

Header Text: c4591001

Visit: COHORT_SELECTION

Form: COHORT_SELECTION

Form Version: 15-Sep-2020 21:55

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1008

Site Name: (1008) Clinical Research Professionals Inc.

Subject No: 10081337

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

090177e196ae3fd5\Final\Final On: 01-Apr-2021 05:24 (GMT)

Header Text: c4591001

Visit: COHORT_SELECTION

Form: MAIN INFORMED CONSENT

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1008

Site Name: (1008) Clinical Research Professionals Inc.

Subject No: 10081337

Subject Initials: ---

Generated By: pfe.levissc

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

[eCRF Audit Trail History](#)

Informed Consent

1.	Consent Was:	OBTAINED Date Written Consent Obtained Sep/15/2020
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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: 10081337

Subject Initials: ---

Generated By: pfe.levissc

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

[eCRF Audit Trail History](#)

Demography

1.	Subject ID	[10081337]
2.	Birth Date:	(b) (6) 1981
3.	Sex:	FEMALE
4.	Ethnicity:	NOT HISPANIC OR LATINO(A) OR OF SPANISH ORIGIN
5.	Race: (Check X all that apply):	WHITE
6.	Racial Designation:	

090177e196ae3fd5\Final\Final On: 01-Apr-2021 05:24 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:02

Site No: 1008

Subject No: 10081337

Generated By: pfe.lewissc

Form: DATE OF VISIT

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1008) Clinical Research Professionals Inc.

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Date of Visit

1.	Date of Visit	Sep/15/2020
2.	Erroneous Visit	

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 15-Sep-2020 21:53

Site No: 1008

Subject No: 10081337

Generated By: pfe.levissc

Form: INCLUSION/EXCLUSION CRITERIA

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1008) Clinical Research Professionals Inc.

Subject Initials: ---

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

Form Comments

Inclusion Criteria Not Met

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

Exclusion Criteria Met

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

090177e196ae3fd5\Final\Final On: 01-Apr-2021 05:24 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 15-Sep-2020 21:52

Site No: 1008

Subject No: 10081337

Generated By: pfe.levissc

Form: DISPOSITION - SCREENING

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1008) Clinical Research Professionals Inc.

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Disposition - Screening

1.	Date of Completion/Discontinuation /Death	Sep/15/2020
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: 10081337

Generated By: pfe.levissc

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:	[Seasonal allergies]
	Start Date:	UNK/UNK/2000
	Ongoing:	YES
1.b	Line/MH Number:	[2]
	Disease/Syndrome /Surgery/Non-Drug Allergies/Drug Allergies:	[Gastroesophageal reflux disease]
	Start Date:	UNK/UNK/2000
	Ongoing:	YES
1.c	Line/MH Number:	[3]
	Disease/Syndrome /Surgery/Non-Drug Allergies/Drug Allergies:	[Hypertension]
	Start Date:	UNK/UNK/2019
	Ongoing:	YES

090177e196ae3fd5\Final\Final On: 01-Apr-2021 05:24 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: GENERAL MEDICAL HISTORY

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1008

Site Name: (1008) Clinical Research Professionals Inc.

Subject No: 10081337

Subject Initials: ---

Generated By: pfe.levisse

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

1.d	Line/MH Number:	[4]
	Disease/Syndrome /Surgery/Non-Drug Allergies/Drug Allergies:	[Generalized anxiety disorder]
	Start Date:	UNK/UNK/2010
	Ongoing:	YES

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 15-Sep-2020 21:57

Site No: 1008

Subject No: 10081337

Generated By: pfe.levissc

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
----	--	---

090177e196ae3fd5\Final\Final On: 01-Apr-2021 05:24 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: VITAL SIGNS - BASELINE

Form Version: 15-Sep-2020 21:56

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1008

Site Name: (1008) Clinical Research Professionals Inc.

Subject No: 10081337

Subject Initials: ---

Generated By: pfe.levissc

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

eCRF Audit Trail History

Vital Signs

1.	Date:	Sep/15/2020
2.	Weight:	[174.6]
3.	Unit:	LB
4.	Height:	[64.0]
5.	Unit:	in
6.	Body Mass Index:	[30.0]

Vital Signs Details

7.a	Record Identifier:	1
	Temperature:	[97.4]
	Unit:	F
	Temperature Location:	FOREHEAD

090177e196ae3fd5\Final\Final On: 01-Apr-2021 05:24 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 15-Sep-2020 21:51

Site No: 1008

Subject No: 10081337

Generated By: pfe.levissc

Form: LAB URINALYSIS - PREGNANCY TEST

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](#)

Lab Urinalysis

1.	Lab Panel:	URINALYSIS
2.	Lab Sub-Panel:	PREGNANCY
3.	Collection Date:	Sep/15/2020
4.	Laboratory Name and Address (Derived)	[STUDY SITE]
5.	Specimen Type:	URINE

Lab Result

6.a	Sponsor ID:	[113]
	Test:	Choriogonadotropin Beta_PX113
	Result:	NEGATIVE
	Not Done:	

090177e196ae3fd5\Final\Final On: 01-Apr-2021 05:24 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1008

Subject No: 10081337

Generated By: pfe.levissc

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 :	Sep/15/2020
2.	Randomization Number:	[90313]
3.	Randomization Group:	[]

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1008

Site Name: (1008) Clinical Research Professionals Inc.

Subject No: 10081337

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: Sep/15/2020
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	[BPTR2N]
5.b	Sample ID	[BPRLF7]
5.c	Sample ID	[BPRLF8]

090177e196ae3fd5\Final\Final On: 01-Apr-2021 05:24 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1008

Site Name: (1008) Clinical Research Professionals Inc.

Subject No: 10081337

Subject Initials: ---

Generated By: pfe.levissc

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

[eCRF Audit Trail History](#)

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Sep/15/2020
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	[BPTR5P]
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090177e196ae3fd5\Final\Final On: 01-Apr-2021 05:24 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:04

Site No: 1008

Subject No: 10081337

Generated By: pfe.levissc

Form: VACCINATION

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1008) Clinical Research Professionals Inc.

Subject Initials: ---

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

eCRF Audit Trail History

Vaccination

1.	Was there a temporary delay of vaccination?	NO
2.	Treatment Name	[BLINDED THERAPY]
3.	Formulation:	INJECTION
4.	Dose Date Time:	Sep/15/2020 11:36
5.	Anatomical Location:	DELTOID MUSCLE
6.	Body Side:	LEFT
7.	Route:	INTRAMUSCULAR
8.	Actual Dose:	[]
9.	Unit:	
10.	Timeframe Subject Was Observed	THE PROTOCOL SPECIFIED OBSERVATION PERIOD
11.	Was the subject observed for at least the protocol specified observation period after investigational product administration?	YES

090177e196ae3fd5\Final\Final On: 01-Apr-2021 05:24 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 06-Jul-2020 21:53

Site No: 1008

Subject No: 10081337

Generated By: pfe.levissc

Form: REACTOGENICITY DIARY

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1008) Clinical Research Professionals Inc.

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Reactogenicity Diary

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

Visit: V2_VAX2_L

Form: DATE OF VISIT

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1008

Site Name: (1008) Clinical Research Professionals Inc.

Subject No: 10081337

Subject Initials: ---

Generated By: pfe.levissc

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

[eCRF Audit Trail History](#)

Date of Visit

1.	Date of Visit	Oct/6/2020
2.	Erroneous Visit	

090177e196ae3fd5\Final\Final On: 01-Apr-2021 05:24 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form: VITAL SIGNS - TEMP

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: 10081337

Subject Initials: ---

Generated By: pfe.levissc

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

[eCRF Audit Trail History](#)

Vital Signs

1.	Date:	Oct/6/2020
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Vital Signs Details

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

090177e196ae3fd5\Final\Final On: 01-Apr-2021 05:24 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 15-Sep-2020 21:51

Site No: 1008

Subject No: 10081337

Generated By: pfe.levissc

Form: LAB URINALYSIS - PREGNANCY TEST

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

Lab Urinalysis

1.	Lab Panel:	URINALYSIS
2.	Lab Sub-Panel:	PREGNANCY
3.	Collection Date:	Oct/6/2020
4.	Laboratory Name and Address (Derived)	[STUDY SITE]
5.	Specimen Type:	URINE

Lab Result

6.a	Sponsor ID:	[113]
	Test:	Choriogonadotropin Beta_PX113
	Result:	NEGATIVE
	Not Done:	

090177e196ae3fd5\Final\Final On: 01-Apr-2021 05:24 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1008

Site Name: (1008) Clinical Research Professionals Inc.

Subject No: 10081337

Subject Initials: ---

Generated By: pfe.levisse

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

[eCRF Audit Trail History](#)

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Oct/6/2020
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	[BGL568]
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090177e196ae3fd5\Final\Final On: 01-Apr-2021 05:24 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1008

Subject No: 10081337

Generated By: pfe.levissc

Form: VACCINATION

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1008) Clinical Research Professionals Inc.

Subject Initials: ---

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

eCRF Audit Trail History

Vaccination

1.	Was there a temporary delay of vaccination?	NO
2.	Treatment Name	[BLINDED THERAPY]
3.	Formulation:	INJECTION
4.	Dose Date Time:	Oct/6/2020 09:10
5.	Anatomical Location:	DELTOID MUSCLE
6.	Body Side:	LEFT
7.	Route:	INTRAMUSCULAR
8.	Actual Dose:	[]
9.	Unit:	
10.	Timeframe Subject Was Observed	THE PROTOCOL SPECIFIED OBSERVATION PERIOD
11.	Was the subject observed for at least the protocol specified observation period after investigational product administration?	YES

090177e196ae3fd5\Final\Final On: 01-Apr-2021 05:24 (GMT)

Header Text: c4591001

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

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

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

Subject No: 10081337 **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	Nov/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: 10081337 **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: Nov/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	[BPZ8KV]
5.b	Sample ID	[BRZD6C]
5.c	Sample ID	[BRZD6D]

090177e196ae3fd5\Final\Final On: 01-Apr-2021 05:24 (GMT)

Header Text: c4591001

Visit: V4_MONTH6_L

Form Version: 22-Apr-2020 21:02

Site No: 1008

Subject No: 10081337

Generated By: pfe.lewissc

Form: DATE OF VISIT

Form Status: Not Started

Site Name: (1008) Clinical Research Professionals Inc.

Subject Initials: ---

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

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

Header Text: c4591001

Visit: V4_MONTH6_L

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1008

Site Name: (1008) Clinical Research Professionals Inc.

Subject No: 10081337

Subject Initials: ---

Generated By: pfe.levissc

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

Electronic Sample Tracking

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

Aliquot

Please enter barcode for each aliquot.

5.	Sample ID	[]
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090177e196ae3fd5\Final\Final On: 01-Apr-2021 05:24 (GMT)

Header Text: c4591001

Visit: V5_MONTH12_L

Form Version: 22-Apr-2020 21:02

Site No: 1008

Subject No: 10081337

Generated By: pfe.lewissc

Form: DATE OF VISIT

Form Status: Not Started

Site Name: (1008) Clinical Research Professionals Inc.

Subject Initials: ---

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

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

Header Text: c4591001

Visit: V5_MONTH12_L

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1008

Site Name: (1008) Clinical Research Professionals Inc.

Subject No: 10081337

Subject Initials: ---

Generated By: pfe.lewissc

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

Electronic Sample Tracking

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

Aliquot

Please enter barcode for each aliquot.

5.	Sample ID	[]
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090177e196ae3fd5\Final\Final On: 01-Apr-2021 05:24 (GMT)

Header Text: c4591001

Visit: V6_MONTH24_L

Form Version: 22-Apr-2020 21:02

Site No: 1008

Subject No: 10081337

Generated By: pfe.lewissc

Form: DATE OF VISIT

Form Status: Not Started

Site Name: (1008) Clinical Research Professionals Inc.

Subject Initials: ---

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

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

Header Text: c4591001

Visit: V6_MONTH24_L

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1008

Site Name: (1008) Clinical Research Professionals Inc.

Subject No: 10081337

Subject Initials: ---

Generated By: pfe.levissc

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

Electronic Sample Tracking

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

Aliquot

Please enter barcode for each aliquot.

5.	Sample ID	[]
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090177e196ae3fd5\Final\Final On: 01-Apr-2021 05:24 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL - New
Unscheduled Visit

Form: DATE OF VISIT - ILLNESS ONSET

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1008

Site Name: (1008) Clinical Research Professionals Inc.

Subject No: 10081337

Subject Initials: ---

Generated By: pfe.lewissc

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

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

COVID-19 Illness Visit

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

Visit: POT_COVID_ILL - New
Unscheduled Visit

Form Version: 20-Feb-2021 02:17

Site No: 1008

Subject No: 10081337

Generated By: pfe.lewissc

Form: SIGNS AND SYMPTOMS OF POTENTIAL
COVID-19

Form Status: Not Started

Site Name: (1008) Clinical Research Professionals Inc.

Subject Initials: ---

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

Signs and Symptoms

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

Symptoms

4.	Symptoms:	
	Was symptom present?	

Symptoms - Other

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

090177e196ae3fd5\Final\Final On: 01-Apr-2021 05:24 (GMT)

Header Text: c4591001**Visit:** POT_COVID_ILL - New
Unscheduled Visit**Form:** ELECTRONIC SAMPLE TRACKING - NASAL
SWAB SELF**Form Version:** 22-Apr-2020 21:03**Form Status:** Not Started**Site No:** 1008**Site Name:** (1008) Clinical Research Professionals Inc.**Subject No:** 10081337**Subject Initials:** ---**Generated By:** pfe.levissc**Generated Time (GMT):** 29-Mar-2021 04:12**Electronic Sample Tracking**

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

Aliquot

Please enter barcode for each aliquot.

5.	Sample ID	[]
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Header Text: c4591001

Visit: POT_COVID_ILL - New
Unscheduled Visit

Form: ELECTRONIC SAMPLE TRACKING - NASAL
SWAB

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1008

Site Name: (1008) Clinical Research Professionals Inc.

Subject No: 10081337

Subject Initials: ---

Generated By: pfe.lewissc

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

Electronic Sample Tracking

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

Aliquot

Please enter barcode for each aliquot.

5.	Sample ID	[]
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090177e196ae3fd5\Final\Final On: 01-Apr-2021 05:24 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL - New
Unscheduled Visit

Form: HEALTH CARE UTILIZATION

Form Version: 20-Feb-2021 02:19

Form Status: Not Started

Site No: 1008

Site Name: (1008) Clinical Research Professionals Inc.

Subject No: 10081337

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?	
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090177e196ae3fd5\Final\Final On: 01-Apr-2021 05:24 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL - New
Unscheduled Visit

Form: ILLNESS DETAILS

Form Version: 06-Jul-2020 21:52

Form Status: Not Started

Site No: 1008

Site Name: (1008) Clinical Research Professionals Inc.

Subject No: 10081337

Subject Initials: ---

Generated By: pfe.lewissc

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

Illness Details

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

Header Text: c4591001

Visit: POT_COVID_CONVA - New
Unscheduled Visit

Form: DATE OF VISIT - ILLNESS CONVALESCENT

Form Version: 22-Apr-2020 21:04

Form Status: Not Started

Site No: 1008

Site Name: (1008) Clinical Research Professionals Inc.

Subject No: 10081337

Subject Initials: ---

Generated By: pfe.lewissc

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

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

COVID-19 Illness Visit

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

Header Text: c4591001

Visit: POT_COVID_CONVA - New
Unscheduled Visit

Form: ELECTRONIC SAMPLE TRACKING -
IMMUNOGENICITY

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1008

Site Name: (1008) Clinical Research Professionals Inc.

Subject No: 10081337

Subject Initials: ---

Generated By: pfe.lewissc

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

Electronic Sample Tracking

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

Aliquot

Please enter barcode for each aliquot.

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

090177e196ae3fd5\Final\Final On: 01-Apr-2021 05:24 (GMT)

Header Text: c4591001

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

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

Site No: 1008

Site Name: (1008) Clinical Research Professionals Inc.

Subject No: 10081337

Subject Initials: ---

Generated By: pfe.lewissc

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

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

COVID-19 Repeat Swab

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

Header Text: c4591001

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

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

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

Subject No: 10081337 **Subject Initials:** ---

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

Electronic Sample Tracking

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

Aliquot

Please enter barcode for each aliquot.

5.	Sample ID	[]
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090177e196ae3fd5\Final\Final On: 01-Apr-2021 05:24 (GMT)

Header Text: c4591001

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

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

Site No: 1008

Site Name: (1008) Clinical Research Professionals Inc.

Subject No: 10081337

Subject Initials: ---

Generated By: pfe.lewissc

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

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

Header Text: c4591001

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

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

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

Subject No: 10081337 **Subject Initials:** ---

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

Unplanned Assessments

1.	Assessments	
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090177e196ae3fd5\Final\Final On: 01-Apr-2021 05:24 (GMT)

Header Text: c4591001

Visit: Logs

Form: ADVERSE EVENT REPORT

Form Version: 22-Apr-2020 21:02

Site No: 1008

Site Name: (1008) Clinical Research Professionals Inc.

Subject No: 10081337

Subject Initials: ---

Generated By: pfe.levisse

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

#	Category	AE Identifier	Adverse Event	Start Date	Is the Adverse Event Still Ongoing	Form Instance
1.	ADVERSE EVENT	1	Injection site pain	Sep/16/2020 UNK:UNK	NO End Date Time: Sep/17/2020 UN K:UNK	Repeating Pages
2.	ADVERSE EVENT	2	Injection site pain	Oct/7/2020 UNK:UNK	NO End Date Time: Oct/8/2020 UN K:UNK	Repeating Pages
3.	ADVERSE EVENT	3	Body aches	Oct/7/2020 UNK:UNK	NO End Date Time: Oct/9/2020 UN K:UNK	Repeating Pages
4.	ADVERSE EVENT	4	EXPOSURE DURING PREGNANCY	Dec/23/2020 UNK:UNK	YES	Repeating Pages

090177e196ae3fd5\Final\Final On: 01-Apr-2021 05:24 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Locked, Frozen

Site No: 1008

Site Name: (1008) Clinical Research Professionals Inc.

Subject No: 10081337

Subject Initials: ---

Generated By: pfe.levisse

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

[Back to Form](#)

[eCRF Audit Trail History](#)

[Form Audit Trail](#)

Adverse Event Report

1.	Category:	ADVERSE EVENT
2.	AE ID:	[1]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[Injection site pain]
4.	Start Date Time:	Sep/16/2020 UNK:UNK
5.	Is the adverse event still ongoing?	NO End Date Time: Sep/17/2020 UNK:UNK
6.	Toxicity Grade:	1

090177e196ae3fd5\Final\Final On: 01-Apr-2021 05:24 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Locked, Frozen

Site No: 1008

Site Name: (1008) Clinical Research Professionals Inc.

Subject No: 10081337

Subject Initials: ---

Generated By: pfe.levisse

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

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

090177e196ae3fd5\Final\Final On: 01-Apr-2021 05:24 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Locked, Frozen

Site No: 1008

Site Name: (1008) Clinical Research Professionals Inc.

Subject No: 10081337

Subject Initials: ---

Generated By: pfe.levisse

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

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

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1008

Subject No: 10081337

Generated By: pfe.levissc

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Locked, 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:	[2]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[Injection site pain]
4.	Start Date Time:	Oct/7/2020 UNK:UNK
5.	Is the adverse event still ongoing?	NO End Date Time: Oct/8/2020 UNK:UNK
6.	Toxicity Grade:	1

090177e196ae3fd5\Final\Final On: 01-Apr-2021 05:24 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Locked, Frozen

Site No: 1008

Site Name: (1008) Clinical Research Professionals Inc.

Subject No: 10081337

Subject Initials: ---

Generated By: pfe.levisse

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

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

090177e196ae3fd5\Final\Final On: 01-Apr-2021 05:24 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Locked, Frozen

Site No: 1008

Site Name: (1008) Clinical Research Professionals Inc.

Subject No: 10081337

Subject Initials: ---

Generated By: pfe.levisse

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

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

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1008

Subject No: 10081337

Generated By: pfe.levissc

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Locked, 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)	[Body aches]
4.	Start Date Time:	Oct/7/2020 UNK:UNK
5.	Is the adverse event still ongoing?	NO End Date Time: Oct/9/2020 UNK:UNK
6.	Toxicity Grade:	1

090177e196ae3fd5\Final\Final On: 01-Apr-2021 05:24 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1008

Subject No: 10081337

Generated By: pfe.levisse

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Locked, Frozen

Site Name: (1008) Clinical Research Professionals Inc.

Subject Initials: ---

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

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

090177e196ae3fd5\Final\Final On: 01-Apr-2021 05:24 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Locked, Frozen

Site No: 1008

Site Name: (1008) Clinical Research Professionals Inc.

Subject No: 10081337

Subject Initials: ---

Generated By: pfe.levisse

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

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

090177e196ae3fd5\Final\Final On: 01-Apr-2021 05:24 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1008

Subject No: 10081337

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)	[EXPOSURE DURING PREGNANCY]	
4.	Start Date Time:	Dec/23/2020 UNK:UNK	
5.	Is the adverse event still ongoing?	YES	
6.	Toxicity Grade:	Not Applicable	Comments

090177e196ae3fd5\Final\Final On: 01-Apr-2021 05:24 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete

Site No: 1008

Site Name: (1008) Clinical Research Professionals Inc.

Subject No: 10081337

Subject Initials: ---

Generated By: pfe.levisse

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

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

090177e196ae3fd5\Final\Final On: 01-Apr-2021 05:24 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete

Site No: 1008

Site Name: (1008) Clinical Research Professionals Inc.

Subject No: 10081337

Subject Initials: ---

Generated By: pfe.lewissc

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

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

090177e196ae3fd5\Final\Final On: 01-Apr-2021 05:24 (GMT)

Header Text: c4591001

Visit: Logs

Form: MEDICATION ERROR

Form Version: 17-Jul-2020 21:54

Site No: 1008

Site Name: (1008) Clinical Research Professionals Inc.

Subject No: 10081337

Subject Initials: ---

Generated By: pfe.levissc

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

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

Header Text: c4591001

Visit: Logs - Unscheduled

Form: MEDICATION ERROR

Form Version: 17-Jul-2020 21:54

Form Status: Not Started

Site No: 1008

Site Name: (1008) Clinical Research Professionals Inc.

Subject No: 10081337

Subject Initials: ---

Generated By: pfe.levisse

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

[Back to Form](#)

Medication Error

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

090177e196ae3fd5\Final\Final On: 01-Apr-2021 05:24 (GMT)

Header Text: c4591001

Visit: Logs

Form: CONCOMITANT MEDICATIONS - NON
STUDY VACCINATIONS

Form Version: 22-Apr-2020 21:03

Site No: 1008

Site Name: (1008) Clinical Research Professionals Inc.

Subject No: 10081337

Subject Initials: ---

Generated By: pfe.lewissc

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

#	Sponsor-Defined Identifier	Category of Medication	Concomitant Medications Pre-specified	Name of Medication	Start Date	Form Instance
1.	1	VACCINATIONS	NO	Quadrivalent flu vaccine prophylaxis intramuscular 0.5 ml once	Oct/21/2020	Repeating Pages

090177e196ae3fd5\Final\Final On: 01-Apr-2021 05:24 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - NON STUDY VACCINATIONS

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1008

Site Name: (1008) Clinical Research Professionals Inc.

Subject No: 10081337

Subject Initials: ---

Generated By: pfe.lewissc

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

[Back to Form](#)

[eCRF Audit Trail History](#)

[Form Audit Trail](#)

Concomitant Medications

1.	What is the medication identifier?	[1]
2.	Category:	VACCINATIONS
3.	Concomitant Medications Pre-specified:	NO
4.	Medication: Provide the complete generic drug name (including salt form, where applicable). Where generic name is unknown, enter the full trade or proprietary name. Include clarifying information in the Medication text (e.g., Ingredient(s), route, use, formulation).	[Quadrivalent flu vaccine prophylaxis intramuscular 0.5 ml once]
5.	Date:	Oct/21/2020

090177e196ae3fd5\Final\Final On: 01-Apr-2021 05:24 (GMT)

Header Text: c4591001

Visit: Logs

Form: CONCOMITANT MEDICATIONS - PROHIBITED

Form Version: 22-Apr-2020 21:03

Site No: 1008

Site Name: (1008) Clinical Research Professionals Inc.

Subject No: 10081337

Subject Initials: ---

Generated By: pfe.lewissc

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

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

090177e196ae3fd5\Final\Final On: 01-Apr-2021 05:24 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - PROHIBITED

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1008

Site Name: (1008) Clinical Research Professionals Inc.

Subject No: 10081337

Subject Initials: ---

Generated By: pfe.lewissc

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

[Back to Form](#)

Concomitant Medications

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

090177e196ae3fd5\Final\Final On: 01-Apr-2021 05:24 (GMT)

Header Text: c4591001

Visit: Logs

Form: RADIATION TREATMENT

Form Version: 22-Apr-2020 21:02

Site No: 1008

Site Name: (1008) Clinical Research Professionals Inc.

Subject No: 10081337

Subject Initials: ---

Generated By: pfe.levissc

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

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

090177e196ae3fd5\Final\Final On: 01-Apr-2021 05:24 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: RADIATION TREATMENT

Form Version: 22-Apr-2020 21:02

Form Status: Not Started

Site No: 1008

Site Name: (1008) Clinical Research Professionals Inc.

Subject No: 10081337

Subject Initials: ---

Generated By: pfe.levisse

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

[Back to Form](#)

Radiation Treatment

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

090177e196ae3fd5\Final\Final On: 01-Apr-2021 05:24 (GMT)

Header Text: c4591001

Visit: Logs

Form: TRANSFUSIONS

Form Version: 22-Apr-2020 21:03

Site No: 1008

Site Name: (1008) Clinical Research Professionals Inc.

Subject No: 10081337

Subject Initials: ---

Generated By: pfe.levissc

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

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

090177e196ae3fd5\Final\Final On: 01-Apr-2021 05:24 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: TRANSFUSIONS

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1008

Site Name: (1008) Clinical Research Professionals Inc.

Subject No: 10081337

Subject Initials: ---

Generated By: pfe.levisse

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

[Back to Form](#)

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

Header Text: c4591001

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

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

Site No: 1008

Site Name: (1008) Clinical Research Professionals Inc.

Subject No: 10081337

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 :	Nov/3/2020
2.	Phase of Disposition:	VACCINATION
3.	Status:	COMPLETED
4.	Specify Status:	[]

090177e196ae3fd5\Final\Final On: 01-Apr-2021 05:24 (GMT)

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: 10081337

Subject Initials: ---

Generated By: pfe.lewissc

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

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

Header Text: c4591001

Visit: Unplanned Vaccination -
Unscheduled

Form: VITAL SIGNS - TEMP

Form Version: 20-Feb-2021 02:16

Form Status: Not Started

Site No: 1008

Site Name: (1008) Clinical Research Professionals Inc.

Subject No: 10081337

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:	

090177e196ae3fd5\Final\Final On: 01-Apr-2021 05:24 (GMT)

Header Text: c4591001**Visit:** Unplanned Vaccination -
Unscheduled**Form:** LAB URINALYSIS - PREGNANCY TEST**Form Version:** 20-Feb-2021 02:14**Form Status:** Not Started**Site No:** 1008**Site Name:** (1008) Clinical Research Professionals Inc.**Subject No:** 10081337**Subject Initials:** ---**Generated By:** pfe.levisse**Generated Time (GMT):** 29-Mar-2021 04:12**Lab Urinalysis**

1.	Lab Panel:	
2.	Lab Sub-Panel:	
3.	Collection Date:	//
4.	Laboratory Name and Address (Derived)	[]
5.	Specimen Type:	

Lab Result

6.	Sponsor ID:	[]
	Test:	
	Result:	
	Not Done:	

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: 10081337

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?	

090177e196ae3fd5\Final\Final On: 01-Apr-2021 05:24 (GMT)

Header Text: c4591001

Visit: Unplanned Vaccination -
Unscheduled

Form: CONTACT OUTCOME - MONTH 1

Form Version: 10-Oct-2020 15:57

Form Status: Not Started

Site No: 1008

Site Name: (1008) Clinical Research Professionals Inc.

Subject No: 10081337

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: 10081337

Subject Initials: ---

Generated By: pfe.lewissc

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

Contact Outcome

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

Header Text: c4591001

Visit: V201_SURVEIL_CONSENT - **Form:** DATE OF VISIT
Unscheduled

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

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

Subject No: 10081337 **Subject Initials:** ---

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

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

Header Text: c4591001

Visit: V201_SURVEIL_CONSENT -
Unscheduled

Form: INFORMED CONSENT - ASYMPTOMATIC
SURVEILLANCE

Form Version: 14-Jan-2021 02:29

Form Status: Not Started

Site No: 1008

Site Name: (1008) Clinical Research Professionals Inc.

Subject No: 10081337

Subject Initials: ---

Generated By: pfe.lewissc

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

Informed Consent - Asymptomatic Surveillance

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

Header Text: c4591001**Visit:** V201_SURVEIL_CONSENT -
Unscheduled**Form:** ELECTRONIC SAMPLE TRACKING -
IMMUNOGENICITY**Form Version:** 22-Apr-2020 21:03**Form Status:** Not Started**Site No:** 1008**Site Name:** (1008) Clinical Research Professionals Inc.**Subject No:** 10081337**Subject Initials:** ---**Generated By:** pfe.levissc**Generated Time (GMT):** 29-Mar-2021 04:12**Electronic Sample Tracking**

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

Aliquot

Please enter barcode for each aliquot.

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

Header Text: c4591001

Visit: V201_SURVEIL_CONSENT -
Unscheduled

Form: ELECTRONIC SAMPLE TRACKING - NASAL
SWAB

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1008

Site Name: (1008) Clinical Research Professionals Inc.

Subject No: 10081337

Subject Initials: ---

Generated By: pfe.levissc

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

Electronic Sample Tracking

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

Aliquot

Please enter barcode for each aliquot.

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

090177e196ae3fd5\Final\Final On: 01-Apr-2021 05:24 (GMT)

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: 10081337

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

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen, Verified

Site No: 1008

Site Name: (1008) Clinical Research Professionals Inc.

Subject No: 10081337

Subject Initials: ---

Generated By: pfe.lewissc

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

[eCRF Audit Trail History](#)

Date of Visit		
1.	Date of Visit	Jan/15/2021
2.	Erroneous Visit	

Header Text: c4591001

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

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

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

Subject No: 10081337 **Subject Initials:** ---

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

[eCRF Audit Trail History](#)

Further Vaccination Confirmation

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

Header Text: c4591001

Visit: Disposition - Unscheduled

Form: TREATMENT UNBLINDED

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1008

Site Name: (1008) Clinical Research Professionals Inc.

Subject No: 10081337

Subject Initials: ---

Generated By: pfe.levisse

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

[eCRF Audit Trail History](#)

Treatment Unblinded

1.	Date Treatment Unblinded :	Jan/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: 10081337

Subject Initials: ---

Generated By: pfe.levissc

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

Withdrawal Of Consent

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

Header Text: c4591001

Visit: Disposition - Unscheduled

Form: DEATH DETAILS CODED

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1008

Site Name: (1008) Clinical Research Professionals Inc.

Subject No: 10081337

Subject Initials: ---

Generated By: pfe.levissc

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

Death Details

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

Cause of Death

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

Header Text: c4591001

Visit: Subject Status - Unscheduled

Form: SUBJECT STATUS

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Verified

Site No: 1008

Site Name: (1008) Clinical Research Professionals Inc.

Subject No: 10081337

Subject Initials: ---

Generated By: pfe.levisse

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

[eCRF Audit Trail History](#)

Subject Status

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

Header Text: c4591001

Visit: Investigator Signature -
Unscheduled

Form: CASEBOOK SIGNATURE FORM

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Signed, Verified

Site No: 1008

Site Name: (1008) Clinical Research Professionals Inc.

Subject No: 10081337

Subject Initials: ---

Generated By: pfe.levissc

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

[eCRF Audit Trail History](#)

Casebook Signature Form

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

Visit: Investigator Signature -
Unscheduled

Form: CASEBOOK SIGNATURE FORM

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Signed, Verified

Site No: 1008

Site Name: (1008) Clinical Research Professionals Inc.

Subject No: 10081337

Subject Initials: ---

Generated By: pfe.lewissc

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

[Audit Trail](#)

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

- CRF_Sign

Name	Signature Meaning	Date	Type	Action
Timothy Jennings	Approved	Feb-22-2021 17:46:30 (UTC-06:00) Central Time (US & Canada)	BOOK	Signed

Affidavit:

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

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

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

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: INCLUSION/EXCLUSION CRITERIA -
Comments

Form Version: 15-Sep-2020 21:53

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1008

Site Name: (1008) Clinical Research Professionals Inc.

Subject No: 10081337

Subject Initials: ---

Generated By: pfe.lewissc

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

[Back to Form](#)

Item	Date	User	Comment
Form	Sep-17-2020 08:17:52 (UTC-06:00) Central Time (US & Canada)	Tiffany Baum (pfe.tbaum)	Not Applicable

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - Comments

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Locked, Frozen

Site No: 1008

Site Name: (1008) Clinical Research Professionals Inc.

Subject No: 10081337

Subject Initials: ---

Generated By: pfe.levisse

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

[Back to Form](#)

Item	Date	User	Comment
6	Jan-29-2021 14:23:40 (UTC-06:00) Central Time (US & Canada)	Ann Patek (pfe.apatek)	Not Applicable

Header Text: c4591001

Visit: Investigator Signature -
Unscheduled

Form: CASEBOOK SIGNATURE FORM - Signature
History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Signed, Verified

Site No: 1008

Site Name: (1008) Clinical Research Professionals Inc.

Subject No: 10081337

Subject Initials: ---

Generated By: pfe.levissc

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

[Back to Form](#)

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

- CRF_Sign

Name	Signature Meaning	Date	Type	Action
Timothy Jennings	Approved	Feb-22-2021 17:46:30 (UTC-06:00) Central Time (US & Canada)	BOOK	Signed

Affidavit:

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

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

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

Ann Patek	N/A	Feb-22-2021 13:22:25 (UTC-06:00) Central Time (US & Canada)		Edit - All signatures invalidated
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Affidavit:

N/A

Timothy Jennings	Approved	Feb-01-2021 17:25:59 (UTC-06:00) Central Time (US & Canada)	BOOK	Signed
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090177e196ae3fd5\Final\Final On: 01-Apr-2021 05:24 (GMT)

Header Text: c4591001

Visit: Investigator Signature -
Unscheduled

Form: CASEBOOK SIGNATURE FORM - Signature
History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Signed, Verified

Site No: 1008

Site Name: (1008) Clinical Research Professionals Inc.

Subject No: 10081337

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.

Tiffany Baum	N/A	Jan-29-2021 08:30:52 (UTC-06:00) Central Time (US & Canada)		Edit - All signatures invalidated
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Affidavit:

N/A

Timothy Jennings	Approved	Jan-22-2021 09:22:58 (UTC-06:00) Central Time (US & Canada)	BOOK	Signed
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Affidavit:

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

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

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

090177e196ae3fd5\Final\Final On: 01-Apr-2021 05:24 (GMT)

Header Text: c4591001

Visit: Investigator Signature -
Unscheduled

Form: CASEBOOK SIGNATURE FORM - Signature
History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Signed, Verified

Site No: 1008

Site Name: (1008) Clinical Research Professionals Inc.

Subject No: 10081337

Subject Initials: ---

Generated By: pfe.levissc

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

Sherri Pangburn	N/A	Jan-22-2021 08:12:42 (UTC-06:00) Central Time (US & Canada)		Edit - All signatures invalidated
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Affidavit:

N/A

Timothy Jennings	Approved	Nov-09-2020 16:52:51 (UTC-06:00) Central Time (US & Canada)	BOOK	Signed
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Affidavit:

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

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

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

090177e196ae3fd5\Final\Final On: 01-Apr-2021 05:24 (GMT)

Header Text: c4591001

Visit: COHORT_SELECTION

Form: COHORT SELECTION - eCRF Audit Trail History

Form Version: 15-Sep-2020 21:55

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1008

Site Name: (1008) Clinical Research Professionals Inc.

Subject No: 10081337

Subject Initials: ---

Generated By: pfe.lewissc

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

[Back to Form](#)

1. Select appropriate response - Protocol version

Date	Location	User	Value	Reason
Sep-17-2020 08:17:23 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Tiffany Baum (pfe.tbaum)	Data Entry: 08 SEP 2020	Initial Entry

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

Date	Location	User	Value	Reason
Sep-17-2020 08:17:23 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Tiffany Baum (pfe.tbaum)	Data Entry: STAGE 3 COHORTS	Initial Entry

090177e196ae3fd5\Final\Final On: 01-Apr-2021 05:24 (GMT)

Header Text: c4591001

Visit: COHORT_SELECTION

Form: MAIN INFORMED CONSENT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1008

Site Name: (1008) Clinical Research Professionals Inc.

Subject No: 10081337

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
Sep-17-2020 08:49:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Sep-17-2020 08:49:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Cheyenne Brooks (pfe.cbrooks)	Data Entry: OBTAINED Date Written Cons ent Obtained Sep/15/2020	Transcription Error
Sep-17-2020 08:17:46 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	Date Informed Consent Obtained is not the same as the Date of Visit. Please correct as necessary.
Sep-17-2020 08:17:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Tiffany Baum (pfe.tbaum)	Data Entry: OBTAINED Date Written Cons ent Obtained Sep/13/2020	Initial Entry

090177e196ae3fd5\Final\Final On: 01-Apr-2021 05:24 (GMT)

Header Text: c4591001

Visit: COHORT_SELECTION

Form: DEMOGRAPHY - eCRF Audit Trail History

Form Version: 15-Sep-2020 21:54

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1008

Site Name: (1008) Clinical Research Professionals Inc.

Subject No: 10081337

Subject Initials: ---

Generated By: pfe.levissc

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

[Back to Form](#)

1. Subject ID

Date	Location	User	Value	Reason
Sep-17-2020 08:17:17 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 10081337	Item copied from previous form

2. Birth Date:

Date	Location	User	Value	Reason
Sep-17-2020 08:17:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: (b) (6) /1981	Enrollment Entry

3. Sex:

Date	Location	User	Value	Reason
Sep-17-2020 08:17:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Tiffany Baum (pfe.tbaum)	Data Entry: FEMALE	Initial Entry

4. Ethnicity:

Date	Location	User	Value	Reason
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090177e196ae3fd5\Final\Final On: 01-Apr-2021 05:24 (GMT)

Header Text: c4591001

Visit: COHORT_SELECTION

Form: DEMOGRAPHY - eCRF Audit Trail History

Form Version: 15-Sep-2020 21:54

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1008

Site Name: (1008) Clinical Research Professionals Inc.

Subject No: 10081337

Subject Initials: ---

Generated By: pfe.levissc

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

Sep-17-2020 08:17:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Tiffany Baum (pfe.tbaum)	Data Entry: NOT HISPANIC OR LATINO(A) OR OF S PANISH ORIGIN	Initial Entry
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5. Race: (Check X all that apply):

Date	Location	User	Value	Reason
Sep-17-2020 08:17:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Tiffany Baum (pfe.tbaum)	Data Entry: WHITE	Initial Entry

090177e196ae3fd5\Final\Final On: 01-Apr-2021 05:24 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:02

Site No: 1008

Subject No: 10081337

Generated By: pfe.levissc

Form: DATE OF VISIT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1008) Clinical Research Professionals Inc.

Subject Initials: ---

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

[Back to Form](#)

1. Date of Visit

Date	Location	User	Value	Reason
Sep-17-2020 08:17:46 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Tiffany Baum (pfe.tbaum)	Data Entry: Sep/15/2020	Initial Entry

090177e196ae3fd5\Final\Final On: 01-Apr-2021 05:24 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 15-Sep-2020 21:52

Site No: 1008

Subject No: 10081337

Generated By: pfe.lewissc

Form: DISPOSITION - SCREENING - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1008) Clinical Research Professionals Inc.

Subject Initials: ---

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

[Back to Form](#)

1. Date of Completion/Discontinuation/Death

Date	Location	User	Value	Reason
Sep-17-2020 08:18:04 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Tiffany Baum (pfe.tbaum)	Data Entry: Sep/15/2020	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Sep-17-2020 08:18:04 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SCREENING	Initial Entry

3. Status:

Date	Location	User	Value	Reason
Sep-17-2020 08:18:04 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Tiffany Baum (pfe.tbaum)	Data Entry: COMPLETED	Initial Entry

090177e196ae3fd5\Final\Final On: 01-Apr-2021 05:24 (GMT)

Header Text: c4591001**Visit:** V1_DAY1_VAX1_L**Form:** GENERAL MEDICAL HISTORY - eCRF Audit Trail History**Form Version:** 22-Apr-2020 21:03**Form Status:** Data Complete, Locked, Frozen, Verified**Site No:** 1008**Site Name:** (1008) Clinical Research Professionals Inc.**Subject No:** 10081337**Subject Initials:** ---**Generated By:** pfe.lewissc**Generated Time (GMT):** 29-Mar-2021 04:12[Back to Form](#)*I.a*

Date	Location	User	Value	Reason
Sep-17-2020 08:19:46 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH N umber: Medical Hi story Term: Seasonal allergies Start Date: UNK/U NK/2000 Ongoing: YES	Initial Entry

I.a Line/MH Number:

Date	Location	User	Value	Reason
Sep-17-2020 08:19:46 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 1	Initial Entry

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

Date	Location	User	Value	Reason
Sep-17-2020 08:19:46 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Tiffany Baum (pfe.tbaum)	Data Entry: Seasonal allergies	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1008

Site Name: (1008) Clinical Research Professionals Inc.

Subject No: 10081337

Subject Initials: ---

Generated By: pfe.lewissc

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

1.a Start Date:

Date	Location	User	Value	Reason
Sep-17-2020 08:19:46 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Tiffany Baum (pfe.tbaum)	Data Entry: UNK/UNK/2000	Initial Entry

1.a Ongoing:

Date	Location	User	Value	Reason
Sep-17-2020 08:19:46 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Tiffany Baum (pfe.tbaum)	Data Entry: YES	Initial Entry

1.b

Date	Location	User	Value	Reason
Sep-17-2020 08:20:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH 2 Number: Medical History Gastroesop hageal refl Term: x disease Start Date: UNK/UNK/ 2000 Ongoing : YES	Initial Entry

090177e196ae3fd5\Final\Final On: 01-Apr-2021 05:24 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1008

Site Name: (1008) Clinical Research Professionals Inc.

Subject No: 10081337

Subject Initials: ---

Generated By: pfe.lewissc

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

1.b Line/MH Number:

Date	Location	User	Value	Reason
Sep-17-2020 08:20:05 (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
Sep-17-2020 08:20:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Tiffany Baum (pfe.tbaum)	Data Entry: Gastroesophageal refl ux disease	Initial Entry

1.b Start Date:

Date	Location	User	Value	Reason
Sep-17-2020 08:20:05 (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
Sep-17-2020 08:20:05	ACV0PFEINFP6000	Tiffany Baum	Data Entry: YES	Initial Entry

090177e196ae3fd5\Final\Final On: 01-Apr-2021 05:24 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1008

Site Name: (1008) Clinical Research Professionals Inc.

Subject No: 10081337

Subject Initials: ---

Generated By: pfe.lewissc

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

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

(pfe.tbaum)

I.c

Date	Location	User	Value	Reason
Sep-17-2020 08:20:18 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH N umber: 3 Medical History Term: Hypertension Start Date: UNK/UNK/2019 Ongoing: YES	Initial Entry

090177e196ae3fd5\Final\Final On: 01-Apr-2021 05:24 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1008

Site Name: (1008) Clinical Research Professionals Inc.

Subject No: 10081337

Subject Initials: ---

Generated By: pfe.lewissc

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

1.c Line/MH Number:

Date	Location	User	Value	Reason
Sep-17-2020 08:20:18 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 3	Initial Entry

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

Date	Location	User	Value	Reason
Sep-17-2020 08:20:18 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Tiffany Baum (pfe.tbaum)	Data Entry: Hypertension	Initial Entry

1.c Start Date:

Date	Location	User	Value	Reason
Sep-17-2020 08:20:18 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Tiffany Baum (pfe.tbaum)	Data Entry: UNK/UNK/2019	Initial Entry

1.c Ongoing:

Date	Location	User	Value	Reason
Sep-17-2020 08:20:18	ACV0PFEINFP6000	Tiffany Baum	Data Entry: YES	Initial Entry

090177e196ae3fd5\Final\Final On: 01-Apr-2021 05:24 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1008

Site Name: (1008) Clinical Research Professionals Inc.

Subject No: 10081337

Subject Initials: ---

Generated By: pfe.lewissc

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

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

(pfe.tbaum)

1.d

Date	Location	User	Value	Reason
Sep-17-2020 08:20:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH 4 Number: Medical History Term: Generalize d anxiety d isorder Start Date: UNK/UNK /2010 Ongoing: YES	Initial Entry

090177e196ae3fd5\Final\Final On: 01-Apr-2021 05:24 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1008

Site Name: (1008) Clinical Research Professionals Inc.

Subject No: 10081337

Subject Initials: ---

Generated By: pfe.lewissc

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

1.d Line/MH Number:

Date	Location	User	Value	Reason
Sep-17-2020 08:20:40 (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
Sep-17-2020 08:20:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Tiffany Baum (pfe.tbaum)	Data Entry: Generalized anxiety disorder	Initial Entry

1.d Start Date:

Date	Location	User	Value	Reason
Sep-17-2020 08:20:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Tiffany Baum (pfe.tbaum)	Data Entry: UNK/UNK/2010	Initial Entry

1.d Ongoing:

Date	Location	User	Value	Reason
Sep-17-2020 08:20:40	ACV0PFEINFP6000	Tiffany Baum	Data Entry: YES	Initial Entry

090177e196ae3fd5\Final\Final On: 01-Apr-2021 05:24 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1008

Site Name: (1008) Clinical Research Professionals Inc.

Subject No: 10081337

Subject Initials: ---

Generated By: pfe.levisse

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

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

Visit: V1_DAY1_VAX1_L

Form Version: 15-Sep-2020 21:57

Site No: 1008

Subject No: 10081337

Generated By: pfe.lewissc

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
Sep-17-2020 08:18:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Tiffany Baum (pfe.tbaum)	Data Entry: The subject is NOT kn own to be HIV POSIT IVE	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: VITAL SIGNS - BASELINE - eCRF Audit Trail History

Form Version: 15-Sep-2020 21:56

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1008

Site Name: (1008) Clinical Research Professionals Inc.

Subject No: 10081337

Subject Initials: ---

Generated By: pfe.lewissc

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

[Back to Form](#)

1. Date:

Date	Location	User	Value	Reason
Sep-17-2020 08:19:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Tiffany Baum (pfe.tbaum)	Data Entry: Sep/15/2020	Initial Entry

2. Weight:

Date	Location	User	Value	Reason
Sep-17-2020 08:19:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Tiffany Baum (pfe.tbaum)	Data Entry: 174.6	Initial Entry

3. Unit:

Date	Location	User	Value	Reason
Sep-17-2020 08:19:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Tiffany Baum (pfe.tbaum)	Data Entry: LB	Initial Entry

4. Height:

Date	Location	User	Value	Reason
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090177e196ae3fd5\Final\Final On: 01-Apr-2021 05:24 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: VITAL SIGNS - BASELINE - eCRF Audit Trail History

Form Version: 15-Sep-2020 21:56

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1008

Site Name: (1008) Clinical Research Professionals Inc.

Subject No: 10081337

Subject Initials: ---

Generated By: pfe.levisse

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

Sep-17-2020 08:19:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Tiffany Baum (pfe.tbaum)	Data Entry: 64.0	Initial Entry
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5. Unit:

Date	Location	User	Value	Reason
Sep-17-2020 08:19:15 (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
Sep-17-2020 08:19:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 30.0	Initial Entry

7.a

Date	Location	User	Value	Reason
Sep-17-2020 08:19:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Tiffany Baum (pfe.tbaum)	Data Entry: Record Iden 1 tifier:: Temperatur 97.4 e:	Initial Entry

090177e196ae3fd5\Final\Final On: 01-Apr-2021 05:24 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: VITAL SIGNS - BASELINE - eCRF Audit Trail History

Form Version: 15-Sep-2020 21:56

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1008

Site Name: (1008) Clinical Research Professionals Inc.

Subject No: 10081337

Subject Initials: ---

Generated By: pfe.lewissc

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

			Temperature Unit:	
			Temperature Location: HEAD	

7.a Record Identifier:

Date	Location	User	Value	Reason
Sep-17-2020 08:19:15 (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
Sep-17-2020 08:19:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Tiffany Baum (pfe.tbaum)	Data Entry: 97.4	Initial Entry

7.a Unit:

Date	Location	User	Value	Reason
Sep-17-2020 08:19:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Tiffany Baum (pfe.tbaum)	Data Entry: F	Initial Entry

090177e196ae3fd5\Final\Final On: 01-Apr-2021 05:24 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: VITAL SIGNS - BASELINE - eCRF Audit Trail History

Form Version: 15-Sep-2020 21:56

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1008

Site Name: (1008) Clinical Research Professionals Inc.

Subject No: 10081337

Subject Initials: ---

Generated By: pfe.levissc

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

7.a Temperature Location:

Date	Location	User	Value	Reason
Sep-17-2020 08:19:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Tiffany Baum (pfe.tbaum)	Data Entry: FOREHEAD	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: LAB URINALYSIS - PREGNANCY TEST -
eCRF Audit Trail History

Form Version: 15-Sep-2020 21:51

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1008

Site Name: (1008) Clinical Research Professionals Inc.

Subject No: 10081337

Subject Initials: ---

Generated By: pfe.lewissc

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

[Back to Form](#)

1. Lab Panel:

Date	Location	User	Value	Reason
Sep-17-2020 08:19:23 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: URINALYSIS	Initial Entry

2. Lab Sub-Panel:

Date	Location	User	Value	Reason
Sep-17-2020 08:19:23 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: PREGNANCY	Initial Entry

3. Collection Date:

Date	Location	User	Value	Reason
Sep-17-2020 08:19:23 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Tiffany Baum (pfe.tbaum)	Data Entry: Sep/15/2020	Initial Entry

4. Laboratory Name and Address (Derived)

Date	Location	User	Value	Reason
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090177e196ae3fd5\Final\Final On: 01-Apr-2021 05:24 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: LAB URINALYSIS - PREGNANCY TEST -
eCRF Audit Trail History

Form Version: 15-Sep-2020 21:51

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1008

Site Name: (1008) Clinical Research Professionals Inc.

Subject No: 10081337

Subject Initials: ---

Generated By: pfe.levissc

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

Sep-17-2020 08:19:23 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: STUDY SITE	Initial Entry
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5. Specimen Type:

Date	Location	User	Value	Reason
Sep-17-2020 08:19:23 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: URINE	Initial Entry

6.a

Date	Location	User	Value	Reason
Sep-17-2020 08:19:23 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sponsor- 113 Defined I dentifier: Test:: Choriogon adotropin Beta_PX11 3 Result:: NEGATIV E Not Done ::	Initial Entry

6.a Sponsor ID:

090177e196ae3fd5\Final\Final On: 01-Apr-2021 05:24 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: LAB URINALYSIS - PREGNANCY TEST -
eCRF Audit Trail History

Form Version: 15-Sep-2020 21:51

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1008

Site Name: (1008) Clinical Research Professionals Inc.

Subject No: 10081337

Subject Initials: ---

Generated By: pfe.lewissc

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

Date	Location	User	Value	Reason
Sep-17-2020 08:19:23 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 113	Initial Entry

6.a Test:

Date	Location	User	Value	Reason
Sep-17-2020 08:19:23 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Tiffany Baum (pfe.tbaum)	Data Entry: Choriogonadotropin B eta_PX113	Initial Entry

6.a Result:

Date	Location	User	Value	Reason
Sep-17-2020 08:19:23 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Tiffany Baum (pfe.tbaum)	Data Entry: NEGATIVE	Initial Entry

090177e196ae3fd5\Final\Final On: 01-Apr-2021 05:24 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1008

Subject No: 10081337

Generated By: pfe.lewissc

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
Sep-17-2020 08:18:18 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Tiffany Baum (pfe.tbaum)	Data Entry: Sep/15/2020	Initial Entry

2. Randomization Number:

Date	Location	User	Value	Reason
Sep-17-2020 08:18:18 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Tiffany Baum (pfe.tbaum)	Data Entry: 90313	Initial Entry

090177e196ae3fd5\Final\Final On: 01-Apr-2021 05:24 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1008

Subject No: 10081337

Generated By: pfe.levisse

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

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1008) Clinical Research Professionals Inc.

Subject Initials: ---

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

[Back to Form](#)

1. Data Origin

Date	Location	User	Value	Reason
Sep-17-2020 08:36:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Sep-17-2020 08:36:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SERUM	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Sep-17-2020 08:37:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Sep-17-2020 08:36:52 (UTC-06:00)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however

090177e196ae3fd5\Final\Final On: 01-Apr-2021 05:24 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1008

Site Name: (1008) Clinical Research Professionals Inc.

Subject No: 10081337

Subject Initials: ---

Generated By: pfe.levisse

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

Central Time (US & Canada)				no barcodes are entered. Please review and correct as appropriate.
Sep-17-2020 08:36:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Cheyenne Brooks (pfe.cbrooks)	Data Entry: YES Date of Collection: Sep/15/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Sep-17-2020 08:37:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Cheyenne Brooks (pfe.cbrooks)	Data Entry: Sample ID BPTR2 : N	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Sep-17-2020 08:37:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Cheyenne Brooks (pfe.cbrooks)	Data Entry: BPTR2N	Initial Entry

5.b

Date	Location	User	Value	Reason
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090177e196ae3fd5\Final\Final On: 01-Apr-2021 05:24 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1008

Site Name: (1008) Clinical Research Professionals Inc.

Subject No: 10081337

Subject Initials: ---

Generated By: pfe.levisse

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

Sep-17-2020 08:37:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Cheyenne Brooks (pfe.cbrooms)	Data Entry: Sample ID BPRLF : 7	Initial Entry
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5.b Sample ID

Date	Location	User	Value	Reason
Sep-17-2020 08:37:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Cheyenne Brooks (pfe.cbrooms)	Data Entry: BPRLF7	Initial Entry

5.c

Date	Location	User	Value	Reason
Sep-17-2020 08:37:16 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Cheyenne Brooks (pfe.cbrooms)	Data Entry: Sample ID BPRLF : 8	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Sep-17-2020 08:37:16 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Cheyenne Brooks (pfe.cbrooms)	Data Entry: BPRLF8	Initial Entry

090177e196ae3fd5\Final\Final On: 01-Apr-2021 05:24 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1008

Subject No: 10081337

Generated By: pfe.lewissc

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB - 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. Data Origin

Date	Location	User	Value	Reason
Sep-17-2020 08:37:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Sep-17-2020 08:37:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: NASAL_SWAB	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Sep-17-2020 08:37:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Sep-17-2020 08:37:26 (UTC-06:00)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however

090177e196ae3fd5\Final\Final On: 01-Apr-2021 05:24 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1008

Site Name: (1008) Clinical Research Professionals Inc.

Subject No: 10081337

Subject Initials: ---

Generated By: pfe.lewissc

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

Central Time (US & Canada)				no barcodes are entered. Please review and correct as appropriate.
Sep-17-2020 08:37:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Cheyenne Brooks (pfe.cbrooms)	Data Entry: YES Date of Collection: Sep/15/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Sep-17-2020 08:37:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Cheyenne Brooks (pfe.cbrooms)	Data Entry: Sample ID BPTR5 : P	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Sep-17-2020 08:37:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Cheyenne Brooks (pfe.cbrooms)	Data Entry: BPTR5P	Initial Entry

090177e196ae3fd5\Final\Final On: 01-Apr-2021 05:24 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:04

Site No: 1008

Subject No: 10081337

Generated By: pfe.lewissc

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1008) Clinical Research Professionals Inc.

Subject Initials: ---

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

[Back to Form](#)

1. Was there a temporary delay of vaccination?

Date	Location	User	Value	Reason
Sep-17-2020 08:18:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Tiffany Baum (pfe.tbaum)	Data Entry: NO	Initial Entry

2. Treatment Name

Date	Location	User	Value	Reason
Sep-17-2020 08:18:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: BLINDED THERAPY	Initial Entry

3. Formulation:

Date	Location	User	Value	Reason
Sep-17-2020 08:18:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INJECTION	Initial Entry

4. Dose Date Time:

Date	Location	User	Value	Reason
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090177e196ae3fd5\Final\Final On: 01-Apr-2021 05:24 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: VACCINATION - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1008

Site Name: (1008) Clinical Research Professionals Inc.

Subject No: 10081337

Subject Initials: ---

Generated By: pfe.lewissc

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

Sep-17-2020 08:18:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Tiffany Baum (pfe.tbaum)	Data Entry: Sep/15/2020 11:36	Initial Entry
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5. Anatomical Location:

Date	Location	User	Value	Reason
Sep-17-2020 08:18:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: DELTOID MUSCLE	Initial Entry

6. Body Side:

Date	Location	User	Value	Reason
Sep-17-2020 08:18:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Tiffany Baum (pfe.tbaum)	Data Entry: LEFT	Initial Entry

7. Route:

Date	Location	User	Value	Reason
Sep-17-2020 08:18:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INTRAMUSCULAR	Initial Entry

090177e196ae3fd5\Final\Final On: 01-Apr-2021 05:24 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: VACCINATION - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1008

Site Name: (1008) Clinical Research Professionals Inc.

Subject No: 10081337

Subject Initials: ---

Generated By: pfe.levissc

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

10. Timeframe Subject Was Observed

Date	Location	User	Value	Reason
Sep-17-2020 08:18:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: THE PROTOCOL SPE CIFIED OBSERVATIO N PERIOD	Initial Entry

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

Date	Location	User	Value	Reason
Sep-17-2020 08:18:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Tiffany Baum (pfe.tbaum)	Data Entry: YES	Initial Entry

090177e196ae3fd5\Final\Final On: 01-Apr-2021 05:24 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 06-Jul-2020 21:53

Site No: 1008

Subject No: 10081337

Generated By: pfe.lewissc

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
Sep-17-2020 08:18:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Tiffany Baum (pfe.tbaum)	Data Entry: NO - REACTOGENI CITY E-DIARY NOT COLLECTED FOR T HIS SUBJECT	Initial Entry

090177e196ae3fd5\Final\Final On: 01-Apr-2021 05:24 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 1008

Subject No: 10081337

Generated By: pfe.levissc

Form: DATE OF VISIT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1008) Clinical Research Professionals Inc.

Subject Initials: ---

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

[Back to Form](#)

1. Date of Visit

Date	Location	User	Value	Reason
Oct-06-2020 09:59:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Tiffany Baum (pfe.tbaum)	Data Entry: Oct/6/2020	Initial Entry

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 15-Sep-2020 21:54

Site No: 1008

Subject No: 10081337

Generated By: pfe.lewissc

Form: VITAL SIGNS - TEMP - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1008) Clinical Research Professionals Inc.

Subject Initials: ---

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

[Back to Form](#)

1. Date:

Date	Location	User	Value	Reason
Oct-06-2020 10:00:19 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Tiffany Baum (pfe.tbaum)	Data Entry: Oct/6/2020	Initial Entry

2.a

Date	Location	User	Value	Reason
Oct-06-2020 10:00:19 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Tiffany Baum (pfe.tbaum)	Data Entry: Record Identifier:: Temperature: 97.6 Temperature Unit: Temperature Location:: HEAD	Initial Entry

2.a Record Identifier:

Date	Location	User	Value	Reason
Oct-06-2020 10:00:19 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Tiffany Baum (pfe.tbaum)	Data Entry: 1	Initial Entry

090177e196ae3fd5\Final\Final On: 01-Apr-2021 05:24 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form: VITAL SIGNS - TEMP - eCRF Audit Trail History

Form Version: 15-Sep-2020 21:54

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1008

Site Name: (1008) Clinical Research Professionals Inc.

Subject No: 10081337

Subject Initials: ---

Generated By: pfe.levissc

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

2.a Temperature:

Date	Location	User	Value	Reason
Oct-06-2020 10:00:19 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Tiffany Baum (pfe.tbaum)	Data Entry: 97.6	Initial Entry

2.a Unit:

Date	Location	User	Value	Reason
Oct-06-2020 10:00:19 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Tiffany Baum (pfe.tbaum)	Data Entry: F	Initial Entry

2.a Temperature Location:

Date	Location	User	Value	Reason
Oct-06-2020 10:00:19 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Tiffany Baum (pfe.tbaum)	Data Entry: FOREHEAD	Initial Entry

090177e196ae3fd5\Final\Final On: 01-Apr-2021 05:24 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form: LAB URINALYSIS - PREGNANCY TEST -
eCRF Audit Trail History

Form Version: 15-Sep-2020 21:51

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1008

Site Name: (1008) Clinical Research Professionals Inc.

Subject No: 10081337

Subject Initials: ---

Generated By: pfe.lewissc

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

[Back to Form](#)

1. Lab Panel:

Date	Location	User	Value	Reason
Oct-06-2020 10:00:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: URINALYSIS	Initial Entry

2. Lab Sub-Panel:

Date	Location	User	Value	Reason
Oct-06-2020 10:00:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: PREGNANCY	Initial Entry

3. Collection Date:

Date	Location	User	Value	Reason
Oct-06-2020 10:00:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Tiffany Baum (pfe.tbaum)	Data Entry: Oct/6/2020	Initial Entry

4. Laboratory Name and Address (Derived)

Date	Location	User	Value	Reason
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090177e196ae3fd5\Final\Final On: 01-Apr-2021 05:24 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form: LAB URINALYSIS - PREGNANCY TEST -
eCRF Audit Trail History

Form Version: 15-Sep-2020 21:51

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1008

Site Name: (1008) Clinical Research Professionals Inc.

Subject No: 10081337

Subject Initials: ---

Generated By: pfe.lewissc

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

Oct-06-2020 10:00:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: STUDY SITE	Initial Entry
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5. Specimen Type:

Date	Location	User	Value	Reason
Oct-06-2020 10:00:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: URINE	Initial Entry

6.a

Date	Location	User	Value	Reason
Oct-06-2020 10:00:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sponsor- 113 Defined I dentifier: Test:: Choriogon adotropin Beta_PX11 3 Result:: NEGATIV E Not Done ::	Initial Entry

6.a Sponsor ID:

090177e196ae3fd5\Final\Final On: 01-Apr-2021 05:24 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form: LAB URINALYSIS - PREGNANCY TEST -
eCRF Audit Trail History

Form Version: 15-Sep-2020 21:51

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1008

Site Name: (1008) Clinical Research Professionals Inc.

Subject No: 10081337

Subject Initials: ---

Generated By: pfe.lewissc

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

Date	Location	User	Value	Reason
Oct-06-2020 10:00:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 113	Initial Entry

6.a Test:

Date	Location	User	Value	Reason
Oct-06-2020 10:00:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Tiffany Baum (pfe.tbaum)	Data Entry: Choriogonadotropin B eta_PX113	Initial Entry

6.a Result:

Date	Location	User	Value	Reason
Oct-06-2020 10:00:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Tiffany Baum (pfe.tbaum)	Data Entry: NEGATIVE	Initial Entry

090177e196ae3fd5\Final\Final On: 01-Apr-2021 05:24 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1008

Site Name: (1008) Clinical Research Professionals Inc.

Subject No: 10081337

Subject Initials: ---

Generated By: pfe.lewissc

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

[Back to Form](#)

1. Data Origin

Date	Location	User	Value	Reason
Oct-06-2020 13:08:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Oct-06-2020 13:08:01 (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-06-2020 13:08:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Oct-06-2020 13:08:01 (UTC-06:00)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however

090177e196ae3fd5\Final\Final On: 01-Apr-2021 05:24 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1008

Site Name: (1008) Clinical Research Professionals Inc.

Subject No: 10081337

Subject Initials: ---

Generated By: pfe.lewissc

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

Central Time (US & Canada)				no barcodes are entered. Please review and correct as appropriate.
Oct-06-2020 13:08:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Cheyenne Brooks (pfe.cbrooms)	Data Entry: YES Date of Collection: Oct/6/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Oct-06-2020 13:08:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Cheyenne Brooks (pfe.cbrooms)	Data Entry: Sample ID BGL56 : 8	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Oct-06-2020 13:08:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Cheyenne Brooks (pfe.cbrooms)	Data Entry: BGL568	Initial Entry

090177e196ae3fd5\Final\Final On: 01-Apr-2021 05:24 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1008

Subject No: 10081337

Generated By: pfe.levissc

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1008) Clinical Research Professionals Inc.

Subject Initials: ---

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

[Back to Form](#)

1. Was there a temporary delay of vaccination?

Date	Location	User	Value	Reason
Oct-06-2020 10:00:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Tiffany Baum (pfe.tbaum)	Data Entry: NO	Initial Entry

2. Treatment Name

Date	Location	User	Value	Reason
Oct-06-2020 10:00:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: BLINDED THERAPY	Initial Entry

3. Formulation:

Date	Location	User	Value	Reason
Oct-06-2020 10:00:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INJECTION	Initial Entry

4. Dose Date Time:

Date	Location	User	Value	Reason
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090177e196ae3fd5\Final\Final On: 01-Apr-2021 05:24 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form: VACCINATION - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1008

Site Name: (1008) Clinical Research Professionals Inc.

Subject No: 10081337

Subject Initials: ---

Generated By: pfe.lewissc

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

Oct-06-2020 10:00:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Tiffany Baum (pfe.tbaum)	Data Entry: Oct/6/2020 09:10	Initial Entry
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5. Anatomical Location:

Date	Location	User	Value	Reason
Oct-06-2020 10:00:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: DELTOID MUSCLE	Initial Entry

6. Body Side:

Date	Location	User	Value	Reason
Oct-06-2020 10:00:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Tiffany Baum (pfe.tbaum)	Data Entry: LEFT	Initial Entry

7. Route:

Date	Location	User	Value	Reason
Oct-06-2020 10:00:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INTRAMUSCULAR	Initial Entry

090177e196ae3fd5\Final\Final On: 01-Apr-2021 05:24 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form: VACCINATION - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1008

Site Name: (1008) Clinical Research Professionals Inc.

Subject No: 10081337

Subject Initials: ---

Generated By: pfe.lewissc

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

10. Timeframe Subject Was Observed

Date	Location	User	Value	Reason
Oct-06-2020 10:00:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: THE PROTOCOL SPE CIFIED OBSERVATIO N PERIOD	Initial Entry

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

Date	Location	User	Value	Reason
Oct-06-2020 10:00:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Tiffany Baum (pfe.tbaum)	Data Entry: YES	Initial Entry

090177e196ae3fd5\Final\Final On: 01-Apr-2021 05:24 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L **Form:** DATE OF VISIT - eCRF Audit Trail History

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

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

Subject No: 10081337 **Subject Initials:** ---

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

[Back to Form](#)

1. Date of Visit

Date	Location	User	Value	Reason
Nov-03-2020 10:00:32 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Tiffany Baum (pfe.tbaum)	Data Entry: Nov/3/2020	Initial Entry

090177e196ae3fd5\Final\Final On: 01-Apr-2021 05:24 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L **Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF Audit Trail History

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

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

Subject No: 10081337 **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-03-2020 11:37:50 (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-03-2020 11:37:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SERUM	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Nov-03-2020 11:38:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Nov-03-2020 11:37:50 (UTC-06:00)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidat e	'Sample Collected?' is Yes, however

090177e196ae3fd5\Final\Final On: 01-Apr-2021 05:24 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L **Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF Audit Trail History

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

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

Subject No: 10081337 **Subject Initials:** ---

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

Central Time (US & Canada)				no barcodes are entered. Please review and correct as appropriate.
Nov-03-2020 11:37:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Sherri Pangburn (pfe.spangburn)	Data Entry: YES Date of Collection: Nov/3/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Nov-03-2020 11:38:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Sherri Pangburn (pfe.spangburn)	Data Entry: Sample I BPZ8K D: V	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Nov-03-2020 11:38:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Sherri Pangburn (pfe.spangburn)	Data Entry: BPZ8KV	Initial Entry

5.b

090177e196ae3fd5\Final\Final On: 01-Apr-2021 05:24 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L **Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF Audit Trail History

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

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

Subject No: 10081337 **Subject Initials:** ---

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

Date	Location	User	Value	Reason
Nov-03-2020 11:38:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Sherri Pangburn (pfe.spangburn)	Data Entry: Sample I BRZD6 D: C	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Nov-03-2020 11:38:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Sherri Pangburn (pfe.spangburn)	Data Entry: BRZD6C	Initial Entry

5.c

Date	Location	User	Value	Reason
Nov-03-2020 11:38:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Sherri Pangburn (pfe.spangburn)	Data Entry: Sample I BRZD6 D: D	Initial Entry

090177e196ae3fd5\Final\Final On: 01-Apr-2021 05:24 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L **Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF Audit Trail History

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

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

Subject No: 10081337 **Subject Initials:** ---

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

5.c Sample ID

Date	Location	User	Value	Reason
Nov-03-2020 11:38:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Sherri Pangburn (pfe.spangburn)	Data Entry: BRZD6D	Initial Entry

090177e196ae3fd5\Final\Final On: 01-Apr-2021 05:24 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - Audit Trail

Form Version: 22-Apr-2020 21:02

Form Status:

Site No: 1008

Site Name: (1008) Clinical Research Professionals Inc.

Subject No: 10081337

Subject Initials: ---

Generated By: pfe.levisse

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

[Back to Form](#)

Date	Location	User	Value	Reason
Nov-03-2020 10:03:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Tiffany Baum (pfe.tbaum)	Form Created	

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - Audit Trail

Form Version: 22-Apr-2020 21:02

Form Status:

Site No: 1008

Site Name: (1008) Clinical Research Professionals Inc.

Subject No: 10081337

Subject Initials: ---

Generated By: pfe.lewissc

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

[Back to Form](#)

Date	Location	User	Value	Reason
Nov-03-2020 10:03:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Tiffany Baum (pfe.tbaum)	Form Created	

090177e196ae3fd5\Final\Final On: 01-Apr-2021 05:24 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - Audit Trail

Form Version: 22-Apr-2020 21:02

Form Status:

Site No: 1008

Site Name: (1008) Clinical Research Professionals Inc.

Subject No: 10081337

Subject Initials: ---

Generated By: pfe.levisse

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

[Back to Form](#)

Date	Location	User	Value	Reason
Nov-03-2020 10:04:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Tiffany Baum (pfe.tbaum)	Form Created	

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - Audit Trail

Form Version: 22-Apr-2020 21:02

Form Status:

Site No: 1008

Site Name: (1008) Clinical Research Professionals Inc.

Subject No: 10081337

Subject Initials: ---

Generated By: pfe.lewissc

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

[Back to Form](#)

Date	Location	User	Value	Reason
Jan-29-2021 08:30:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Tiffany Baum (pfe.tbaum)	Form Created	

090177e196ae3fd5\Final\Final On: 01-Apr-2021 05:24 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Locked, Frozen

Site No: 1008

Site Name: (1008) Clinical Research Professionals Inc.

Subject No: 10081337

Subject Initials: ---

Generated By: pfe.lewissc

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

[Back to Form](#)

1. Category:

Date	Location	User	Value	Reason
Nov-03-2020 10:03:07 (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-03-2020 10:03:07 (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-03-2020 10:03:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Tiffany Baum (pfe.tbaum)	Data Entry: Injection site pain	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason
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090177e196ae3fd5\Final\Final On: 01-Apr-2021 05:24 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Locked, Frozen

Site No: 1008

Site Name: (1008) Clinical Research Professionals Inc.

Subject No: 10081337

Subject Initials: ---

Generated By: pfe.levisse

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

Nov-03-2020 10:03:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Tiffany Baum (pfe.tbaum)	Data Entry: Sep/16/2020 UNK:U NK	Initial Entry
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5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Nov-03-2020 10:03:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Tiffany Baum (pfe.tbaum)	Data Entry: NO End Date Time: Sep/17/2020 UNK: UNK	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
Nov-03-2020 10:03:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Tiffany Baum (pfe.tbaum)	Data Entry: 1	Initial Entry

7. Is the adverse event serious?

If Yes, NOTIFY PFIZER IMMEDIATELY.

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

090177e196ae3fd5\Final\Final On: 01-Apr-2021 05:24 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Locked, Frozen

Site No: 1008

Site Name: (1008) Clinical Research Professionals Inc.

Subject No: 10081337

Subject Initials: ---

Generated By: pfe.lewissc

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

Date	Location	User	Value	Reason
Nov-03-2020 10:03:07 (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
Nov-03-2020 10:03:07 (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
Nov-03-2020 10:03:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Tiffany Baum (pfe.tbaum)	Data Entry: RELATED	Initial Entry

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Nov-03-2020 10:03:07 (UTC-06:00)	ACV0PFEINFP6000	Tiffany Baum (pfe.tbaum)	Data Entry: NOT APPLICABLE	Initial Entry

090177e196ae3fd5\Final\Final On: 01-Apr-2021 05:24 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Locked, Frozen

Site No: 1008

Site Name: (1008) Clinical Research Professionals Inc.

Subject No: 10081337

Subject Initials: ---

Generated By: pfe.lewissc

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

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

Date	Location	User	Value	Reason
Nov-03-2020 10:03:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Tiffany Baum (pfe.tbaum)	Data Entry: NO	Initial Entry

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Nov-03-2020 10:03:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Tiffany Baum (pfe.tbaum)	Data Entry: NO	Initial Entry

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

Date	Location	User	Value	Reason
Nov-03-2020 10:03:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Tiffany Baum (pfe.tbaum)	Data Entry: RECOVERED/RESOLVED	Initial Entry

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

090177e196ae3fd5\Final\Final On: 01-Apr-2021 05:24 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Locked, Frozen

Site No: 1008

Site Name: (1008) Clinical Research Professionals Inc.

Subject No: 10081337

Subject Initials: ---

Generated By: pfe.lewissc

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

Date	Location	User	Value	Reason
Nov-03-2020 10:03:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Tiffany Baum (pfe.tbaum)	Data Entry: NO	Initial Entry

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Locked, Frozen

Site No: 1008

Site Name: (1008) Clinical Research Professionals Inc.

Subject No: 10081337

Subject Initials: ---

Generated By: pfe.lewissc

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

[Back to Form](#)

1. Category:

Date	Location	User	Value	Reason
Nov-03-2020 10:03:47 (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
Nov-03-2020 10:03:47 (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-03-2020 10:03:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Tiffany Baum (pfe.tbaum)	Data Entry: Injection site pain	Initial Entry

4. Start Date Time:

090177e196ae3fd5\Final\Final On: 01-Apr-2021 05:24 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Locked, Frozen

Site No: 1008

Site Name: (1008) Clinical Research Professionals Inc.

Subject No: 10081337

Subject Initials: ---

Generated By: pfe.lewissc

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

Date	Location	User	Value	Reason
Nov-03-2020 10:03:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Tiffany Baum (pfe.tbaum)	Data Entry: Oct/7/2020 UNK:UN K	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Nov-03-2020 10:03:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Tiffany Baum (pfe.tbaum)	Data Entry: NO End Date Time: Oct/8/2020 UNK: UNK	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
Nov-03-2020 10:03:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Tiffany Baum (pfe.tbaum)	Data Entry: 1	Initial Entry

7. Is the adverse event serious?

If Yes, NOTIFY PFIZER IMMEDIATELY.

Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important

090177e196ae3fd5\Final\Final On: 01-Apr-2021 05:24 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

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Site Name: (1008) Clinical Research Professionals Inc.

Subject No: 10081337

Subject Initials: ---

Generated By: pfe.lewissc

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

medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).

Date	Location	User	Value	Reason
Nov-03-2020 10:03:47 (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
Nov-03-2020 10:03:47 (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
Nov-03-2020 10:03:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Tiffany Baum (pfe.tbaum)	Data Entry: RELATED	Initial Entry

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
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090177e196ae3fd5\Final\Final On: 01-Apr-2021 05:24 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Locked, Frozen

Site No: 1008

Site Name: (1008) Clinical Research Professionals Inc.

Subject No: 10081337

Subject Initials: ---

Generated By: pfe.lewissc

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

Nov-03-2020 10:03:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Tiffany Baum (pfe.tbaum)	Data Entry: NOT APPLICABLE	Initial Entry
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11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
Nov-03-2020 10:03:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Tiffany Baum (pfe.tbaum)	Data Entry: NO	Initial Entry

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Nov-03-2020 10:03:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Tiffany Baum (pfe.tbaum)	Data Entry: NO	Initial Entry

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

Date	Location	User	Value	Reason
Nov-03-2020 10:03:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Tiffany Baum (pfe.tbaum)	Data Entry: RECOVERED/RESO LVED	Initial Entry

090177e196ae3fd5\Final\Final On: 01-Apr-2021 05:24 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Locked, Frozen

Site No: 1008

Site Name: (1008) Clinical Research Professionals Inc.

Subject No: 10081337

Subject Initials: ---

Generated By: pfe.lewissc

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

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

Date	Location	User	Value	Reason
Nov-03-2020 10:03:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Tiffany Baum (pfe.tbaum)	Data Entry: NO	Initial Entry

090177e196ae3fd5\Final\Final On: 01-Apr-2021 05:24 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Locked, Frozen

Site No: 1008

Site Name: (1008) Clinical Research Professionals Inc.

Subject No: 10081337

Subject Initials: ---

Generated By: pfe.lewissc

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

[Back to Form](#)

1. Category:

Date	Location	User	Value	Reason
Nov-03-2020 10:04:33 (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-03-2020 10:04:33 (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-03-2020 10:04:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Tiffany Baum (pfe.tbaum)	Data Entry: Body aches	Initial Entry

4. Start Date Time:

090177e196ae3fd5\Final\Final On: 01-Apr-2021 05:24 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Locked, Frozen

Site No: 1008

Site Name: (1008) Clinical Research Professionals Inc.

Subject No: 10081337

Subject Initials: ---

Generated By: pfe.lewissc

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

Date	Location	User	Value	Reason
Nov-03-2020 10:04:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Tiffany Baum (pfe.tbaum)	Data Entry: Oct/7/2020 UNK:UN K	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Nov-03-2020 10:04:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Tiffany Baum (pfe.tbaum)	Data Entry: NO End Date Time: Oct/9/2020 UNK: UNK	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
Nov-03-2020 10:04:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Tiffany Baum (pfe.tbaum)	Data Entry: 1	Initial Entry

7. Is the adverse event serious?

If Yes, NOTIFY PFIZER IMMEDIATELY.

Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important

090177e196ae3fd5\Final\Final On: 01-Apr-2021 05:24 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Locked, Frozen

Site No: 1008

Site Name: (1008) Clinical Research Professionals Inc.

Subject No: 10081337

Subject Initials: ---

Generated By: pfe.levissc

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

medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).

Date	Location	User	Value	Reason
Nov-03-2020 10:04:33 (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
Nov-03-2020 10:04:33 (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
Nov-03-2020 10:04:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Tiffany Baum (pfe.tbaum)	Data Entry: RELATED	Initial Entry

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
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090177e196ae3fd5\Final\Final On: 01-Apr-2021 05:24 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Locked, Frozen

Site No: 1008

Site Name: (1008) Clinical Research Professionals Inc.

Subject No: 10081337

Subject Initials: ---

Generated By: pfe.levissc

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

Nov-03-2020 10:04:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Tiffany Baum (pfe.tbaum)	Data Entry: NOT APPLICABLE	Initial Entry
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11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
Nov-03-2020 10:04:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Tiffany Baum (pfe.tbaum)	Data Entry: NO	Initial Entry

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Nov-03-2020 10:04:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Tiffany Baum (pfe.tbaum)	Data Entry: NO	Initial Entry

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

Date	Location	User	Value	Reason
Nov-03-2020 10:04:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Tiffany Baum (pfe.tbaum)	Data Entry: RECOVERED/RESO LVED	Initial Entry

090177e196ae3fd5\Final\Final On: 01-Apr-2021 05:24 (GMT)

Header Text: c4591001

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Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

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Site No: 1008

Site Name: (1008) Clinical Research Professionals Inc.

Subject No: 10081337

Subject Initials: ---

Generated By: pfe.levissc

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

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

Date	Location	User	Value	Reason
Nov-03-2020 10:04:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Tiffany Baum (pfe.tbaum)	Data Entry: NO	Initial Entry

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete

Site No: 1008

Site Name: (1008) Clinical Research Professionals Inc.

Subject No: 10081337

Subject Initials: ---

Generated By: pfe.lewissc

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

[Back to Form](#)

1. Category:

Date	Location	User	Value	Reason
Jan-29-2021 08:30:52 (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
Jan-29-2021 08:30:52 (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
Feb-03-2021 18:02:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 2: Closed	Response satisfies query
Feb-01-2021 15:20:53	ACV0PFEINFP6000	Ann Patek (pfe.apatek)	Query 2: Answer ed	SAE AND PG FORM HAVE

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete

Site No: 1008

Site Name: (1008) Clinical Research Professionals Inc.

Subject No: 10081337

Subject Initials: ---

Generated By: pfe.lewissc

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

(UTC-06:00) Central Time (US & Canada)				BEEN UPDATED AND RESUBMITTED PER SAFETY REQUEST
Feb-01-2021 15:10:02 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 1: Closed	Query closed; will follow for requested event term update.
Feb-01-2021 15:09:19 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 2: Reissue d:Opened	Clinical Please submit a PG safety update w(#2021077774) with contraceptive method being used, and obstetrical history (gravida ?) on PG report form
Feb-01-2021 13:33:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Answer ed	UPDATED TERM PER SAFETY REQUEST
Feb-01-2021 13:33:30 (UTC-06:00) Central Time	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answer ed	UPDATED TERM PER SAFETY REQUEST

090177e196ae3fd5\Final\Final On: 01-Apr-2021 05:24 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete

Site No: 1008

Site Name: (1008) Clinical Research Professionals Inc.

Subject No: 10081337

Subject Initials: ---

Generated By: pfe.lewissc

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

(US & Canada)				
Feb-01-2021 13:33:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Ann Patek (pfe.apatek)	Data Entry: EXPOSURE DURING PREGNANCY	UPDATED TERM PER SAFETY REQUEST
Jan-30-2021 21:24:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 2: Reissued: Opened	Clinical Please submit a PG safety update w(#2021077774) with contraceptive method being used, and obstetrical history (gravida ?) on PG report form
Jan-30-2021 21:21:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 1: Reissued: Opened	Clinical - please update AE term as well to Exposure during Pregnancy
Jan-29-2021 14:23:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Answered	Transcription Error
Jan-29-2021 14:23:09 (UTC-06:00)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Transcription Error

090177e196ae3fd5\Final\Final On: 01-Apr-2021 05:24 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete

Site No: 1008

Site Name: (1008) Clinical Research Professionals Inc.

Subject No: 10081337

Subject Initials: ---

Generated By: pfe.levissc

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

Central Time (US & Canada)				
Jan-29-2021 14:23:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Ann Patek (pfe.apatek)	Data Entry: Pregnancy	Transcription Error
Jan-29-2021 11:41:32 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 2: Opened	Clinical Please submit a PG safety update w(#2021077774) with contraceptive method being used, and obstetrical history (gravida ?) on PG report form
Jan-29-2021 11:38:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 1: Opened	Clinical Event term is Exposure during Pregnancy; however, submitted report (#202107774) has event term of 'Pregnancy'. Please submit an update with the full term 'Exposure during

090177e196ae3fd5\Final\Final On: 01-Apr-2021 05:24 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete

Site No: 1008

Site Name: (1008) Clinical Research Professionals Inc.

Subject No: 10081337

Subject Initials: ---

Generated By: pfe.lewissc

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

				Pregnancy'
Jan-29-2021 08:30:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Tiffany Baum (pfe.tbaum)	Data Entry: Exposure during Pregnancy	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason
Feb-03-2021 18:02:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 1: Closed	Response satisfies query
Feb-02-2021 19:24:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 1: Reissued :Opened	Clinical Thank you; however, 01Feb21 PG safety update still reports 25Dec20 start date, rather than 1st day of LMP (23Dec20)
Feb-01-2021 15:22:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Ann Patek (pfe.apatek)	Query 1: Answered	ALL INFO UPDATED, SAE/EDP FORMS UPDATED/RESUBMITTED PER SAFETY REQUEST
Feb-01-2021 15:11:12 (UTC-06:00)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 1: Reissued :Opened	Clinical Thank you. Please submit this new start date as a PG Safety as well, if not

090177e196ae3fd5\Final\Final On: 01-Apr-2021 05:24 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete

Site No: 1008

Site Name: (1008) Clinical Research Professionals Inc.

Subject No: 10081337

Subject Initials: ---

Generated By: pfe.levissc

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

Central Time (US & Canada)				included with EDP event term update
Feb-01-2021 13:35:16 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	UPDATED TO 1ST DAY OF LMP PER SAFETY REQUEST, NO U/S TO DATE
Feb-01-2021 13:35:16 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Ann Patek (pfe.apatek)	Data Entry: Dec/23/2020 UNK:UNK	UPDATED TO 1ST DAY OF LMP PER SAFETY REQUEST, NO U/S TO DATE
Jan-30-2021 21:24:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 1: Reissued :Opened	Clinical Per Vaccine guidelines, urine PG test is not start date; guidelines state 'For conception date, ultrasound measurement of the fetus during the first trimester is the most accurate method; in the absence of US, use 1st day of the LMP'
Jan-29-2021 14:26:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Ann Patek (pfe.apatek)	Query 1: Answered	estimated date of conception is based off when subject reports intercourse that may have lead to pregnancy. Positive home urine hcg was 25Jan 2021. Site can remove estimated date of conception,

090177e196ae3fd5\Final\Final On: 01-Apr-2021 05:24 (GMT)

Header Text: c4591001
Visit: Logs - Unscheduled **Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History
Form Version: 22-Apr-2020 21:02 **Form Status:** Data Complete
Site No: 1008 **Site Name:** (1008) Clinical Research Professionals Inc.
Subject No: 10081337 **Subject Initials:** ---
Generated By: pfe.lewissc **Generated Time (GMT):** 29-Mar-2021 04:12

				however date of event is when pregnancy is confirmed by test
Jan-29-2021 11:40:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 1: Opened	Clinical Event start date is 25Jan2021 (positive urine PG test); however, estimated date of conception is 09Jan2021. Please update to estimated conception date on AE CRF and safety update
Jan-29-2021 08:30:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Tiffany Baum (pfe.tbaum)	Data Entry: Jan/25/2021 UNK:UNK	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Jan-29-2021 08:30:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Tiffany Baum (pfe.tbaum)	Data Entry: YES	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
Jan-30-2021 21:22:04 (UTC-06:00)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 1: Closed	Response satisfies query

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete

Site No: 1008

Site Name: (1008) Clinical Research Professionals Inc.

Subject No: 10081337

Subject Initials: ---

Generated By: pfe.lewissc

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

Central Time (US & Canada)				
Jan-29-2021 14:23:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Ann Patek (pfe.apatek)	Data Entry: Not Applicable	Initial Entry
Jan-29-2021 14:23:32 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Transcription Error
Jan-29-2021 14:23:32 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Ann Patek (pfe.apatek)	Data Entry:	Transcription Error
Jan-29-2021 11:39:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 1: Opened	Clinical As per CRF CG 8.50.2.5, the toxicity grade for "Exposure During Pregnancy" is reported as Not Applicable
Jan-29-2021 08:30:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Tiffany Baum (pfe.tbaum)	Data Entry: 1	Initial Entry

090177e196ae3fd5\Final\Final On: 01-Apr-2021 05:24 (GMT)

Header Text: c4591001**Visit:** Logs - Unscheduled**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History**Form Version:** 22-Apr-2020 21:02**Form Status:** Data Complete**Site No:** 1008**Site Name:** (1008) Clinical Research Professionals Inc.**Subject No:** 10081337**Subject Initials:** ---**Generated By:** pfe.levissc**Generated Time (GMT):** 29-Mar-2021 04:12**7. Is the adverse event serious?****If Yes, NOTIFY PFIZER IMMEDIATELY.****Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).**

Date	Location	User	Value	Reason
Jan-29-2021 08:30:52 (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
Jan-29-2021 08:30:52 (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
Jan-29-2021 08:30:52 (UTC-06:00) Central Time (US	ACV0PFEINFP6000	Tiffany Baum (pfe.tbaum)	Data Entry: NOT RELATED If Not Related to stu dy treatment(s), this	Initial Entry

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete

Site No: 1008

Site Name: (1008) Clinical Research Professionals Inc.

Subject No: 10081337

Subject Initials: ---

Generated By: pfe.levisse

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

& Canada)			event is due to:	
			OTHER	
			<i>If Other, specify:</i>	
			positive pregnancy test	

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Jan-29-2021 08:30:52 (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
Jan-29-2021 08:30:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Tiffany Baum (pfe.tbaum)	Data Entry: NO	Initial Entry

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Jan-29-2021 08:30:52	ACV0PFEINFP6000	Tiffany Baum	Data Entry: NO	Initial Entry

090177e196ae3fd5\Final\Final On: 01-Apr-2021 05:24 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete

Site No: 1008

Site Name: (1008) Clinical Research Professionals Inc.

Subject No: 10081337

Subject Initials: ---

Generated By: pfe.lewissc

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

(UTC-06:00) Central Time (US & Canada)		(pfe.tbaum)		
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13. What was the outcome of this adverse event?:

Date	Location	User	Value	Reason
Feb-22-2021 16:24:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Gladys Noi (pfe.noig)	Query 2: Closed	Response satisfies query
Feb-22-2021 16:24:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Gladys Noi (pfe.noig)	Query 1: Closed	Response satisfies query
Feb-22-2021 13:24:37 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Ann Patek (pfe.apatek)	Query 2: Answered	updated to unknown per EDC guidelines and DM request
Feb-22-2021 13:22:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Opened	For AE EXPOSURE DURING PREGNANCY: Response to "What was the outcome of this adverse event?" is 'Unknown' but End Date/Time is provided or "Is the adverse event still ongoing?" is

090177e196ae3fd5\Final\Final On: 01-Apr-2021 05:24 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete

Site No: 1008

Site Name: (1008) Clinical Research Professionals Inc.

Subject No: 10081337

Subject Initials: ---

Generated By: pfe.levissc

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

				marked "Yes".
Feb-22-2021 13:22:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Ann Patek (pfe.apatek)	Data Entry: UNKNOWN	updated per EDC guidelines
Feb-22-2021 08:09:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Tiffany Baum (pfe.tbaum)	Query 1: Ans wered	i want to see what page your referring to, because we read the guidance and did not see this.
Feb-21-2021 07:12:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Ricell Ann Piojo (pfe.quitor)	Query 1: Reis sued:Opened	Per 3 Nov EDP guidance (study communication)outcome should be recorded as UNKNOWN. Please confirm and update accordingly.
Feb-19-2021 08:55:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Tiffany Baum (pfe.tbaum)	Query 1: Ans wered	what page are you referring to on EDP guidance?
Feb-17-2021 20:53:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Ricell Ann Piojo (pfe.quitor)	Query 1: Ope ned	SAE RECON: AER#2021077774, the outcome in AE CRF was reported as NOT RECOVERED/NOT RESOLVED. Per 3 Nov EDP guidance , outcome should be recorded as

090177e196ae3fd5\Final\Final On: 01-Apr-2021 05:24 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete

Site No: 1008

Site Name: (1008) Clinical Research Professionals Inc.

Subject No: 10081337

Subject Initials: ---

Generated By: pfe.lewissc

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

				UNKNOWN. Please confirm and update accordingly.
Jan-29-2021 08:30:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Tiffany Baum (pfe.tbaum)	Data Entry: NOT RECOV ERED/NOT R ESOLVED	Initial Entry

090177e196ae3fd5\Final\Final On: 01-Apr-2021 05:24 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete

Site No: 1008

Site Name: (1008) Clinical Research Professionals Inc.

Subject No: 10081337

Subject Initials: ---

Generated By: pfe.lewissc

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

[Back to Form](#)

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

Date	Location	User	Value	Reason
Jan-29-2021 08:30:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Tiffany Baum (pfe.tbaum)	<u>Data Entry:</u> NO	Initial Entry

090177e196ae3fd5\Final\Final On: 01-Apr-2021 05:24 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - NON
STUDY VACCINATIONS - Audit Trail

Form Version: 22-Apr-2020 21:03

Form Status:

Site No: 1008

Site Name: (1008) Clinical Research Professionals Inc.

Subject No: 10081337

Subject Initials: ---

Generated By: pfe.lewissc

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

[Back to Form](#)

Date	Location	User	Value	Reason
Nov-03-2020 10:02:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Tiffany Baum (pfe.tbaum)	Form Created	

Header Text: c4591001

Visit: Logs - Unscheduled

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1008

Site Name: (1008) Clinical Research Professionals Inc.

Subject No: 10081337

Subject Initials: ---

Generated By: pfe.lewissc

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

[Back to Form](#)

1. What is the medication identifier?

Date	Location	User	Value	Reason
Nov-03-2020 10:02:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 1	Initial Entry

2. Category:

Date	Location	User	Value	Reason
Nov-03-2020 10:02:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: VACCINATIONS	Initial Entry

3. Concomitant Medications Pre-specified:

Date	Location	User	Value	Reason
Nov-03-2020 10:02:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: NO	Initial Entry

4. Medication:

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

090177e196ae3fd5\Final\Final On: 01-Apr-2021 05:24 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1008

Site Name: (1008) Clinical Research Professionals Inc.

Subject No: 10081337

Subject Initials: ---

Generated By: pfe.lewissc

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

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

Date	Location	User	Value	Reason
Nov-03-2020 10:02:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Tiffany Baum (pfe.tbaum)	Data Entry: Quadrivalent flu vacci ne prophylaxis intram uscular 0.5 ml once	Initial Entry

5. Date:

Date	Location	User	Value	Reason
Nov-03-2020 10:02:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Tiffany Baum (pfe.tbaum)	Data Entry: Oct/21/2020	Initial Entry

090177e196ae3fd5\Final\Final On: 01-Apr-2021 05:24 (GMT)

Header Text: c4591001

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

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

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

Subject No: 10081337 **Subject Initials:** ---

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

[Back to Form](#)

1. Date of Completion/Discontinuation/Death :

Date	Location	User	Value	Reason
Nov-03-2020 10:00:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Tiffany Baum (pfe.tbaum)	Data Entry: Nov/3/2020	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Nov-03-2020 10:00:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: VACCINATION	Initial Entry

3. Status:

Date	Location	User	Value	Reason
Nov-03-2020 10:00:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Tiffany Baum (pfe.tbaum)	Data Entry: COMPLETED	Initial Entry

090177e196ae3fd5\Final\Final On: 01-Apr-2021 05:24 (GMT)

Header Text: c4591001

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

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

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

Subject No: 10081337 **Subject Initials:** ---

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

[Back to Form](#)

1. Date of Visit

Date	Location	User	Value	Reason
Jan-22-2021 08:12:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Sherri Pangburn (pfe.spangburn)	Data Entry: Jan/15/2021	Initial Entry

090177e196ae3fd5\Final\Final On: 01-Apr-2021 05:24 (GMT)

Header Text: c4591001

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

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

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

Subject No: 10081337 **Subject Initials:** ---

Generated By: pfe.lewissc **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-22-2021 08:13:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Jan-22-2021 08:12:54 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candida te	The response indicates participant was unblinded, however the TREATMENT UNBLINDED date is missing in the DISP visit. Please complete this date.
Jan-22-2021 08:12:54 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Sherri Pangburn (pfe.spangburn)	Data Entry: Participant is will ing to return for V accination 3 Participant is: eligible and N OT confirmed to have receiv ed only placeb	Initial Entry

090177e196ae3fd5\Final\Final On: 01-Apr-2021 05:24 (GMT)

Header Text: c4591001

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

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

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

Subject No: 10081337 **Subject Initials:** ---

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

			o at Vaccinatio n 1/2	
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090177e196ae3fd5\Final\Final On: 01-Apr-2021 05:24 (GMT)

Header Text: c4591001

Visit: Disposition - Unscheduled

Form: TREATMENT UNBLINDED - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1008

Site Name: (1008) Clinical Research Professionals Inc.

Subject No: 10081337

Subject Initials: ---

Generated By: pfe.lewissc

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

[Back to Form](#)

1. Date Treatment Unblinded :

Date	Location	User	Value	Reason
Jan-22-2021 08:13:07 (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-22-2021 08:13:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Sherri Pangburn (pfe.spangburn)	Data Entry: ASSESS ELIGIBIL ITY FOR ADDITI ONAL VACCINAT ION	Initial Entry

090177e196ae3fd5\Final\Final On: 01-Apr-2021 05:24 (GMT)

Header Text: c4591001

Visit: Subject Status - Unscheduled

Form: SUBJECT STATUS - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Verified

Site No: 1008

Site Name: (1008) Clinical Research Professionals Inc.

Subject No: 10081337

Subject Initials: ---

Generated By: pfe.lewissc

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

[Back to Form](#)

1. Subject Status

Date	Location	User	Value	Reason
Nov-03-2020 10:00:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: FOLLOW-UP	Initial Entry
Sep-17-2020 08:18:18 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: ENROLLED/RANDOMIZED	Initial Entry
Sep-17-2020 08:18:04 (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
Feb-03-2021 18:02:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 1: Closed	Response satisfies query
Feb-01-2021 12:48:11	ACV0PFEINFP6000	Pamela Benne prod	Query 2: Closed	Response satisfies query

090177e196ae3fd5\Final\Final On: 01-Apr-2021 05:24 (GMT)

Header Text: c4591001

Visit: Subject Status - Unscheduled

Form: SUBJECT STATUS - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Verified

Site No: 1008

Site Name: (1008) Clinical Research Professionals Inc.

Subject No: 10081337

Subject Initials: ---

Generated By: pfe.lewissc

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

(UTC-06:00) Central Time (US & Canada)		(pfe.bennep07)		
Feb-01-2021 08:52:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Tiffany Baum (pfe.tbaum)	Query 2: Answered	subject inadvertently entered yes in diary no sx to date
Jan-31-2021 10:33:55 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Swaranjali Subhash Pawar (pfe.pawars01)	Query 2: Opened	Illness eDiary: Subject reported "Yes" for the question "Have you experienced any of the following?" for the COVID-19 symptoms or diagnosis on 26JAN2021. But there is no COVID Illness visit reported in the database. Please clarify.
Jan-29-2021 08:31:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Tiffany Baum (pfe.tbaum)	Query 1: Answered	AE added
Jan-28-2021	ACV0PFEINFP6000	Kathryn	Query 1: Opened	Clinical Please

090177e196ae3fd5\Final\Final On: 01-Apr-2021 05:24 (GMT)

Header Text: c4591001

Visit: Subject Status - Unscheduled

Form: SUBJECT STATUS - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Verified

Site No: 1008

Site Name: (1008) Clinical Research Professionals Inc.

Subject No: 10081337

Subject Initials: ---

Generated By: pfe.levissc

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

07:43:44 (UTC-06:00) Central Time (US & Canada)		Sewell (pfe.sewelk02)		enter the (non-serious) event 'Exposure during Pregnancy' on the AE CRF, due to positive urine PG test 25Jan21.
Nov-03-2020 10:00:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Nov/3/2020	Initial Entry
Sep-17-2020 08:18:18 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sep/15/2020	Initial Entry
Sep-17-2020 08:18:04 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sep/15/2020	Initial Entry

090177e196ae3fd5\Final\Final On: 01-Apr-2021 05:24 (GMT)

Header Text: c4591001

Visit: Investigator Signature -
Unscheduled

Form Version: 22-Apr-2020 21:04

Site No: 1008

Subject No: 10081337

Generated By: pfe.lewissc

Form: CASEBOOK SIGNATURE FORM - eCRF Audit
Trail History

Form Status: Data Complete, Signed, Verified

Site Name: (1008) Clinical Research Professionals Inc.

Subject Initials: ---

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

[Back to Form](#)

1. Casebook Signature

Date	Location	User	Value	Reason
Nov-03-2020 10:00:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Tiffany Baum (pfe.tbaum)	Data Entry: Click Here to Enable	Initial Entry