 11:54:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Oct-14-2020 11:54:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Oct-14-2020 11:54:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Tiffany Baum (pfe.tbaum)	Data Entry: YES Date of Collection: Oct/14/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Oct-14-2020 11:54:49 (UTC-06:00) Central	ACV0PFEINFP6000	Tiffany Baum	Data Entry: Sample ID: BGL5DZ	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1008

Site Name: (1008) Clinical Research Professionals Inc.

Subject No: 10081603

Subject Initials: ---

Generated By: pfe.levisse

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

Time (US & Canada)

(pfe.tbaum)

5.a Sample ID

Date	Location	User	Value	Reason
Oct-14-2020 11:54:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Tiffany Baum (pfe.tbaum)	Data Entry: BGL5DZ	Initial Entry

5.b

Date	Location	User	Value	Reason
Oct-14-2020 11:55:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Tiffany Baum (pfe.tbaum)	Data Entry: Sample ID: BPCV02	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Oct-14-2020 11:55:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Tiffany Baum (pfe.tbaum)	Data Entry: BPCV02	Initial Entry

5.c

Date	Location	User	Value	Reason
Oct-14-2020 11:55:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Tiffany Baum (pfe.tbaum)	Data Entry: Sample ID: BPCV03	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Oct-14-2020 11:55:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Tiffany Baum (pfe.tbaum)	Data Entry: BPCV03	Initial Entry

090177e196ae3fd1\Final\Final On: 01-Apr-2021 05:23 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1008

Site Name: (1008) Clinical Research Professionals Inc.

Subject No: 10081603

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
Oct-14-2020 12:49:03 (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-14-2020 12:49:03 (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-14-2020 12:49:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Oct-14-2020 12:49:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Oct-14-2020 12:49:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Cheyenne Brooks (pfe.cbrooms)	Data Entry: YES Date of Collection: Oct/14/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
------	----------	------	-------	--------

090177e196ae3fd1\Final\Final On: 01-Apr-2021 05:23 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1008

Site Name: (1008) Clinical Research Professionals Inc.

Subject No: 10081603

Subject Initials: ---

Generated By: pfe.levisse

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

Oct-14-2020 12:49:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Cheyenne Brooks (pfe.cbrooms)	Data Entry: Sample ID: BGL5BH	Initial Entry
---	-----------------	-------------------------------------	--	---------------

5.a Sample ID

Date	Location	User	Value	Reason
Oct-14-2020 12:49:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Cheyenne Brooks (pfe.cbrooms)	Data Entry: BGL5BH	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:04

Site No: 1008

Subject No: 10081603

Generated By: pfe.levisse

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1008) Clinical Research Professionals Inc.

Subject Initials: ---

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

[Back to Form](#)

1. Was there a temporary delay of vaccination?

Date	Location	User	Value	Reason
Oct-14-2020 13:55:37 (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-14-2020 13:55:37 (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-14-2020 13:55:37 (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
Oct-14-2020 13:55:37 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Tiffany Baum (pfe.tbaum)	Data Entry: Oct/14/2020 11:44	Initial Entry

5. Anatomical Location:

Date	Location	User	Value	Reason
Oct-14-2020 13:55:37 (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
------	----------	------	-------	--------

090177e196ae3fd1\Final\Final On: 01-Apr-2021 05:23 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:04

Site No: 1008

Subject No: 10081603

Generated By: pfe.levisse

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1008) Clinical Research Professionals Inc.

Subject Initials: ---

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

Oct-14-2020 13:55:37 (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-14-2020 13:55:37 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INTRAMUSCULAR	Initial Entry

10. Timeframe Subject Was Observed

Date	Location	User	Value	Reason
Oct-14-2020 13:55:37 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: THE PROTOCOL SPECIFIED OBSERVATION 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-14-2020 13:55:37 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Tiffany Baum (pfe.tbaum)	Data Entry: YES	Initial Entry

090177e196ae3fd1\Final\Final On: 01-Apr-2021 05:23 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 06-Jul-2020 21:53

Site No: 1008

Subject No: 10081603

Generated By: pfe.levisse

Form: REACTOGENICITY DIARY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1008) Clinical Research Professionals Inc.

Subject Initials: ---

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

[Back to Form](#)

1. Select appropriate response - Reactogenicity diary collection

Date	Location	User	Value	Reason
Oct-14-2020 10:53:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Tiffany Baum (pfe.tbaum)	Data Entry: NO - REACTOGENICITY E-D IARY NOT COLLECTED FOR THIS SUBJECT	Initial Entry

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 1008

Subject No: 10081603

Generated By: pfe.levisse

Form: DATE OF VISIT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1008) Clinical Research Professionals Inc.

Subject Initials: ---

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

[Back to Form](#)

1. Date of Visit

Date	Location	User	Value	Reason
Nov-05-2020 15:45:55 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Cheyenne Brooks (pfe.cbrooms)	Data Entry: Nov/5/2020	Initial Entry

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 10-Oct-2020 16:01

Site No: 1008

Subject No: 10081603

Generated By: pfe.levisse

Form: VITAL SIGNS - TEMP - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1008) Clinical Research Professionals Inc.

Subject Initials: ---

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

[Back to Form](#)

1. Date:

Date	Location	User	Value	Reason
Nov-05-2020 15:46:17 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Cheyenne Brooks (pfe.cbrooms)	Data Entry: Nov/5/2020	Initial Entry

2.a

Date	Location	User	Value	Reason
Nov-05-2020 15:46:17 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Cheyenne Brooks (pfe.cbrooms)	Data Entry: Record Identifier: 1 : Temperature: 97.6 Temperature Unit F : Temperature Loca FOREHE tion:: AD	Initial Entry

2.a Record Identifier:

Date	Location	User	Value	Reason
Nov-05-2020 15:46:17 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Cheyenne Brooks (pfe.cbrooms)	Data Entry: 1	Initial Entry

2.a Temperature:

Date	Location	User	Value	Reason
Nov-05-2020 15:46:17 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Cheyenne Brooks (pfe.cbrooms)	Data Entry: 97.6	Initial Entry

2.a Unit:

Date	Location	User	Value	Reason
Nov-05-2020 15:46:17 (UTC-06:00) Central	ACV0PFEINFP6000	Cheyenne Brooks	Data Entry: F	Initial Entry

090177e196ae3fd1\Final\Final On: 01-Apr-2021 05:23 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 10-Oct-2020 16:01

Site No: 1008

Subject No: 10081603

Generated By: pfe.levisse

Form: VITAL SIGNS - TEMP - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1008) Clinical Research Professionals Inc.

Subject Initials: ---

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

Time (US & Canada)		(pfe.cbrooms)		
--------------------	--	---------------	--	--

2.a Temperature Location:

Date	Location	User	Value	Reason
Nov-05-2020 15:46:17 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Cheyenne Brooks (pfe.cbrooms)	<u>Data Entry:</u> FOREHEAD	Initial Entry

Header Text: c4591001

Visit: V2_VAX2_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1008

Site Name: (1008) Clinical Research Professionals Inc.

Subject No: 10081603

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-05-2020 14:39:05 (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-05-2020 14:39:05 (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-05-2020 14:39:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Nov-05-2020 14:39:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Nov-05-2020 14:39:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Sherri Pangburn (pfe.spangburn)	Data Entry: YES Date of Collection: Nov/5/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
------	----------	------	-------	--------

090177e196ae3fd1\Final\Final On: 01-Apr-2021 05:23 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1008

Site Name: (1008) Clinical Research Professionals Inc.

Subject No: 10081603

Subject Initials: ---

Generated By: pfe.levisse

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

Nov-05-2020 14:39:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Sherri Pangburn (pfe.spangburn)	Data Entry: Sample ID: BRGV1M	Initial Entry
---	-----------------	---------------------------------------	--	---------------

5.a Sample ID

Date	Location	User	Value	Reason
Nov-05-2020 14:39:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Sherri Pangburn (pfe.spangburn)	Data Entry: BRGV1M	Initial Entry

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1008

Subject No: 10081603

Generated By: pfe.levisse

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1008) Clinical Research Professionals Inc.

Subject Initials: ---

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

[Back to Form](#)

1. Was there a temporary delay of vaccination?

Date	Location	User	Value	Reason
Nov-05-2020 15:46:47 (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-05-2020 15:46:47 (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-05-2020 15:46:47 (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
Nov-05-2020 15:46:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Cheyenne Brooks (pfe.cbrooms)	Data Entry: Nov/5/2020 15:06	Initial Entry

5. Anatomical Location:

Date	Location	User	Value	Reason
Nov-05-2020 15:46:47 (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
------	----------	------	-------	--------

090177e196ae3fd1\Final\Final On: 01-Apr-2021 05:23 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1008

Subject No: 10081603

Generated By: pfe.levisse

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1008) Clinical Research Professionals Inc.

Subject Initials: ---

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

Nov-05-2020 15:46:47 (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-05-2020 15:46:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INTRAMUSCULAR	Initial Entry

10. Timeframe Subject Was Observed

Date	Location	User	Value	Reason
Nov-05-2020 15:46:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: THE PROTOCOL SPECIFIED OBSERVATION 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-05-2020 15:46:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Cheyenne Brooks (pfe.cbrooms)	Data Entry: YES	Initial Entry

090177e196ae3fd1\Final\Final On: 01-Apr-2021 05:23 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 1008

Subject No: 10081603

Generated By: pfe.levisse

Form: DATE OF VISIT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1008) Clinical Research Professionals Inc.

Subject Initials: ---

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

[Back to Form](#)

1. Date of Visit

Date	Location	User	Value	Reason
Dec-03-2020 12:36:24 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Tiffany Baum (pfe.tbaum)	Data Entry: Dec/3/2020	Initial Entry

090177e196ae3fd1\Final\Final On: 01-Apr-2021 05:23 (GMT)

Header Text: c4591001**Visit:** V3_MONTH1_POSTVAX2_L**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY
- eCRF Audit Trail History**Form Version:** 22-Apr-2020 21:03**Form Status:** Data Complete, Locked, Frozen, Verified**Site No:** 1008**Site Name:** (1008) Clinical Research Professionals Inc.**Subject No:** 10081603**Subject Initials:** ---**Generated By:** pfe.levissc**Generated Time (GMT):** 29-Mar-2021 04:12[Back to Form](#)**1. Data Origin**

Date	Location	User	Value	Reason
Dec-03-2020 13:10:48 (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-03-2020 13:10:48 (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-03-2020 13:10:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Dec-03-2020 13:10:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Dec-03-2020 13:10:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Sherri Pangburn (pfe.spangburn)	Data Entry: YES Date of Collection: Dec/3/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
------	----------	------	-------	--------

Header Text: c4591001
Visit: V3_MONTH1_POSTVAX2_L **Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF Audit Trail History
Form Version: 22-Apr-2020 21:03 **Form Status:** Data Complete, Locked, Frozen, Verified
Site No: 1008 **Site Name:** (1008) Clinical Research Professionals Inc.
Subject No: 10081603 **Subject Initials:** ---
Generated By: pfe.levisse **Generated Time (GMT):** 29-Mar-2021 04:12

Dec-03-2020 13:10:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Sherri Pangburn (pfe.spangburn)	Data Entry: Sample ID: BRD9J6	Initial Entry
---	-----------------	---------------------------------------	--	---------------

5.a Sample ID

Date	Location	User	Value	Reason
Dec-03-2020 13:10:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Sherri Pangburn (pfe.spangburn)	Data Entry: BRD9J6	Initial Entry

5.b

Date	Location	User	Value	Reason
Dec-03-2020 13:11:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Sherri Pangburn (pfe.spangburn)	Data Entry: Sample ID: BRT3NS	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Dec-03-2020 13:11:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Sherri Pangburn (pfe.spangburn)	Data Entry: BRT3NS	Initial Entry

5.c

Date	Location	User	Value	Reason
Dec-03-2020 13:11:18 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Sherri Pangburn (pfe.spangburn)	Data Entry: Sample ID: BRT3NT	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Dec-03-2020 13:11:18 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Sherri Pangburn (pfe.spangburn)	Data Entry: BRT3NT	Initial Entry

090177e196ae3fd1\Final\Final On: 01-Apr-2021 05:23 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1008

Subject No: 10081603

Generated By: pfe.levissc

Form: ADVERSE EVENT REPORT - Audit Trail

Form Status:

Site Name: (1008) Clinical Research Professionals Inc.

Subject Initials: ---

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

[Back to Form](#)

Date	Location	User	Value	Reason
Nov-06-2020 17:55:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Ann Patek (pfe.apatek)	Form Created	

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1008

Subject No: 10081603

Generated By: pfe.levissc

Form: ADVERSE EVENT REPORT - Audit Trail

Form Status:

Site Name: (1008) Clinical Research Professionals Inc.

Subject Initials: ---

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

***** THIS REPEATING FORM HAS BEEN DELETED *****

[Back to Form](#)

Date	Location	User	Value	Reason
Dec-28-2020 13:31:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Ann Patek (pfe.apatek)	Form Deleted	New Information
Nov-06-2020 17:57:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Ann Patek (pfe.apatek)	Form Created	

090177e196ae3fd1\Final\Final On: 01-Apr-2021 05:23 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1008

Subject No: 10081603

Generated By: pfe.levissc

Form: ADVERSE EVENT REPORT - Audit Trail

Form Status:

Site Name: (1008) Clinical Research Professionals Inc.

Subject Initials: ---

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

[Back to Form](#)

Date	Location	User	Value	Reason
Nov-06-2020 17:59:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Ann Patek (pfe.apatek)	Form Created	

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1008

Subject No: 10081603

Generated By: pfe.levissc

Form: ADVERSE EVENT REPORT - Audit Trail

Form Status:

Site Name: (1008) Clinical Research Professionals Inc.

Subject Initials: ---

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

[Back to Form](#)

Date	Location	User	Value	Reason
Mar-11-2021 14:00:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Tiffany Baum (pfe.tbaum)	Form Created	

090177e196ae3fd1\Final\Final On: 01-Apr-2021 05:23 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1008

Subject No: 10081603

Generated By: pfe.levisse

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Frozen

Site Name: (1008) Clinical Research Professionals Inc.

Subject Initials: ---

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

[Back to Form](#)

1. Category:

Date	Location	User	Value	Reason
Nov-06-2020 17:55:05 (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
Nov-06-2020 17:55:05 (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
Nov-06-2020 17:55:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Ann Patek (pfe.apatek)	Data Entry: SCALP ABCESS	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason
Nov-09-2020 16:52:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 2: Closed	Response satisfies query
Nov-09-2020 15:39:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Ann Patek (pfe.apatek)	Query 2: Answered	scalp cyst began 9/2020, treated with bactrim start 09OCT2020, as noted, abcess began 26oct2020
Nov-09-2020 12:46:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 2: Opened	CLINICAL - SAE reports that the subject was receiving BACTRIM since

090177e196ae3fd1\Final\Final On: 01-Apr-2021 05:23 (GMT)

Header Text: c4591001**Visit:** Logs - Unscheduled**Form Version:** 22-Apr-2020 21:02**Site No:** 1008**Subject No:** 10081603**Generated By:** pfe.levisse**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History**Form Status:** Data Complete, Frozen**Site Name:** (1008) Clinical Research Professionals Inc.**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 04:12

				Sept as an outpt, prior to hospitalization on 26Oct20, for this scalp cyst. Please clarify if cyst infection had onset on 26Oct20.
Nov-06-2020 17:55:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Nov-06-2020 17:55:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Ann Patek (pfe.apatek)	Data Entry: Oct/26/2020 UNK:UNK	Transcription Error
Nov-06-2020 17:55:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	For SCALP ABCESS Start Date 26/Nov/2020, is a future date relative to when it was entered on 06/Nov/2020. Please correct.
Nov-06-2020 17:55:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Ann Patek (pfe.apatek)	Data Entry: Nov/26/2020 UNK:UNK	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Dec-23-2020 14:21:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Ann Patek (pfe.apatek)	Data Entry: NO End Date Time: Oct/27/2020 UNK:UNK	New Information
Nov-26-2020 09:14:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Juleen Gayed (pfe.gayedj)	Query 1: Closed	Response satisfies query
Nov-20-2020 11:20:38 (UTC-06:00) Central	ACV0PFEINFP6000	Tiffany Baum	Query 1: Answered	yes ongoing

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1008

Subject No: 10081603

Generated By: pfe.levisse

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Frozen

Site Name: (1008) Clinical Research Professionals Inc.

Subject Initials: ---

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

Time (US & Canada)		(pfe.tbaum)		
Nov-20-2020 11:14:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Juleen Gayed (pfe.gayedj)	Query 1: Opened	Clin: Please confirm if this AE is still ongoing
Nov-06-2020 17:55:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Ann Patek (pfe.apatek)	Data Entry: YES	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
Nov-06-2020 17:55:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Ann Patek (pfe.apatek)	Data Entry: 3	Initial Entry

7. Is the adverse event serious?

If Yes, NOTIFY PFIZER IMMEDIATELY.

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

Date	Location	User	Value	Reason
Jan-07-2021 16:46:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 3: Closed	Response satisfies query
Jan-05-2021 21:05:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Ricell Ann Piojo (pfe.quitor)	Query 2: Deleted	Query can be addressed internally
Dec-28-2020 13:36:02 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Ann Patek (pfe.apatek)	Query 3: Answered	as reported in follow up narrative, no other additional relevant labs/tests were performed/noted, which would include covid 19 testing

090177e196ae3fd1\Final\Final On: 01-Apr-2021 05:23 (GMT)

Header Text: c4591001**Visit:** Logs - Unscheduled**Form Version:** 22-Apr-2020 21:02**Site No:** 1008**Subject No:** 10081603**Generated By:** pfe.levisse**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History**Form Status:** Data Complete, Frozen**Site Name:** (1008) Clinical Research Professionals Inc.**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 04:12

Dec-25-2020 10:48:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 3: Opened	Clinical COVID test status (yes/no) during Hosp was not reported in the SAE. Per the DMC request please submit a SAE F/U [#2020437863] to document if COVID testing was performed (YES/NO or info not available) and if yes, the date and results
Dec-23-2020 14:21:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Candidate	For AE SCALP ABCESS: Response to "Is the adverse event serious?" is 'Yes' but "Serious Adverse Event Number" is blank.
Dec-23-2020 14:21:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Ann Patek (pfe.apatek)	Data Entry: YES Is this serious event associa ted with congenital anomal y or birth defect? NO Did this serious event result in death? NO Did this serious event requi re or prolong hospitalizatio n? YES Did this serious event result in persistent or significant d	New Information

Header Text: c4591001**Visit:** Logs - Unscheduled**Form Version:** 22-Apr-2020 21:02**Site No:** 1008**Subject No:** 10081603**Generated By:** pfe.levissc**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History**Form Status:** Data Complete, Frozen**Site Name:** (1008) Clinical Research Professionals Inc.**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 04:12

			isability/incapacity? NO Is this serious event life threatening? NO Other medically important serious event NO	
Nov-10-2020 10:58:54 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 1: Closed	Query closed; will follow for SAE update with the requested COVID test info
Nov-10-2020 08:26:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Tiffany Baum (pfe.tbaum)	Query 1: Answered	noted
Nov-09-2020 16:51:16 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 1: Reissued:Opened	Clinical - Thank you for your understanding. It is a request of the C4591001 independent Data Monitoring Committee to document the COVID testing status (YES/NO) for all hospitalized subjects, and Date/Result if YES.
Nov-09-2020 15:46:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Ann Patek (pfe.apatek)	Query 1: Answered	no covid testing was performed on this subject while hospitalized. It is a lot to ask the site to send in a FU SAE report to only report

Header Text: c4591001**Visit:** Logs - Unscheduled**Form Version:** 22-Apr-2020 21:02**Site No:** 1008**Subject No:** 10081603**Generated By:** pfe.levissc**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History**Form Status:** Data Complete, Frozen**Site Name:** (1008) Clinical Research Professionals Inc.**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 04:12

				whether a covid test was done or not, answering the query should suffice.
Nov-09-2020 14:19:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 1: Reissued:Opened	CLINICAL - C4591001 independent Data Monitoring Committee has requested a report of all COVID testing when hospitalized (YES/NO), and if date/results if YES. Clinical relevance is their overview; so occult cases are detected; etc.
Nov-09-2020 14:05:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Ann Patek (pfe.apatek)	Query 1: Answered	per SAE completion guidelines, site to report any clinically relevant lab test on SAE form, covid testing was not performed during this hospital stay as noted per discharge summary, no follow up SAE report required
Nov-09-2020 12:48:19 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 1: Opened	Clinical COVID test status (yes/no) during Hospitalization has not been reported in the SAE submitted to safety. Please submit a follow-up SAE form [#2020437863] to document if COVID

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1008

Subject No: 10081603

Generated By: pfe.levisse

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Frozen

Site Name: (1008) Clinical Research Professionals Inc.

Subject Initials: ---

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

				testing was performed (YES/NO) and if yes, the date and results.
Nov-06-2020 17:55:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Ann Patek (pfe.apatek)	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
Nov-06-2020 17:55:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Ann Patek (pfe.apatek)	Data Entry: NO	Initial Entry

9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Nov-06-2020 17:55:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Ann Patek (pfe.apatek)	Data Entry: NOT RELATED If Not Related to study treatment(s), this event is due to: OTHER <i>If Other, specify:</i> HISTORY SCALP CYST	Initial Entry

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Nov-06-2020 17:55:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Ann Patek (pfe.apatek)	Data Entry: NOT APPLICABLE	Initial Entry

11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
------	----------	------	-------	--------

090177e196ae3fd1\Final\Final On: 01-Apr-2021 05:23 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1008

Subject No: 10081603

Generated By: pfe.levisse

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Frozen

Site Name: (1008) Clinical Research Professionals Inc.

Subject Initials: ---

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

Nov-06-2020 17:55:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Ann Patek (pfe.apatek)	Data Entry: YES	Initial Entry
---	-----------------	---------------------------	---------------------------	---------------

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Nov-06-2020 17:55:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Ann Patek (pfe.apatek)	Data Entry: YES	Initial Entry

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

Date	Location	User	Value	Reason
Dec-23-2020 14:22:23 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Dec-23-2020 14:22:23 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Ann Patek (pfe.apatek)	Data Entry: RECOVERED/RESOLVED	New Information
Dec-23-2020 14:21:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	For AE SCALP ABCESS: Response to "What was the outcome of this adverse event?" is 'Not Recovered/Not Resolved' but AE End Date/Time is present.
Nov-06-2020 17:55:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Ann Patek (pfe.apatek)	Data Entry: NOT RECOVERED/NOT RE SOLVED	Initial Entry

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

Date	Location	User	Value	Reason
Nov-06-2020 17:55:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Ann Patek (pfe.apatek)	Data Entry: NO	Initial Entry

090177e196ae3fd1\Final\Final On: 01-Apr-2021 05:23 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1008

Subject No: 10081603

Generated By: pfe.levissc

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Frozen

Site Name: (1008) Clinical Research Professionals Inc.

Subject Initials: ---

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

15. Serious Adverse Event Number: For Pfizer Use Only

Date	Location	User	Value	Reason
Jan-05-2021 22:50:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Ricell Ann Piojo (pfe.quitor)	Data Entry: 2020437863	Initial Entry

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1008

Subject No: 10081603

Generated By: pfe.levissc

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Deleted

Site Name: (1008) Clinical Research Professionals Inc.

Subject Initials: ---

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

***** THIS REPEATING FORM HAS BEEN DELETED *****

[Back to Form](#)

1. Category:

Date	Location	User	Value	Reason
Nov-06-2020 17:57:07 (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
Nov-06-2020 17:57:07 (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
Nov-11-2020 20:48:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 1: Closed	Query closed; will follow for SAE update with the requested sepsis info
Nov-11-2020 08:16:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Ann Patek (pfe.apatek)	Query 1: Answered	per PI no other available test results per hospital records received, will update report with available vital signs
Nov-10-2020 11:05:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 1: Opened	CLINICAL - Please submit a SAE safety update with clinical documentation for sepsis (not only cellulitis),

090177e196ae3fd1\Final\Final On: 01-Apr-2021 05:23 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1008

Subject No: 10081603

Generated By: pfe.levisse

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Deleted

Site Name: (1008) Clinical Research Professionals Inc.

Subject Initials: ---

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

*** THIS REPEATING FORM HAS BEEN DELETED ***

				including cultures, vital signs, or other evidence of systemic sepsis
Nov-06-2020 17:57:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Ann Patek (pfe.apatek)	Data Entry: SEPSIS	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason
Nov-06-2020 17:57:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Ann Patek (pfe.apatek)	Data Entry: Oct/26/2020 UNK:UNK	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Nov-06-2020 17:57:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Ann Patek (pfe.apatek)	Data Entry: NO End Date Time: Nov/2/2020 UNK:UNK	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
Nov-06-2020 17:57:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Ann Patek (pfe.apatek)	Data Entry: 3	Initial Entry

7. Is the adverse event serious?

If Yes, NOTIFY PFIZER IMMEDIATELY.

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

Date	Location	User	Value	Reason
------	----------	------	-------	--------

090177e196ae3fd1\Final\Final On: 01-Apr-2021 05:23 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1008

Subject No: 10081603

Generated By: pfe.levissc

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Deleted

Site Name: (1008) Clinical Research Professionals Inc.

Subject Initials: ---

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

***** THIS REPEATING FORM HAS BEEN DELETED *****

Jan-07-2021 16:48:54 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 3: Closed	closing query on a deleted AE
Dec-28-2020 13:31:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Ann Patek (pfe.apatek)	Query 3: Answered	per updated information, sepsis to be removed
Dec-25-2020 10:46:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 3: Opened	Clinical Sepsis Event serious is reported as YES; however, SAE report has no SAE of Sepsis and reports that Sepsis workup was negative. Please review, harmonize reporting and update in the appropriate location.
Nov-09-2020 03:31:27 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Ricell Ann Piojo (pfe.quoter)	Query 2: Closed	event recorded in SDB
Nov-07-2020 11:05:37 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Ricell Ann Piojo (pfe.quoter)	Query 2: Opened	SAE RECON: SEPSIS(Onset date:26Oct2020) is not reported to Safety database but marked serious on AE CRF. Confirm seriousness and report to Pfizer immediately. If this event is not serious, downgrade the event on AE CRF
Nov-07-2020 11:04:54 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Ricell Ann Piojo (pfe.quoter)	Query 1: Deleted	Query can be addressed internally

090177e196ae3fd1\Final\Final On: 01-Apr-2021 05:23 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1008

Subject No: 10081603

Generated By: pfe.levissc

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Deleted

Site Name: (1008) Clinical Research Professionals Inc.

Subject Initials: ---

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

***** THIS REPEATING FORM HAS BEEN DELETED *****

Nov-06-2020 17:57:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	For AE SEPSIS: Response to "Is the adverse event serious?" is 'Yes' but "Serious Adverse Event Number" is blank.
Nov-06-2020 17:57:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Ann Patek (pfe.apatek)	<p>Data Entry: YES</p> <p>Is this serious event associated with congenital anomaly or birth defect?</p> <p>NO</p> <p>Did this serious event result in death?</p> <p>NO</p> <p>Did this serious event require or prolong hospitalization?</p> <p>YES</p> <p>Did this serious event result in persistent or significant disability/incapacity?</p> <p>NO</p> <p>Is this serious event life threatening?</p> <p>NO</p> <p>Other medically important serious event</p> <p>NO</p>	Initial Entry

090177e196ae3fd1\Final\Final On: 01-Apr-2021 05:23 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1008

Subject No: 10081603

Generated By: pfe.levisse

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Deleted

Site Name: (1008) Clinical Research Professionals Inc.

Subject Initials: ---

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

*** THIS REPEATING FORM HAS BEEN DELETED ***

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

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

Date	Location	User	Value	Reason
Nov-06-2020 17:57:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Ann Patek (pfe.apatek)	Data Entry: NO	Initial Entry

9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Nov-06-2020 17:57:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Ann Patek (pfe.apatek)	Data Entry: NOT RELATED If Not Related to study treatment(s), this event is due to: OTHER If Other, specify: SCALP ABCESS	Initial Entry

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Nov-06-2020 17:57:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Ann Patek (pfe.apatek)	Data Entry: NOT APPLICABLE	Initial Entry

11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
Nov-06-2020 17:57:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Ann Patek (pfe.apatek)	Data Entry: YES	Initial Entry

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
------	----------	------	-------	--------

090177e196ae3fd1\Final\Final On: 01-Apr-2021 05:23 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1008

Subject No: 10081603

Generated By: pfe.levisse

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Deleted

Site Name: (1008) Clinical Research Professionals Inc.

Subject Initials: ---

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

***** THIS REPEATING FORM HAS BEEN DELETED *****

Nov-06-2020 17:57:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Ann Patek (pfe.apatek)	Data Entry: NO	Initial Entry
---	-----------------	---------------------------	--------------------------	---------------

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

Date	Location	User	Value	Reason
Nov-06-2020 17:57:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Ann Patek (pfe.apatek)	Data Entry: RECOVERED/RESOLVED	Initial Entry

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

Date	Location	User	Value	Reason
Nov-06-2020 17:57:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Ann Patek (pfe.apatek)	Data Entry: NO	Initial Entry

15. Serious Adverse Event Number: For Pfizer Use Only

Date	Location	User	Value	Reason
Nov-09-2020 03:32:18 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Ricell Ann Piojo (pfe.quitor)	Data Entry: 2020437863	Initial Entry

090177e196ae3fd1\Final\Final On: 01-Apr-2021 05:23 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1008

Subject No: 10081603

Generated By: pfe.levissc

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Frozen

Site Name: (1008) Clinical Research Professionals Inc.

Subject Initials: ---

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

[Back to Form](#)

1. Category:

Date	Location	User	Value	Reason
Nov-06-2020 17:59:22 (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
Nov-06-2020 17:59:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 3	Initial Entry

3. Adverse Event:

(If possible specify diagnosis, not individual symptoms)

Date	Location	User	Value	Reason
Nov-06-2020 17:59:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Ann Patek (pfe.apatek)	Data Entry: CELLULITIS UPPER BACK	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason
Nov-06-2020 17:59:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Ann Patek (pfe.apatek)	Data Entry: Oct/26/2020 UNK:UNK	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Nov-06-2020 17:59:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Ann Patek (pfe.apatek)	Data Entry: NO End Date Time: Nov/2/2020 UNK:UNK	Initial Entry

6. Toxicity Grade:

090177e196ae3fd1\Final\Final On: 01-Apr-2021 05:23 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1008

Subject No: 10081603

Generated By: pfe.levisse

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Frozen

Site Name: (1008) Clinical Research Professionals Inc.

Subject Initials: ---

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

Date	Location	User	Value	Reason
Nov-06-2020 17:59:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Ann Patek (pfe.apatek)	Data Entry: 3	Initial Entry

7. Is the adverse event serious?

If Yes, NOTIFY PFIZER IMMEDIATELY.

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

Date	Location	User	Value	Reason
Nov-09-2020 03:32:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Ricell Ann Piojo (pfe.quitor)	Query 2: Closed	SDB entered in SDB
Nov-07-2020 11:06:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Ricell Ann Piojo (pfe.quitor)	Query 2: Opened	SAE RECON: CELLULITIS UPPER BACK(Onset date:26Oct2020) is not reported to Safety database but marked serious on AE CRF. Confirm seriousness and report to Pfizer immediately. If this event is not serious, downgrade the event on AE CRF
Nov-07-2020 11:05:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Ricell Ann Piojo (pfe.quitor)	Query 1: Deleted	Query can be addressed internally
Nov-06-2020 17:59:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	For AE CELLULITIS UPPER BACK: Response to "Is the adverse event serious?" is 'Yes' but

090177e196ae3fd1\Final\Final On: 01-Apr-2021 05:23 (GMT)

Header Text: c4591001
Visit: Logs - Unscheduled
Form Version: 22-Apr-2020 21:02
Site No: 1008
Subject No: 10081603
Generated By: pfe.levisse
Form: ADVERSE EVENT REPORT - eCRF Audit Trail History
Form Status: Data Complete, Frozen
Site Name: (1008) Clinical Research Professionals Inc.
Subject Initials: ---
Generated Time (GMT): 29-Mar-2021 04:12

				"Serious Adverse Event Number" is blank.
Nov-06-2020 17:59:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Ann Patek (pfe.apatek)	<p>Data Entry: YES</p> <p>Is this serious event associated with congenital anomaly or birth defect?</p> <p>NO</p> <p>Did this serious event result in death?</p> <p>NO</p> <p>Did this serious event require or prolong hospitalization?</p> <p>YES</p> <p>Did this serious event result in persistent or significant disability/incapacity?</p> <p>NO</p> <p>Is this serious event life threatening?</p> <p>NO</p> <p>Other medically important serious event</p> <p>NO</p>	Initial Entry

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

Date	Location	User	Value	Reason
Nov-06-2020 17:59:22 (UTC-06:00) Central	ACV0PFEINFP6000	Ann Patek (pfe.apatek)	<p>Data Entry: NO</p>	Initial Entry

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1008

Subject No: 10081603

Generated By: pfe.levissc

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Frozen

Site Name: (1008) Clinical Research Professionals Inc.

Subject Initials: ---

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

Time (US & Canada)

9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Nov-13-2020 00:12:04 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Astrud van der Merwe (pfe.vandea62)	Query 1 : Closed	AE#1
Nov-12-2020 08:02:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Tiffany Baum (pfe.tbaum)	Query 1 : Answered	scalp abcess is what caused the CELLULITIS UPPER BACK, so yes its not related to study treatment, and this is the condition that lead to CELLULITIS UPPER BACK
Nov-12-2020 03:39:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	PFE SDQ PROD (pfe.PFESDQ_PROD)	Query 1 : Opened	Please review "If not related to study treatment other" field, the following text was indicated in the comment field [scalp abcess]. Any symptoms, AEs or other key data should be collected on

090177e196ae3fd1\Final\Final On: 01-Apr-2021 05:23 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1008

Subject No: 10081603

Generated By: pfe.levissc

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Frozen

Site Name: (1008) Clinical Research Professionals Inc.

Subject Initials: ---

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

				the appropriate page. Please review and update as necessary. "[suryas18 SDQ=48342]"
Nov-06-2020 17:59:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Ann Patek (pfe.apatek)	Data Entry: NOT RELATED If Not Related to study treatment(s), this event is due to: OTHER <i>If Other; specify:</i> S C A L P A B C E S S	Initial Entry

090177e196ae3fd1\Final\Final On: 01-Apr-2021 05:23 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1008

Subject No: 10081603

Generated By: pfe.levisse

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Frozen

Site Name: (1008) Clinical Research Professionals Inc.

Subject Initials: ---

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

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Nov-06-2020 17:59:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Ann Patek (pfe.apatek)	Data Entry: NOT APPLICABLE	Initial Entry

11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
Nov-06-2020 17:59:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Ann Patek (pfe.apatek)	Data Entry: YES	Initial Entry

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Nov-06-2020 17:59:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Ann Patek (pfe.apatek)	Data Entry: NO	Initial Entry

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

Date	Location	User	Value	Reason
Nov-06-2020 17:59:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Ann Patek (pfe.apatek)	Data Entry: RECOVERED/RESOLVED	Initial Entry

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

Date	Location	User	Value	Reason
Nov-06-2020 17:59:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Ann Patek (pfe.apatek)	Data Entry: NO	Initial Entry

15. Serious Adverse Event Number: For Pfizer Use Only

Date	Location	User	Value	Reason
Nov-09-2020 03:32:55 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Ricell Ann Piojo (pfe.quitor)	Data Entry: 2020437863	Initial Entry

090177e196ae3fd1\Final\Final On: 01-Apr-2021 05:23 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1008

Subject No: 10081603

Generated By: pfe.levissc

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete

Site Name: (1008) Clinical Research Professionals Inc.

Subject Initials: ---

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

[Back to Form](#)

1. Category:

Date	Location	User	Value	Reason
Mar-11-2021 14:00:47 (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-11-2021 14:00:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 4	Initial Entry

3. Adverse Event:

(If possible specify diagnosis, not individual symptoms)

Date	Location	User	Value	Reason
Mar-11-2021 14:00:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Tiffany Baum (pfe.tbaum)	Data Entry: Surgical wound scalp	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason
Mar-11-2021 14:00:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Tiffany Baum (pfe.tbaum)	Data Entry: Oct/27/2020 UNK:UNK	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Mar-11-2021 14:16:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Tiffany Baum (pfe.tbaum)	Data Entry: NO End Date Time: Jan/21/2021 UNK:UNK	New Information
Mar-11-2021 14:00:47	ACV0PFEINFP6000	Tiffany	Data Entry:	Initial Entry

090177e196ae3fd1\Final\Final On: 01-Apr-2021 05:23 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1008

Subject No: 10081603

Generated By: pfe.levisse

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete

Site Name: (1008) Clinical Research Professionals Inc.

Subject Initials: ---

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

(UTC-06:00) Central Time (US & Canada)		Baum (pfe.tbaum)	YES	
--	--	------------------	-----	--

6. Toxicity Grade:

Date	Location	User	Value	Reason
Mar-11-2021 14:00:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Tiffany Baum (pfe.tbaum)	Data Entry: 2	Initial Entry

7. Is the adverse event serious?

If Yes, NOTIFY PFIZER IMMEDIATELY.

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

Date	Location	User	Value	Reason
Mar-11-2021 14:00:47 (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-11-2021 14:00:47 (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-11-2021 14:00:47 (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: OTHER If Other, specify:	Initial Entry

090177e196ae3fd1\Final\Final On: 01-Apr-2021 05:23 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1008

Subject No: 10081603

Generated By: pfe.levisse

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete

Site Name: (1008) Clinical Research Professionals Inc.

Subject Initials: ---

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

			Post I&D scalp abcess	
--	--	--	-----------------------	--

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Mar-11-2021 14:00:47 (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-11-2021 14:00:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Tiffany Baum (pfe.tbaum)	Data Entry: YES	Initial Entry

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Mar-11-2021 14:00:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Tiffany Baum (pfe.tbaum)	Data Entry: YES	Initial Entry

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

Date	Location	User	Value	Reason
Mar-11-2021 14:17:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Mar-11-2021 14:17:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Tiffany Baum (pfe.tbaum)	Data Entry: RECOVERED/RESOLVED	New Information
Mar-11-2021 14:16:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	For AE Surgical wound scalp: Response to "What was the outcome of this adverse event?" is 'Recovering/Resolving' but AE End Date/Time

090177e196ae3fd1\Final\Final On: 01-Apr-2021 05:23 (GMT)

Header Text: c4591001
Visit: Logs - Unscheduled
Form Version: 22-Apr-2020 21:02
Site No: 1008
Subject No: 10081603
Generated By: pfe.levissc

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History
Form Status: Data Complete
Site Name: (1008) Clinical Research Professionals Inc.
Subject Initials: ---
Generated Time (GMT): 29-Mar-2021 04:12

				is present.
Mar-11-2021 14:00:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Tiffany Baum (pfe.tbaum)	Data Entry: RECOVERING/RESOLVIN G	Initial Entry

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

Date	Location	User	Value	Reason
Mar-11-2021 14:00:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Tiffany Baum (pfe.tbaum)	Data Entry: NO	Initial Entry

090177e196ae3fd1\Final\Final On: 01-Apr-2021 05:23 (GMT)

Header Text: c4591001

Visit: End of Treatment - Unscheduled

Form: DISPOSITION - TREATMENT - eCRF Audit Trail History

Form Version: 15-Sep-2020 21:55

Form Status: Data Complete, Frozen, Verified

Site No: 1008

Site Name: (1008) Clinical Research Professionals Inc.

Subject No: 10081603

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
Dec-03-2020 12:36:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Tiffany Baum (pfe.tbaum)	Data Entry: Dec/3/2020	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Dec-03-2020 12:36:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: VACCINATION	Initial Entry

3. Status:

Date	Location	User	Value	Reason
Dec-03-2020 12:36:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Tiffany Baum (pfe.tbaum)	Data Entry: COMPLETED	Initial Entry

090177e196ae3fd1\Final\Final On: 01-Apr-2021 05:23 (GMT)

Header Text: c4591001

Visit: Potential ReVax Initial Contact -
Unscheduled

Form: DATE OF VISIT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen, Verified

Site No: 1008

Site Name: (1008) Clinical Research Professionals Inc.

Subject No: 10081603

Subject Initials: ---

Generated By: pfe.levisse

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

[Back to Form](#)

1. Date of Visit

Date	Location	User	Value	Reason
Jan-18-2021 08:46:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Sherri Pangburn (pfe.spangburn)	Data Entry: Jan/15/2021	Initial Entry

Header Text: c4591001

Visit: Potential ReVax Initial Contact -
Unscheduled

Form: FURTHER VACCINATION CONFIRMATION - 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: 10081603

Subject Initials: ---

Generated By: pfe.levisse

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-18-2021 08:47:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Jan-18-2021 08:46:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	The response indicates participant was unblinded, however the TREATMENT UNBLINDED date is missing in the DISP visit. Please complete this date.
Jan-18-2021 08:46:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Sherri Pangburn (pfe.spangburn)	Data Entry: 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	Initial Entry

090177e196ae3fd1\Final\Final On: 01-Apr-2021 05:23 (GMT)

Header Text: c4591001

Visit: Disposition - Unscheduled

Form: TREATMENT UNBLINDED - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1008

Site Name: (1008) Clinical Research Professionals Inc.

Subject No: 10081603

Subject Initials: ---

Generated By: pfe.levisse

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

[Back to Form](#)

1. Date Treatment Unblinded :

Date	Location	User	Value	Reason
Jan-18-2021 08:47:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Sherri Pangburn (pfe.spangburn)	Data Entry: Jan/15/2021	Initial Entry

2. Primary Reason for Unblinding:

Date	Location	User	Value	Reason
Jan-18-2021 08:47:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Sherri Pangburn (pfe.spangburn)	Data Entry: ASSESS ELIGIBILITY FOR ADDITIONAL VACCINATI ON	Initial Entry

090177e196ae3fd1\Final\Final On: 01-Apr-2021 05:23 (GMT)

Header Text: c4591001

Visit: V101_VAX3

Form Version: 22-Apr-2020 21:02

Site No: 1008

Subject No: 10081603

Generated By: pfe.levisse

Form: DATE OF VISIT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1008) Clinical Research Professionals Inc.

Subject Initials: ---

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

[Back to Form](#)

1. Date of Visit

Date	Location	User	Value	Reason
Jan-21-2021 15:12:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Tiffany Baum (pfe.tbaum)	Data Entry: Jan/21/2021	Initial Entry

Header Text: c4591001

Visit: V101_VAX3

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

Form Version: 10-Dec-2020 02:31

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1008

Site Name: (1008) Clinical Research Professionals Inc.

Subject No: 10081603

Subject Initials: ---

Generated By: pfe.levisse

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

[Back to Form](#)

1. Consent Was:

Date	Location	User	Value	Reason
Jan-21-2021 15:12:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Tiffany Baum (pfe.tbaum)	Data Entry: OBTAINED Date Written Consent Obtained Jan/21/2021	Initial Entry

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, Locked, Frozen, Verified

Site No: 1008

Site Name: (1008) Clinical Research Professionals Inc.

Subject No: 10081603

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
Jan-21-2021 15:12:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Tiffany Baum (pfe.tbaum)	Data Entry: Jan/21/2021	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Jan-21-2021 15:12:58 (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-21-2021 15:12:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Tiffany Baum (pfe.tbaum)	Data Entry: COMPLETED	Initial Entry

090177e196ae3fd1\Final\Final On: 01-Apr-2021 05:23 (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, Locked, Frozen, Verified**Site No:** 1008**Site Name:** (1008) Clinical Research Professionals Inc.**Subject No:** 10081603**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-21-2021 15:47:24 (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-21-2021 15:47:24 (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-21-2021 15:47:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Jan-21-2021 15:47:24 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Jan-21-2021 15:47:24 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Kim Ringling (pfe kringling)	Data Entry: YES Date of Collection: Jan/21/2021	Initial Entry

5.a

Date	Location	User	Value	Reason
------	----------	------	-------	--------

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, Locked, Frozen, Verified

Site No: 1008

Site Name: (1008) Clinical Research Professionals Inc.

Subject No: 10081603

Subject Initials: ---

Generated By: pfe.levisse

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

Jan-21-2021 15:47:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Kim Ringling (pfe kringling)	Data Entry: Sample ID: BRF0PW	Initial Entry
---	-----------------	---------------------------------	--	---------------

5.a Sample ID

Date	Location	User	Value	Reason
Jan-21-2021 15:47:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Kim Ringling (pfe kringling)	Data Entry: BRF0PW	Initial Entry

5.b

Date	Location	User	Value	Reason
Jan-21-2021 15:47:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Kim Ringling (pfe kringling)	Data Entry: Sample ID: BSJSG0	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Jan-21-2021 15:47:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Kim Ringling (pfe kringling)	Data Entry: BSJSG0	Initial Entry

5.c

Date	Location	User	Value	Reason
Jan-21-2021 15:48:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Kim Ringling (pfe kringling)	Data Entry: Sample ID: BSJSG1	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Jan-21-2021 15:48:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Kim Ringling (pfe kringling)	Data Entry: BSJSG1	Initial Entry

090177e196ae3fd1\Final\Final On: 01-Apr-2021 05:23 (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, Locked, Frozen, Verified**Site No:** 1008**Site Name:** (1008) Clinical Research Professionals Inc.**Subject No:** 10081603**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-21-2021 15:15:00 (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-21-2021 15:15:00 (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-21-2021 15:15:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Jan-21-2021 15:15:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Jan-21-2021 15:15:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Kim Ringling (pfe kringling)	Data Entry: YES Date of Collection: Jan/21/2021	Initial Entry

5.a

Date	Location	User	Value	Reason
------	----------	------	-------	--------

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, Locked, Frozen, Verified

Site No: 1008

Site Name: (1008) Clinical Research Professionals Inc.

Subject No: 10081603

Subject Initials: ---

Generated By: pfe.levisse

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

Jan-21-2021 15:15:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Kim Ringling (pfe kringling)	Data Entry: Sample ID: BRK9R7	Initial Entry
---	-----------------	---------------------------------	--	---------------

5.a Sample ID

Date	Location	User	Value	Reason
Jan-21-2021 15:15:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Kim Ringling (pfe kringling)	Data Entry: BRK9R7	Initial Entry

Header Text: c4591001

Visit: V101_VAX3

Form Version: 10-Dec-2020 02:26

Site No: 1008

Subject No: 10081603

Generated By: pfe.levisse

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1008) Clinical Research Professionals Inc.

Subject Initials: ---

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

[Back to Form](#)

1. Was there a temporary delay of vaccination?

Date	Location	User	Value	Reason
Jan-21-2021 15:13:13 (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-21-2021 15:13:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: BNT162b2	Initial Entry

3. Formulation:

Date	Location	User	Value	Reason
Jan-21-2021 15:13:13 (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
Jan-21-2021 15:13:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Tiffany Baum (pfe.tbaum)	Data Entry: Jan/21/2021 13:58	Initial Entry

5. Anatomical Location:

Date	Location	User	Value	Reason
Jan-21-2021 15:13:13 (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
------	----------	------	-------	--------

090177e196ae3fd1\Final\Final On: 01-Apr-2021 05:23 (GMT)

Header Text: c4591001

Visit: V101_VAX3

Form Version: 10-Dec-2020 02:26

Site No: 1008

Subject No: 10081603

Generated By: pfe.levisse

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1008) Clinical Research Professionals Inc.

Subject Initials: ---

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

Jan-21-2021 15:13:13 (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-21-2021 15:13:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INTRAMUSCULAR	Initial Entry

8. Actual Dose:

Date	Location	User	Value	Reason
Jan-21-2021 15:13:13 (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-21-2021 15:13:13 (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-21-2021 15:13:13 (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-21-2021 15:13:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Tiffany Baum (pfe.tbaum)	Data Entry: YES	Initial Entry

090177e196ae3fd1\Final\Final On: 01-Apr-2021 05:23 (GMT)

Header Text: c4591001

Visit: V102_VAX4

Form Version: 22-Apr-2020 21:02

Site No: 1008

Subject No: 10081603

Generated By: pfe.levisse

Form: DATE OF VISIT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1008) Clinical Research Professionals Inc.

Subject Initials: ---

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

[Back to Form](#)

1. Date of Visit

Date	Location	User	Value	Reason
Feb-11-2021 13:06:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Tiffany Baum (pfe.tbaum)	Data Entry: Feb/11/2021	Initial Entry

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, Locked, Frozen, Verified

Site No: 1008

Site Name: (1008) Clinical Research Professionals Inc.

Subject No: 10081603

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-11-2021 12:05:22 (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-11-2021 12:05:22 (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-11-2021 12:06:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Feb-11-2021 12:05:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Feb-11-2021 12:05:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Megan Felty (pfe.mfelty)	Data Entry: YES Date of Collection: Feb/11/2021	Initial Entry

5.a

Date	Location	User	Value	Reason
Feb-11-2021 12:06:08 (UTC-06:00) Central	ACV0PFEINFP6000	Megan Felty	Data Entry: Sample ID: BRG1VV	Initial Entry

090177e196ae3fd1\Final\Final On: 01-Apr-2021 05:23 (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, Locked, Frozen, Verified

Site No: 1008

Site Name: (1008) Clinical Research Professionals Inc.

Subject No: 10081603

Subject Initials: ---

Generated By: pfe.levisse

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

Time (US & Canada)

(pfe.mfelty)

5.a Sample ID

Date	Location	User	Value	Reason
Feb-11-2021 12:06:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Megan Felty (pfe.mfelty)	Data Entry: BRG1VV	Initial Entry

Header Text: c4591001

Visit: V102_VAX4

Form Version: 10-Dec-2020 02:26

Site No: 1008

Subject No: 10081603

Generated By: pfe.levisse

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1008) Clinical Research Professionals Inc.

Subject Initials: ---

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

[Back to Form](#)

1. Was there a temporary delay of vaccination?

Date	Location	User	Value	Reason
Feb-11-2021 13:07:04 (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-11-2021 13:07:04 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: BNT162b2	Initial Entry

3. Formulation:

Date	Location	User	Value	Reason
Feb-11-2021 13:07:04 (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
Feb-11-2021 13:07:04 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Tiffany Baum (pfe.tbaum)	Data Entry: Feb/11/2021 12:20	Initial Entry

5. Anatomical Location:

Date	Location	User	Value	Reason
Feb-11-2021 13:07:04 (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
------	----------	------	-------	--------

090177e196ae3fd1\Final\Final On: 01-Apr-2021 05:23 (GMT)

Header Text: c4591001

Visit: V102_VAX4

Form Version: 10-Dec-2020 02:26

Site No: 1008

Subject No: 10081603

Generated By: pfe.levisse

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1008) Clinical Research Professionals Inc.

Subject Initials: ---

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

Feb-11-2021 13:07:04 (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-11-2021 13:07:04 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INTRAMUSCULAR	Initial Entry

8. Actual Dose:

Date	Location	User	Value	Reason
Feb-11-2021 13:07:04 (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-11-2021 13:07:04 (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-11-2021 13:07:04 (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-11-2021 13:07:04 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Tiffany Baum (pfe.tbaum)	Data Entry: YES	Initial Entry

090177e196ae3fd1\Final\Final On: 01-Apr-2021 05:23 (GMT)

Header Text: c4591001

Visit: V103_MONTH1

Form Version: 22-Apr-2020 21:02

Site No: 1008

Subject No: 10081603

Generated By: pfe.levisse

Form: DATE OF VISIT - eCRF Audit Trail History

Form Status: Data Complete, 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-11-2021 13:41:27 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Sherri Pangburn (pfe.spangburn)	Data Entry: Mar/11/2021	Initial Entry

090177e196ae3fd1\Final\Final On: 01-Apr-2021 05:23 (GMT)

Header Text: c4591001

Visit: V103_MONTH1

Form Version: 22-Apr-2020 21:04

Site No: 1008

Subject No: 10081603

Generated By: pfe.levisse

Form: CONTACT OUTCOME - eCRF Audit Trail History

Form Status: Data Complete, Verified

Site Name: (1008) Clinical Research Professionals Inc.

Subject Initials: ---

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

[Back to Form](#)

1. Contact Type:

Date	Location	User	Value	Reason
Mar-11-2021 13:41:37 (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-11-2021 13:41:37 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Sherri Pangburn (pfe.spangburn)	Data Entry: YES Date of Contact: Mar/11/2021	Initial Entry

090177e196ae3fd1\Final\Final On: 01-Apr-2021 05:23 (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, Verified

Site No: 1008

Site Name: (1008) Clinical Research Professionals Inc.

Subject No: 10081603

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
Mar-11-2021 13:41:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Sherri Pangburn (pfe.spangburn)	Data Entry: Mar/11/2021	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Mar-11-2021 13:41:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: OPEN LABEL TREATMENT	Initial Entry

3. Status:

Date	Location	User	Value	Reason
Mar-11-2021 13:41:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Sherri Pangburn (pfe.spangburn)	Data Entry: COMPLETED	Initial Entry

090177e196ae3fd1\Final\Final On: 01-Apr-2021 05:23 (GMT)

Header Text: c4591001

Visit: Subject Status - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1008

Subject No: 10081603

Generated By: pfe.levisse

Form: SUBJECT STATUS - eCRF Audit Trail History

Form Status: Data Complete, Verified

Site Name: (1008) Clinical Research Professionals Inc.

Subject Initials: ---

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

[Back to Form](#)

1. Subject Status

Date	Location	User	Value	Reason
Dec-03-2020 12:36:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: FOLLOW-UP	Initial Entry
Oct-14-2020 13:55:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: ENROLLED/RANDOMIZED	Initial Entry
Oct-14-2020 10:53:31 (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
Dec-03-2020 12:36:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Dec/3/2020	Initial Entry
Oct-14-2020 13:55:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Oct/14/2020	Initial Entry
Oct-14-2020 10:53:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Oct/14/2020	Initial Entry

090177e196ae3fd1\Final\Final On: 01-Apr-2021 05:23 (GMT)

Header Text: c4591001

Visit: Investigator Signature - Unscheduled

Form: CASEBOOK SIGNATURE FORM - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Verified

Site No: 1008

Site Name: (1008) Clinical Research Professionals Inc.

Subject No: 10081603

Subject Initials: ---

Generated By: pfe.levisse

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

[Back to Form](#)

1. Casebook Signature

Date	Location	User	Value	Reason
Dec-03-2020 12:47:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Tiffany Baum (pfe.tbaum)	Data Entry: Click Here to Enable	Initial Entry

090177e196ae3fd1\Final\Final On: 01-Apr-2021 05:23 (GMT)